Delivering
PEACE OF MIND
in an uncertain world

2019 Annual Report

Dear Fellow Shareholders,

This past year has been transformational for Emergent. We are now on a path to delivering on our commitment to protect one billion lives by 2030. I am pleased to share our progress and our vision for the future.

Major milestones in 2019 included the first deliveries of our next-generation anthrax vaccine candidate, AV7909, and full integration of both the NARCAN® Nasal Spray and travel health businesses. As a result, we now have three key franchises — anthrax, smallpox, and opioid overdose reversal — each of which is positioned to generate in excess of $250 million in annual revenue, allowing us to grow revenue while diversifying our product, customer, and market mix.

We also made significant progress on our pipeline. We initiated a Phase 3 study for AV7909, and completed Phase 2 studies for both FLU-IGIV, our flu therapeutic candidate, and CHIKV VLP, our chikungunya vaccine candidate. And, we advanced programs related to our auto-injector platform for chemical threats as well as drug-device combinations that address the opioid crisis.

Finally, we met our goal of total revenues of $1 billion a full year ahead of plan, supported by our success in securing over $3 billion of new contracts with the U.S. government.

Behind all of these milestones was consistent execution and prudent investment yielding significant operational and financial results. Looking ahead, our new five-year Growth Strategy outlines a clear path for both financial and operational growth and expansion of our ability to address public health threats. Key goals include doubling our revenues to $2 billion by 2024, advancing our development programs, building scalable capabilities, balancing organic growth with targeted acquisitions, and continuing to evolve our culture.

Emergent colleagues around the world live our values of innovation, accountability, teamwork and commitment to customers and patients every day. Their dedication to Protecting and Enhancing Life ensured our successes in 2019 and created the strong momentum we have going into 2020. After more than 20 years as a fellow colleague, 2019 was my first year as CEO. I couldn't be more proud and excited to lead this team into our future.

Sincerely,

Robert G. Kramer
President and Chief Executive Officer

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, 2019

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, Suite 400
(Address of Principal Executive Offices)
Gaithersburg MD 21079
(City) (State) (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	*Trading Symbol(s)*	*Name of Each Exchange on Which Registered*
Common stock, $0.001 par value per	**EBS**	**New York Stock Exchange**

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

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

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

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

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

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

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

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, 2019 was approximately $2.5 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 14, 2020, the registrant had 52.0 million shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2020 annual meeting of stockholders scheduled to be held in May 2020, 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, 2019, 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 2020 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, 2019

INDEX

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)), 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 HCl) Nasal Spray and any and all Emergent brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent 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,'' ''estimates'' and similar expressions in conjunction with, among other things, discussions of financial performance or financial condition, growth strategy, product sales, manufacturing capabilities, product development, regulatory approvals or expenditures. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. You should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. You are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by law, we do not undertake to update any forward- looking statement to reflect new information, events or circumstances.

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

- the availability of U.S. government (USG) funding for procurement for our products;
- our ability to perform under our contracts with the USG including the timing of and specifications relating to deliveries;
- the continued exercise of discretion by the Biomedical Advanced Research and Development Authority (BARDA) to procure additional doses of AV7909 (anthrax vaccine adsorbed with adjuvant) prior to approval by the U.S. Food and Drug Administration (FDA);
- our ability to secure licensure of AV7909 from the FDA within the anticipated timeframe, if at all;
- our ability to secure follow-on procurement contracts for our public health threat (PHT) products that are under procurement contracts that have expired or will be expiring;
- our ability and the ability of our collaborators to enforce patents related to NARCAN Nasal Spray against potential generic entrants;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- our ability and the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices and other regulatory obligations;
- our ability to comply with the operating and financial covenants required by 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 USG entities under regulatory exemptions prior to approval by the FDA and corresponding procurement by government entities outside of the United States under regulatory exemptions prior to approval by the corresponding regulatory authorities in the applicable country;
- the success of our commercialization, marketing and manufacturing capabilities and strategy; and
- the accuracy of our estimates regarding future revenues, expenses, capital requirements and needs for additional financing.

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

ITEM 1. BUSINESS

OVERVIEW

Emergent BioSolutions Inc. is a global life sciences company focused on providing a portfolio of innovative preparedness and response products and solutions to civilian and military populations that address accidental, deliberate and naturally occurring public health threats (PHTs). We were incorporated in the State of Michigan in May 1998 and subsequently reorganized as a Delaware corporation in June 2004.

We are currently focused on innovative preparedness and response products and solutions that address the following six distinct PHT categories: Chemical, Biological, Radiological, Nuclear and Explosives (CBRNE); emerging infectious diseases (EID); travel health; emerging health crises; acute/emergency care; and contract development and manufacturing (CDMO). We have a product portfolio of ten marketed products (vaccines, therapeutics, and drug-device combination products) that have been approved by the FDA, and a clinical-stage vaccine product candidate, currently being procured by the U.S. Government (USG) under specific authorization for delivery to the Strategic National Stockpile (SNS) that collectively generate the majority of our revenue. We also have a development pipeline consisting of a diversified mix of both pre-clinical and clinical-stage product candidates, including Trobigard® a combination drug- device auto injector product candidate. In addition, we have a fully integrated molecule-to-market biologics CDMO business offerings (development services, drug substance and drug product) for the pharma and biotech industry and government agencies, as well as non- government organizations. The USG is our largest customer and also 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.

STRATEGY

Our core strategy to drive the business is focused on addressing a PHT market that includes CBRNE, EID, travel health, emerging health crises, acute/emergency care, and CDMO services. Our 2020-2024 growth strategy contemplates that we continue to:

- Execute on the core business, building leadership positions across this expanded landscape of PHTs;
- Grow through a disciplined approach toward acquiring products and businesses that are strategically aligned;
- Build and strengthen our research and development (R&D) portfolio for it to become a meaningful contributor to growth after 2024;
- Build scalable capabilities by investing in operational excellence and innovation to support a growing enterprise that will deliver greater impact; and
- Continue to evolve our culture as we grow to support even greater employee engagement and empowerment.

In executing on our strategy, we are leveraging our core competencies that we have developed and honed over the last 21 years. These competencies include:

- Quality development and manufacturing services across a spectrum of specialized and complex manufacturing processes, using multiple platform technologies;
- Specialized federal, state, and local government relations and contracting operations to support the enterprise; and
- Successful execution and integration of business and product acquisitions.

GROWTH THROUGH ACQUISITIONS AND COLLABORATIONS

We have a track record of growth through the acquisition of businesses, products and technologies that are aligned with our long-term strategic objectives. Our goal is to continue our development activity by seeking and entering into acquisition and collaboration transactions that we believe will allow us to achieve our 2024 strategic goals. Below is a summary of our recent significant acquisitions, transactions and collaborations.

Adapt Pharma Limited

In October 2018, we completed the acquisition of Adapt, and its NARCAN® (naloxone HCl) Nasal Spray marketed product, the first 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. This acquisition included 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.

PaxVax Holding Company Ltd.

In October 2018, we completed the acquisition of PaxVax, a company focused on developing, manufacturing, and commercializing specialty vaccines that protect against existing and emerging infectious diseases. This acquisition included 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; and additional clinical-stage vaccine candidates targeting chikungunya and other EIDs; 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.

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, a vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection; 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 SNS, all of which have been delivered to date. On September 3, 2019, we announced the award by the U.S. Department of Health and Human Services (HHS) of a new contract valued at approximately $2 billion over 10 years for the continued supply of ACAM2000 into the SNS.

raxibacumab

In October 2017, we completed the acquisition of raxibacumab from Human Genome Sciences, Inc. and GlaxoSmithKline LLC (collectively GSK). Our raxibacumab product is the first fully human monoclonal antibody product licensed by the FDA for the treatment and prophylaxis of inhalational anthrax. With the acquisition, we assumed responsibility for a multi-year contract with BARDA with a remaining value at acquisition of up to approximately $130 million and all deliveries of raxibacumab to the SNS under this contract have been completed. We intend to submit a proposal for a follow-on contract with the USG to continue to supply this medical countermeasure (MCM) to the SNS. 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.

OUR BUSINESS UNITS

We are organized into four business units: Vaccines, Devices, Therapeutics and Contract Development and Manufacturing.

Vaccines

Products

Our Vaccines business unit contains a portfolio of specialty vaccines that address existing and emerging PHTs. The current portfolio of marketed or procured products consists of the following products:

VACCINES BUSINESS UNIT		
Product	**Indication(s)**	**Regulatory Approvals**
BioThrax® (Anthrax Vaccine Adsorbed)	Vaccine for active immunization for the prevention of disease caused by Bacillus anthracis in persons 18 through 65 years of age	United States, Germany, Singapore, UK, the Netherlands, France (where it is known as BaciThrax®), Poland, Italy, Canada
ACAM2000® (Smallpox (Vaccinia) Vaccine, Live)	Vaccine for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection	United States, Australia, Singapore
Vivotif® (Typhoid Vaccine Live Oral Ty21a)	Oral vaccine for the prevention of typhoid fever in adults and children greater than 6 years of age	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
Vaxchora® (Cholera Vaccine Live Oral)	Oral vaccine for the pre vention of cholera in adults 18 through 64 years of age traveling to cholera-affected areas	United States

BioThrax® (Anthrax Vaccine Adsorbed). BioThrax is the only vaccine licensed by the FDA for pre-exposure prophylaxis (PrEP) of anthrax disease in persons at high risk of exposure. In April 2014, the FDA granted orphan drug designation to BioThrax for post-exposure prophylaxis (PEP) of disease following suspected or confirmed *Bacillus anthracis* exposure, when administered in conjunction with recommended antibacterial drugs (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 PrEP setting by intramuscular injection as a three-dose primary series over a six-month period. The vaccine is considered protective after completion of this three-dose primary series. Per the US label, booster doses are administered 6 and 12 months after completion of the primary series and at 12 month intervals 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 zero, two and four-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 the remainder of deliveries under this contract in 2017.

***ACAM2000®* (Smallpox (Vaccinia) Vaccine, Live).** ACAM2000 is a smallpox vaccine licensed by the FDA

and is the primary smallpox vaccine designated for use in a bioterrorism emergency. 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 genus. According to the CDC, it is one of the most devastating diseases with a mortality rate as high as 30%. ACAM2000 is administered by the 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.

Despite being eradicated in 1979, smallpox poses a significant risk to national security and public health due to its ease of transmission, high mortality rate, and potential for major public health impact and social disruption. It remains a continued threat to the U.S. population if it were to reemerge naturally or due to an intentional act. Recent advances in synthetic biology have enabled easier access to the smallpox virus. Smallpox vaccines have been foundational to the USG's preparedness and response efforts as documented in legislation such as the Project BioShield Act of 2004 and its predecessor, the Public Health Security and Bioterrorism Act of 2002.

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. At acquisition, there was $160 million of remaining value on the prior contract, all doses of which have been delivered to date.

On September 3, 2019, we announced the award by the USG of a new contract valued at approximately $2 billion over 10 years for the continued supply of ACAM2000 into the SNS. This multiple-year contract is intended to support the replacement of the smallpox vaccine stockpile and included a one-year base period of performance in 2019 valued at approximately $170 million, and nine option years. The number of doses under the base period were delivered by year end 2019. The actual number of ACAM2000 doses to be procured is dependent on certain timing and tiered-pricing terms that are subject to the discretion of HHS.

***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, 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 *Salmonella* Typhi.

***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.

Product Candidates

The chart below highlights our primary Vaccines product candidates:

Product Candidate	Partner	Platform	Threat Type
AV7909* Next-generation anthrax vaccine	**HHS - BARDA**	**Vaccine**	**Biological**
CHIKV VLP Chikungunya virus VLP vaccine	**–**	**Vaccine**	**EID**
** AV7909 is not approved by the FDA or any other health regulatory agency, but it is being procured by BARDA under special circumstances under government authorization.*			

AV7909 (anthrax vaccine adsorbed with CPG 7909 adjuvant). We are developing AV7909, an anthrax vaccine product candidate based on BioThrax combined with CPG 7909. We are developing AV7909, 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. In October 2014, we completed a Phase 2 clinical trial of AV7909 in which all endpoints were successfully met, including a two-dose regimen (versus the BioThrax three-dose regimen) for anthrax post-exposure prophylaxis. In September 2014, we obtained funding through a five-year development contract with NIAID of up to $29 million to support the development of a dry formulation of AV7909, which includes the preparation of an Investigational New Drug (IND) application to the FDA. The objective of the dry formulation is to eliminate 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 AV7909 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 AV7909 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. The contract also includes procurement options for the delivery of an additional 7.5 million to 50 million doses of AV7909 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. In 2019, we initiated and completed enrollment of a Phase 3 study; a 3,850 subject trial evaluating safety and lot consistency. We also initiated a Phase 2 study exploring drug-drug interaction of AV7909 and antibiotics. In collaboration with us, the CDC filed with the FDA a submission package related to AV7909, which triggered BARDA to begin procurement of AV7909 in 2019. On May 15, 2019, we announced that BARDA had informed us that it would begin procuring AV7909 for delivery into the SNS and on July 30, 2019, BARDA exercised its first contract option valued at approximately $261 million to procure doses to be delivered to the SNS through June of 2020. See ''Management's Discussion and Analysis of Financial Conditions and Results of Operations - Overview - Highlights and Business Accomplishments for 2019'' for additional details.

CHIKV VLP. We licensed the chikungunya virus (CHIKV), 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 potentially safer alternative to attenuated and inactivated vaccines throughout production and use and can likely be administered in unrestricted target populations. VRC has previously evaluated in this product candidate both nonclinical and clinical (Phase 1 and Phase 2) safety, immunogenicity and efficacy data. Key nonclinical studies suggested protective efficacy in nonhuman primates (NHPs) and a passive transfer study demonstrated that mice dosed with purified antibody from the VLP-immunized NHPs were protected from an otherwise lethal CHIKV infection. The NIH recently completed a Phase 2 clinical study with 200 subjects that was conducted at multiple endemic sites in the Caribbean, which suggested that protective levels of antibodies can persist at least 18 months post-vaccination. Emergent's CHIKV VLP vaccine candidate is currently being investigated in a Phase 2 clinical study of approximately 430 healthy adults at three U.S. sites. Upcoming development activities include Phase 3 development, including process validation and manufacture, and licensure-enabling nonclinical toxicity and efficacy studies. Collectively, these studies are intended to support regulatory filings in both the U.S. and European Union. The CHIKV VLP vaccine received FDA Fast Track designation in May 2018 and EMA PRIority MEdicines (PRIME) designation in September 2019. In January 2020, the Company received agreement from the European Medicines Agency (EMA) to pursue its proposed development plan for CHIKV VLP.

Additional Pipeline Candidates. Our Vaccines business unit also has other discovery and preclinical product candidates addressing PHTs, including viral hemorrhagic fevers caused by Ebola, Marburg, Sudan and Lassa viruses, prevention of diarrheal disease caused by Shigella and heat-labile toxin producing enterotoxigenic Escherichia coli, among others.

Devices

Products

Our Devices business unit contains a broad portfolio of products that incorporate convergent technologies that address PHTs. The current portfolio consists of the following 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 from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin.	United States (510k), Canada, Australia, European Union, Israel

NARCAN® (naloxone HCl) Nasal Spray. NARCAN® (naloxone HCl) Nasal Spray is the first 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 pharmacies fulfilling 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 Department of Defense (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 U.S. 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.

Product Candidates

Within our Devices business unit, we develop several investigational stage product candidates, including:

Auto-Injector Drug-Device Product Candidates. We have been developing a suite of drug-device combination product candidates in an auto-injector platform based on our proprietary technology, primarily for military and other government use. Included in these are Trobigard® (atropine sulfate and obidoxime chloride), which is currently under review for approval by the health regulatory authority in Belgium; D4 (atropine and pralidoxime chloride), for which we received a $23 million development award from the U.S. Department of Defense (DoD); and PC2A (diazepam), for which we received a $20 million development award from the DoD. Trobigard has not been approved by the FDA or any other health regulatory authority but has been procured by various government buyers under special circumstances.

SIAN (stabilized isoamyl nitrite). In September 2017, we were awarded a contract by BARDA valued at approximately $63 million to develop an antidote intranasal 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.

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, including the following:

AP004 (Naloxone prefilled syringe). A naloxone pre-filled syringe for emergency care providers, offering a titratable dose. We expect to launch this product in the second half of 2020.

AP003 (Naloxone multidose nasal spray). A nasal delivery device which can deliver multiple 4mg doses to treat acute opioid overdose.

AP007 (Sustained release Nalmefene injectable). In September we were awarded an NIH grant of approximately $6.3 million over two years, to develop the company's sustained release nalmefene formulation. This formulation will be administered through intramuscular (IM) injection and is designed to continually release an effective dose of nalmefene for up to three months. It is intended to treat addiction and reduce the potential for relapse in patients undergoing treatment for opioid use disorder (OUD). The award is being made under the Helping to End Addiction Long- term Initiative, or the NIH HEAL Initiative, to improve prevention and treatment strategies for opioid misuse and addiction and enhance pain management. Upon meeting milestones there is an opportunity to exercise a further three years funding taking the product through early stage clinical development.

Therapeutics

Products

Our Therapeutics business unit contains a broad portfolio of specialty antibody-based therapeutics that address various existing and emerging PHTs. The current portfolio consists of the following marketed products:

THERAPEUTICS BUSINESS UNIT		
Product	**Indication(s)**	**Regulatory Approvals**
VIGIV **CNJ-016®** [Vaccinia Immune Globulin Intravenous (Human)]	Treatment of complications due to vaccinia vaccination, including: Eczema vaccinatum; Progressive vaccinia; Severe generalized vaccinia; Vaccinia infections in individuals who have skin conditions; Aberrant infections induced by vaccinia virus (except in cases of isolated keratitis).	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, Ukraine, Singapore
raxibacumab	Treatment 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

raxibacumab. Our raxibacumab product 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. Our raxibacumab product 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. Our raxibacumab product 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. All deliveries under this contract are complete. We intend to submit a proposal for a follow- on contract with the USG to continue the supply of this medical countermeasure (MCM) to the SNS. 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 inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs. Simultaneous with FDA approval in 2015, Anthrasil also received orphan drug designation for that indication, 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 HHS for delivery into the SNS. We have two current contracts with HHS: 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 under this contract to extend the plasma collection storage, and to include options for manufacturing and product delivery; this contract is available to be exercised by HHS 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 Defense, 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 symptomatic botulism following suspected or documented exposure to botulinum neurotoxin serotypes A, B, C, D, E, F or G in adults and pediatric patients. It was also licensed in Canada in December 2016 pursuant to Health Canada's EUND regulations. Simultaneous with FDA licensure in 2013, BAT also received orphan drug designation for the FDA-licensed indication, resulting in market exclusivity in the United States until March 2020. BAT was also approved in Singapore and Ukraine in 2019. 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 two procurement contracts. The first contract is with BARDA, and Emergent is currently executing on the manufacturing and supply of the bulk drug until 2022 valued at $53 million. The second contract was awarded by ASPR in HHS in 2019, and is valued at up to $490 million over 10 years ($90 million agreed to now and the remaining $400 million to be negotiated and finalized over the next 6 months) for the continued supply of BAT into the SNS in support of botulism preparedness and response capability. In addition to domestic government sales, BAT continues to be sold internationally, with deliveries to over 20 foreign governments in 2019. 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 replicating virus smallpox

vaccination. VIGIV is comprised of purified polyclonal human immune globulins (antibodies) directed to the vaccinia virus, which is the virus used in replicating smallpox virus vaccines, such as ACAM2000. VIGIV 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 a specific type of reaction or 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 replicating virus smallpox vaccination. Although VIGIV has been sold to foreign governments, to date, the principal customer for VIGIV has been the USG, specifically HHS. On June 3, 2019, we announced a contract award by HHS valued at approximately $535 million over 10 years for the continued supply of VIGIV into the SNS for smallpox preparedness.

Product Candidates

The chart below highlights our primary 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 has completed enrollment and data analysis is ongoing.

ZIKV-IG (NP024). NP024 is also being developed based on our hyperimmune platform and is an 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) or vaccinated donors that have high levels of neutralizing antibody for ZIKV. The Phase 1 trial to evaluate the safety of ZIKV-IG has been completed. 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. Fast Track designation for prophylaxis of Zika virus in at-risk populations, including women of child- bearing potential and pregnant women was granted by FDA in December 2017.

Our 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 (CDMO)

Our CDMO business unit, which is based on our established development and manufacturing infrastructure, technology platforms and expertise, consists of a fully integrated molecule-to-market contract development and manufacturing services business offering across development services, drug substance and drug product for the for small to mid to large pharma and biotech industry and government agencies/non-governmental organizations. These services include process development, formulation and analytical development, drug substance manufacturing and drug product manufacturing and packaging for supply through launch and commercial supply pharma and biotech. The biologics technology platforms consist of mammalian, microbial, viral, plasma and advanced therapies.

See ''Item 2 Properties'' below for additional information on our development and manufacturing facilities.

Marketing and Sales

Our product sales can be divided into two primary categories: i) sales to governments; and ii) commercial sales.

Government Procurement

For our Vaccines, Therapeutics and Devices business units, our largest customers are the USG and domestic non-government organizations. We also sell certain products to state governments, local governments and emergency management teams. 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 sales and business development, marketing and customer experience, and commercial development professionals qualified to represent our full breadth of service offerings to the global pharma and biotech industry.

Commercial Sales

NARCAN® Nasal Spray is sold commercially through physician-directed or standing order prescriptions at retail pharmacies and first responders including police, fire fighters and emergency medical teams.

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, travel health emerging health crises, acute/emergency care and opioid overdose face 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:

- ***AV7909 and BioThrax®***. *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 AV7909 into Phase 3 and through 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), and in 2018 Perrigo UK FINCO Limited Partnership (Perrigo), filed Abbreviated New Drug Applications (ANDAs, each an ANDA) with the FDA seeking regulatory approval to market a generic version of NARCAN® Nasal Spray. Teva may also decide to launch its approved generic product although the launch would be at risk since the litigation we instituted against Teva is still ongoing. Although NARCAN® Nasal Spray was the first FDA-approved needle-free 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 now faces competition from JYNNEOS™, which was licensed by the FDA in September 2019 for the prevention of smallpox disease in adults 18 years of age and older determined to be at high risk for smallpox infection. JYNNEOS is approved in Canada and in the European Union where it is marketed under the trade name Imvanex®.
- ***raxibacumab and Anthrasil®.*** Our raxibacumab product 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 inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs. However, Elusys Therapeutics, Inc. has obtained FDA licensure for Anthim® (obiltoxaximab) injection, a monoclonal antibody indicated for the treatment and prophylaxis of inhalational anthrax.
- ***BAT®.*** Our botulinum antitoxin immune globulin product is the only heptavalent therapeutic licensed by the FDA and Health Canada for the treatment of symptomatic botulism and has orphan drug designation. Other companies may be developing therapies aimed at treating or preventing botulism infections, however, direct competition is currently limited.
- ***VIGIV.*** Our VIGIV product is the only therapeutic licensed by the FDA and Health Canada to address adverse events from smallpox vaccination with replicating virus smallpox vaccines. 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 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 FDA-approved oral typhoid vaccine. 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 vaccine available indicated to prevent cholera.
- ***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., Par Pharmaceutical Companies, Inc., Thermo Fisher Scientific, Hospira Inc., Ajinomoto Bio-Pharma Services, 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, 2019, 2018 and 2017, the Company's revenue from U.S. customers as a percentage of total revenues were 90%, 91% and 89%, respectively.

MANUFACTURING OPERATIONS

Our development and manufacturing network allows us to deploy capabilities and capacity for clinical and commercial supply needs. Please refer to ''Item 2. Properties'' for a description of our development and manufacturing facilities.

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 AV7909, 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 the naloxone active pharmaceutical ingredient 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.

We rely on single source suppliers for our plasma collection to support the VIGIV and BAT programs. We work closely with our suppliers for these specialty programs and operate under long term agreements. We order quantities of material in advance in quantities believed to be sufficient to meet upcoming demand requirements.

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 or for cases brought in non-U.S. tribunals or under non-U.S. law, 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 (i.e. in an artificial environment outside of a living organism), and in vivo (i.e. 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 serious or life-threatening conditions caused by exposure to lethal or permanently disabling toxic biological, chemical, radiological, or nuclear substances, 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 clinical protocol detailing the first phase of the proposed clinical investigation as well as information on the qualifications of clinical investigators. 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. The protocol must also be reviewed and approved by an institutional review board (IRB), and all study subjects must provide informed consent.

- Phase 1 clinical trials test the candidate in a small group (typically 20-100) of healthy volunteers and/or patients with the target disease or condition to evaluate its 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 larger group of patients (typically several hundred) with the target disease or condition 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 review and potential 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.

Progress reports with the results of the clinical trials must be submitted at least annually to the FDA and there are additional, more frequent reporting requirements for certain adverse events.

The FDA may impose a temporary or permanent clinical hold, or other sanctions, if it believes that the clinical trial either is not being conducted in accordance with the FDA requirements or presents an unacceptable risk to the clinical trial subjects. An IRB also may require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

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 biologics license application (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. Most applications are subject to a substantial application fee and, if approved, will be assessed an annual fee, both of which are adjusted annually. Applications for orphan drugs are not subject to an application fee, unless the application includes an indication other than the orphan-designated indication. Under the U.S. Food, Drug, and Cosmetic Act (FDCA), the FDA also has the authority to grant waivers of certain user fees.

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 substantial evidence of effectiveness for the proposed indication and/or that the drug is not safe for use under the conditions of use in the proposed labeling. 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 FDA will also typically inspect one or more clinical sites to ensure compliance with GCPs as well as the facility or facilities at which the candidate is manufactured to ensure compliance with current good manufacturing practices (cGMPs).

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 inserts, 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.

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 abbreviated new drug application (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 reference listed drugs (RLDs)). Because the safety and efficacy of RLDs have already been established by the brand company (sometimes referred to as the innovator), the FDA does not require ANDA applicants to independently demonstrate safety and efficacy of generic products. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the RLD in order to demonstrate that their product performs in the same manner as the RLD. 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 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 RLD 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 RLD's 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.

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 frequent 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 AV7909 in June 2011, to CHIKV VLP in 2018 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, which is afforded to the first applicant to receive approval for an orphan designated drug for an indication covered by the orphan drug designation prevents FDA approval of applications by other applicants 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 for the same disease or condition or the same drug for a 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® (anthrax vaccine adsorbed) for post-exposure prophylaxis of disease following suspected or confirmed *Bacillus anthracis* exposure, when administered in conjunction with recommended antibacterial drugs, with exclusivity though November 2022;
- Anthrasil® (Anthrax Immune Globulin Intravenous (Human)) for the treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs, with exclusivity through March 2022; and
- BAT for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients, 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 regulates the content and format of prescription drug labeling, advertising, and promotion, as well as permissible non-promotional communications between industry and the medical community (e.g., industry-supported scientific and educational activities). The FDA 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 investigational products and we may not promote our approved 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. The FDA and other agencies actively enforce these laws and regulations, and a company that is found to have improperly promoted unapproved or off-label uses or otherwise not to have met applicable promotion rules may be subject to significant liability under both the FDCA and other statutes, including the False Claims Act.

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. Several of our vaccines 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.

In addition, if changes are made to the manufacturing process, we may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after the changes.

Priority Review Vouchers. In 2007, the Food and Drug Administration Amendments Act added Section 524 to the FDCA 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 (PHSA). 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. 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 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.

- Class I devices are those that present minimal potential for harm to the user and 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 those that generally present a moderate potential for harm to the user and 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.
- Class III devices are those that sustains or supports life, is implanted, or presents high risk of illness or injury. A Class III device requires approval of a pre-market application (PMA), which must demonstrate that the device is safe and effective when used. The PMA process 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.

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 are therapeutic and diagnostic products that combine drugs, devices, and/or biological products. The FDA determines whether a combination product is regulated as a drug, device, or biologic based on the product's primary mode of action. Our Trobigard auto-injector 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. It is not manufactured or distributed in the United States.

Emergency Use Authorization

As amended by Project BioShield and subsequent legislation, including the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) and the 21st Century Cures Act, the FDCA permits the Secretary of HHS to authorize the introduction into interstate commerce of unapproved MCMs, or approved MCMs for unapproved uses, in the context of an actual or potential emergency that has been declared by designated government officials (known as ''emergency use''). The types of emergencies that trigger these authorities include public health emergencies announced by the Secretary of HHS, military emergencies announced by the Secretary of Defense, domestic emergencies announced by the Secretary of Homeland Security, and the identification of a material threat pursuant to Section 319-F-2 of the PHSA that is sufficient to affect national security or the health and security of United States citizens living abroad. After one of the emergencies has been announced, the Secretary of HHS may authorize the issuance of, and the FDA Commissioner may issue, Emergency Use Authorizations (EUAs) for the use of specific products based on criteria established by statute, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives. EUAs are subject to additional conditions and restrictions, are product-specific, and terminate when the emergency determination underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product.

Potential Sanctions.

For all FDA-regulated products, if the FDA finds that a manufacturer has failed to comply with applicable laws and regulations, or that a product is ineffective or poses an unreasonable health risk, it can institute or seek a wide variety of enforcement actions and remedies, including but not limited to:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that are submitted;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

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.

Fraud, Abuse and Anti-Corruption Laws

The U.S. and most other jurisdictions have detailed requirements that apply to government and private health care programs, and a broad range of fraud and abuse laws, transparency laws, and other laws. Relevant U.S. federal and state healthcare laws and regulations include:

- The federal Anti-Kickback Statute;
- The federal civil False Claims Act;
- The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act;
- The federal criminal False Claims Act;
- The price reporting requirements under the Medicaid Drug Rebate Program and the Veterans Health Care Act of 1992;

- The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program; and
- Analogous and similar state laws and regulations.

Failure to comply with these laws and regulations could subject us to criminal or 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.

Regulations Governing Reimbursement

The marketing practices of U.S. pharmaceutical manufacturers are also subject to federal and state healthcare laws related to government funded healthcare programs.

In the United States, certain of our products are reimbursed under federal and state health care programs such as Medicaid, Medicare, TriCare, and or state pharmaceutical assistance programs. Many foreign countries have similar laws.

Various U.S. federal health care laws apply when we or customers submit claims for items or services that are reimbursed under federally funded health care programs, including federal and state anti-kickback laws, false claims laws, and anti-self-referral laws, which may apply to federal and state-funded Medicaid and other health care programs and private third-party payers.

Failure to comply with these laws and regulations could subject us to criminal or civil penalties.

Additionally, drug pricing is an active area for regulatory reform at the federal and state levels, and significant changes to current drug pricing and reimbursement structures in the U.S. continue to be enacted and considered.

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 14, 2020, we had 1,834 full-time employees. None of our employees are represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

AVAILABLE INFORMATION

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 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 USG procurement of AV7909, BioThrax and ACAM2000. If the USG's demand for and/or funding for procurement of AV7909, BioThrax or ACAM2000 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 USG procurement of AV7909 and BioThrax. As AV7909 is a product development candidate, there is a higher level of risk that we may encounter challenges causing delays or an inability to deliver AV7909 than with BioThrax, which may have a material effect on our ability to generate and recognize revenue.

The success of our business and our future operating results are significantly dependent on anticipated funding for the procurement of our anthrax vaccines and the terms of our BioThrax and AV7909 sales to the USG, including the price per dose, the number of doses and the timing of deliveries. We have no certainty that funding will be made available for the procurement of these vaccines. If priorities for the SNS change with respect to our anthrax vaccines, funding to procure future doses of BioThrax or AV7909 may be limited or not available, BARDA may never complete the anticipated full transition to stockpiling AV7909 in support of anthrax preparedness, and our future business, financial condition, operating results and cash flows could be materially harmed.

In addition, we currently derive a substantial portion of our revenues from sales of ACAM2000 to the USG. If priorities for the SNS change with respect to ACAM2000 or the USG decides not to exercise options under our ACAM2000 contract our future business, financial condition, operating results and cash flows could be materially harmed.

Although a pre-EUA submission package related to AV7909 has been submitted to the FDA, we may not receive an EUA and eventual FDA licensure in a timely manner or at all. Delays in our ability to achieve a favorable outcome from the FDA could prevent us from realizing the full potential value of our BARDA contract for the advanced development and procurement of AV7909.

In collaboration with us, the CDC filed with the FDA a pre-EUA submission package related to AV7909, which enables FDA review of data in anticipation of a request for an EUA. This submission triggered BARDA to exercise its first contract option (valued at $261M) in July 2019 to procure 10M doses of AV7909 for inclusion into the SNS in support of anthrax preparedness.

Notwithstanding, the FDA may decide that our data are insufficient and require additional pre-clinical, clinical or other studies. If we are unsuccessful in obtaining an EUA and, ultimately, 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. Furthermore, prior to FDA licensure, if we obtain an EUA, the EUA could be terminated if the emergency determination underlying the EUA terminates.

Our USG procurement and development contracts require ongoing funding decisions by the USG. Simultaneous reduction or discontinuation of 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 most of our product candidates in our development pipeline, most notably our AV7909 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 AV7909 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 AV7909 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, the BARDA procurement contract for raxibacumab that we acquired in our acquisition of raxibacumab from Human Genome Sciences, Inc. and GlaxoSmith-Kline LLC (collectively referred to as GSK), expired in November 2019. We intend to negotiate follow-on procurement contracts for most of our PHT products upon the expiration of a related procurement contract, including our procurement contract for raxibacumab, 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.

There are a number of laws and regulations that pertain to government contracts and compliance with those laws and regulations require significant time and cost, 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 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 U.S. Department of Defense (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;
- trade controls, including export and import control laws, International Traffic in Arms Regulations (ITAR), U.S. sanctions programs, and anti-boycott laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

We may be subject to government investigations of business practices and compliance with government acquisition regulations. 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 or investigated and such audit or investigation were to uncover improper or illegal activities, we could be subject to civil and criminal fines and penalties, administrative sanctions, including suspension or debarment from government contracting, and suffer significant reputational harm. The loss of our status as an eligible government contractor or significant fines or penalties associated with contract non-compliance or resulting from investigations could 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 generally 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.

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 them are subject to extensive FDA regulation and oversight, as well as oversight by other regulatory agencies in the United States and by comparable authorities in other countries. This includes, but is not limited to, laws and regulations governing product development, including testing, manufacturing, record keeping, storage and approval, as well as advertising and promotion. In limited circumstances, governments may procure products that have not obtained regulatory approval. In all other circumstances, failure to obtain regulatory approval for a product candidate will prevent us from selling and commercializing the product candidate.

In the United States, to obtain approval from the FDA to market any of our future drug, biologic, or vaccine products, we will be required to submit a new drug application (NDA) or biologics license application (BLA) to the FDA. Ordinarily, the FDA requires a company to support an NDA or BLA with substantial evidence of the product candidate's effectiveness, safety, purity and potency in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase 3 trials conducted in patients with the disease or condition being targeted.

However, many of our MCM product candidates, for example, may take advantage of 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 any of our PHT MCM candidates under the Animal Rule. Even if we are able to proceed pursuant to the Animal Rule, it can be a very long process, and 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 generally may cause delays in the approval or rejection of an application. There is a high rate of failure inherent in this process, and potential products that appear promising at early stages of development may fail for a number of reasons, and positive results from preclinical studies may not be predictive of similar results in human clinical trials. Similarly, promising results from earlier clinical trials of a product candidate may not be replicated in later clinical trials.

There are many other difficulties and uncertainties inherent in pharmaceutical research and development that could significantly delay or otherwise materially delay our ability to develop future product candidates. These include, but are not limited to:

- Conditions imposed by regulators, ethics committees, or IRBs for preclinical testing and clinical trials relating to the scope or design of our clinical trials;
- Restrictions placed upon, or other difficulties with respect to, clinical trials and clinical trial sites, such as clinical holds or suspension or termination of clinical trials due to, among other things, potential safety or ethical concerns or noncompliance with regulatory requirements;
- Delayed or reduced enrollment in clinical trials, or high discontinuation rates;
- Failure by third-party contractors, contract research organizations (CROs), clinical investigators, clinical laboratories, or suppliers to comply with regulatory requirements or meet their contractual obligations in a timely manner;
- Greater than anticipated cost of or time required to complete our clinical trials; and
- Insufficient product supply or inadequate product quality.

Failure to successfully develop future product candidates for any of these or other reasons may materially adversely affect our business, financial condition, operating results and cash flows.

Once an NDA or BLA is submitted, 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.

Unapproved and investigational products are also subject to FDA's laws and regulations governing advertising and promotion, which prohibit the promotion of both unapproved products and unapproved uses of approved products. There is some risk that the FDA could conclude that our communications relating to unapproved products or unapproved uses of approved products constitute the promotion of an unapproved product or product use in violation of FDA laws and regulations. There is also a risk that a regulatory authority in another country could take a similar position under that country's laws and regulations and conclude that we have violated the laws and regulations related to product development, approval, or promotion in that country. Therefore, there is a risk that we could be subject to enforcement actions if found to be in violation of such laws or regulations.

Even if we or our collaborators obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.

Once approval has been granted, an approved product and its manufacturer and marketer remain subject to ongoing review and extensive regulation.

We and our collaborators must therefore comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to FDA-regulated products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our collaborators and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, were we to receive marketing approval for one or more of our product candidates, we would continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we and our collaborators are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we or our collaborators obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Any product candidate for which we or our collaborators 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 authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a risk evaluation and mitigation strategy.

Certain of our products are subject to postmarketing requirements (PMRs), which we are required to conduct, and postmarketing commitments (PMCs), which we have agreed to conduct. The FDA has the authority to take action against sponsors who fail to meet the obligations of a PMR, including civil monetary penalties and/or misbranding charges.

The FDA and other agencies, including the U.S. Department of Justice (DOJ) and the HHS Office of Inspector General (OIG), closely regulate and monitor the pre-approval and post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA, DOJ, and OIG impose stringent restrictions on manufacturers' communications regarding unapproved products and unapproved uses of approved products and if we market unapproved products or market our approved products for unapproved indications, we may be subject to enforcement action for marketing of unapproved products or unapproved uses of approved products. Violations of the Federal Food, Drug, and Cosmetic Act (FDCA) and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU and other legal and regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Non-compliance with similar requirements in other jurisdictions can also result in enforcement actions and significant penalties.

Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other health care reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the ACA), passed in 2010, contains the following provisions of potential importance to our business and our product candidates:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of health care fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board (IPAB), which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within the Centers for Medicare & Medicaid Services (CMS) to test innovative payment and service delivery models.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the ''individual mandate.'' The repeal of this provision, which required most Americans to carry a minimal level of health insurance, became effective on January 1, 2019. In addition, Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session. It is possible that such initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

There have been executive actions to challenge or delay implementation of the ACA. Since January 2017, there have been two Executive Orders issued designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, health care providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. In addition, the CMS has proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On May 16, 2019, CMS finalized a rule that amends the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the rule changes allow Medicare Advantage plans to use preauthorization (PA) and step therapy (ST) for six protected classes of

drugs and, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs. The first change took effect in January 2020, while the second change will take effect in January 2021. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States, and members of legislative and executive branches have stated that they will address such costs through new legislative and administrative measures. While any proposed measures will require authorization through additional legislation to become effective, there may be new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

If we fail to comply with foreign, federal, state and local health care laws, including fraud and abuse and health information privacy and security laws, and antitrust laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

In the United States, certain of our products are reimbursed under federal and state health care programs such as Medicaid, Medicare, TriCare, and/or state pharmaceutical assistance programs. Many foreign countries have similar laws. Federal and state laws designed to prevent fraud and abuse under these programs prohibit pharmaceutical companies from offering valuable items or services to customers or potential customers to induce them to buy, prescribe, or recommend our product (the so-called ''anti-kickback'' laws). Exceptions are provided for discounts and certain other arrangements if specified requirements are met. Other federal and state laws, and similar foreign laws, not only prohibit us from submitting any false information to government reimbursement programs but also prohibit us, our employees, or any third party acting on our behalf from doing anything to cause, assist, or encourage our customers to submit false claims for payment to these programs. We are also subject to various federal, state and foreign antitrust and competition laws that prohibit certain activities that may have an impact against potential competitors. Violations of the various fraud and abuse and antitrust laws may result in severe penalties against the responsible employees and us, including jail sentences, large fines, and the exclusion of our products from reimbursement under federal and state programs. Some of the laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, overtly or covertly, to induce, or in return for, either the referral of an individual, or the purchase, lease, prescribing or recommendation of an item, good, facility or service reimbursable by a federally funded health care program, such as the Medicare or Medicaid program. The term ''remuneration'' has been interpreted broadly and may constrain our marketing practices, educational programs, pricing policies and relationships with health care providers or other entities, among other activities;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal health care program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $11,181 to $22,363 per false claim;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money

or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement, in connection with the delivery of, or payment for, health care benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their respective implementing regulations mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy, security and transmission of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to ''business associates,'' or independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;
- the Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, biologics, medical devices and medical supplies for which payment is available under Medicare, Medicaid or the Centers for Medicare & Medicaid Services (CMS), certain payments and transfers of value made to U.S. physicians and teaching hospitals, and ownership or investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and transfers of value provided to U.S. physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; state, local and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, obtain pharmaceutical agent licensure, and/or otherwise restrict payments that may be made to health care providers and entities; and state, local and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to health care providers or entities, or marketing expenditures.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Moreover, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal health care fraud statutes, so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, individual imprisonment, integrity obligations, exclusion from funded health care programs and the curtailment or restructuring of our operations. Any such penalties could adversely affect our financial results. We continue to improve our corporate compliance program designed to ensure that our development, marketing, and sales of existing and future products and product candidates are in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we

may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, integrity obligations, exclusion from government funded health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from government funded health care programs. If a third party fails to comply with applicable laws and regulations while acting on our behalf, we may also be subject to criminal, civil, and administrative penalties, including those listed above.

We are committed to conducting the development, sale and marketing of our applicable products and product candidates and all our activities in compliance with all applicable laws and regulations, but certain applicable laws and regulations may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee or third party acting on our behalf violate these laws without our knowledge, a governmental authority may impose civil and/or criminal sanctions.

The United States government, state governments and private payors regularly investigate the pricing and competitive practices of pharmaceutical companies and biotechnology companies, and many file actions alleging that inaccurate reporting of prices has improperly inflated reimbursement rates. We may also be subject to investigations related to our pricing practices. Regardless of merit or eventual outcome, these types of investigations and related litigation can result in:

- Diversion of management time and attention;
- Expenditure of large amounts of cash on legal fees, costs and payment of damages or penalties;
- Limitations on our ability to continue some of our operations;
- Decreased demand for our products; and
- Injury to our reputation.

Moreover, an adverse outcome, or the imposition of penalties or sanctions for failing to comply with the fraud and abuse and antitrust laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

If we fail to comply with our obligations under U.S. governmental pricing programs, we could be required to reimburse government programs for underpayments and could pay penalties, sanctions and fines.

The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid rebate program will continue to increase our costs and the complexity of compliance and will be time-consuming. Changes to the definition of ''average manufacturer price'' (AMP), and the Medicaid rebate amount under the ACA and CMS and the issuance of final regulations implementing those changes has affected and could further affect our 340B ''ceiling price'' calculations. Because we participate in the Medicaid rebate program, we are required to report ''average sales price'' (ASP), information to CMS for certain categories of drugs that are paid for under Part B of the Medicare program. Future statutory or regulatory changes or CMS binding guidance could affect the ASP calculations for our products and the resulting Medicare payment rate and could negatively impact our results of operations.

Pricing and rebate calculations vary among products and programs, involve complex calculations and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current AMP and ''best price'' for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid rebate program. Price recalculations also may affect the ''ceiling price'' at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B/Public Health Service (PHS) drug pricing program.

In addition to retroactive rebate liability and the potential for 340B program refunds, if we are found to have made a misrepresentation in the reporting of ASP, we are subject to civil monetary penalties for each such price misrepresentation and for each day in which such price misrepresentation was applied. If we are found to have knowingly submitted false AMP or ''best price'' information to the government, we may be liable for civil monetary penalties per item of false information. Any refusal of a request for information or knowing provision of false information in connection with an AMP survey verification also would subject us to civil monetary penalties. In addition, our failure to submit monthly/quarterly AMP or ''best price'' information on a timely basis could result in a civil monetary penalty per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B

for our covered outpatient drugs. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure that our submissions will not be found by CMS to be incomplete or incorrect.

In order for our products to be reimbursed by the primary federal governmental programs, we must report certain pricing data to the USG. Compliance with reporting and other requirements of these federal programs is a pre-condition to: (i) the availability of federal funds to pay for our products under Medicaid and Medicare Part B; and (ii) procurement of our products by the Department of Veterans Affairs (DVA), and by covered entities under the 340B/PHS program. The pricing data reported are used as the basis for establishing Federal Supply Schedule (FSS), and 340B/PHS program contract pricing and payment and rebate rates under the Medicare Part B and Medicaid programs, respectively. Pharmaceutical companies have been prosecuted under federal and state false claims laws for submitting inaccurate and/or incomplete pricing information to the government that resulted in increased payments made by these programs. The rules governing the calculation of certain reported prices are highly complex. Although we maintain and follow strict procedures to ensure the maximum possible integrity for our federal pricing calculations, the process for making the required calculations involves some subjective judgments and the risk of errors always exists, which creates the potential for exposure under the false claims laws. If we become subject to investigations or other inquiries concerning our compliance with price reporting laws and regulations, and our methodologies for calculating federal prices are found to include flaws or to have been incorrectly applied, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations.

To be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and certain federal grantees, we also must participate in the DVA FSS pricing program. To participate, we are required to enter into an FSS contract with the DVA, under which we must make our innovator ''covered drugs'' available to the ''Big Four'' federal agencies-the DVA, the DoD, the Public Health Service (including the Indian Health Service), and the Coast Guard-at pricing that is capped pursuant to a statutory federal ceiling price (FCP), formula set forth in Section 603 of the Veterans Health Care Act of 1992 (VHCA). The FCP is based on a weighted average wholesale price known as the Non-Federal Average Manufacturer Price (Non-FAMP), which manufacturers are required to report on a quarterly and annual basis to the DVA. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject us to significant penalties for each item of false information. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to disclose the error and refund the difference to the government. The failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, can be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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, a practice which we follow in connection with AV7909 and Trobigard. In the United States, the Project BioShield Act of 2004 (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. An EUA terminates when the emergency determination underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product. Absent an applicable exception, our MCM product candidates generally will have to be approved by the FDA or other regulatory authorities in the relevant country 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 supplying our product candidates to such entities on a case-by-case basis, which presents certain challenges, both in the case of U.S.

and foreign governments, and particularly under emergency conditions. In addition, agencies or branches of one country's government may take different positions regarding the permissibility of such sales than another country's government or even other agencies or branches of the same government. If we determine that we believe such activities are permissible, local enforcement authorities could disagree with our conclusion and take enforcement action against us.

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

There is also a risk that our communications with governments about our unapproved products, such as in the procurement context, could be considered promotion of an unapproved product or unapproved use of an approved product. Therefore, there is a risk that we could be subject to enforcement actions if found to be in violation of such laws or regulations.

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.

In addition to the requirements and uncertainties related to pre-approval activities discussed previously, 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, plasma donor testing, 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.

Government regulators enforce cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect domestic and foreign manufacturing facilities without prior notice at reasonable times and in a reasonable manner. Health Canada may conduct similar inspections of our domestic and foreign 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. Failure to meet potency, stability or other specification requirements could result in delays in distributions, recalls or other consequences. 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 unapproved products or unapproved uses of approved products (i.e. ''off-label'' uses or uses that are not described in the product's approved labeling and that differ from the uses approved by the applicable regulatory agencies). A company that is found to have improperly promoted an unapproved product or unapproved use of an approved product 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 marketing of an unapproved product or the unapproved use of an approved product, we could be subject to civil or criminal investigations and 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.

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 received market authorization under the mutual recognition procedure to sell BioThrax in France, Italy, the Netherlands, Poland, and the United Kingdom. To market our products in foreign jurisdictions under normal circumstances, we generally 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. There is also a risk that a regulatory authority in another country could conclude that we have violated the rules and regulations related to product development, approval or promotion in that country. Therefore, there is a risk that we could be subject to a foreign enforcement action if found to be in violation of such laws and regulations. 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 reliance on third parties can introduce additional uncertainty into the process.

On January 31, 2020, the United Kingdom formally withdrew from the European Union and entered into a transition period through December 31, 2020 pursuant to a Withdrawal Agreement. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of our products or product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing product candidates in the United Kingdom and/or the European Union and could restrict our ability to generate revenue and achieve and sustain profitability. There is also a risk that a regulatory authority in another country could conclude that we have violated the rules and regulations related to product development, approval, or promotion in that country. Therefore, there is a risk that we could be subject to an enforcement action if found to be in violation of such laws or regulations.

Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

As we continue to expand our commercialization activities outside of the United States, we are subject to an increased risk of, and must dedicate additional resources towards avoiding inadvertently conducting activities in a manner that violates the U.S. Foreign Corrupt Practices Act (FCPA), the U.K. Bribery Act, Canada's Corruption of Foreign Public Officials Act, and 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. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Many countries, including the United States, also have various lobbying laws and regulations governing the conduct of individuals and companies who interact with government officials. These laws and regulations typically include certain restrictions and disclosure obligations. If we, our employees, or third parties acting on our behalf do not comply with these laws and regulations, we may be subject to civil and criminal penalties.

Many countries, including the United States, restrict the export or import of products to or from certain countries through, for example, bans, sanction programs, and boycotts. Such restrictions may preclude us from supplying products in certain countries, which could limit our growth potential. Furthermore, if we, or third parties acting on our behalf, do not comply with these restrictions, we may be subject to civil and criminal penalties.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we continue to expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

MANUFACTURING RISKS

Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture AV7909, BioThrax, ACAM2000 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 products 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, Bern, Switzerland; 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.

Several of our products, including BioThrax and ACAM2000 and many of our current product candidates, including AV7909, 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.

Additionally, if changes are made to the manufacturing process, we may be required to provide the FDA with pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of any impacted products before and after the changes.

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.

Our products and product candidates procured by the USG and other customers require us to perform tests for and meet certain potency and lot release standards prescribed by the FDA and other agencies, which may not be met on a timely basis or at all.

Our products and product candidates procured by the USG and other customers require us to perform tests for and meet certain potency and lot release standards prescribed by the FDA and other agencies, which may not be met on a timely basis or at all. We are unable to sell any products and product candidates that fail to satisfy such testing specifications. For example, we must provide the FDA with the results of certain tests, including potency tests, before certain lots are released for sale. Potency testing of each applicable lot is performed against qualified control lots that we maintain. We continually monitor the status of such reference lots for FDA compliance and periodically produce and qualify a new reference lot to replace the existing reference lot. If we are unable to satisfy USG requirements for the release of our products or product candidates, our ability to supply such products and product candidates to authorized buyers would be impaired until such time as we become able to meet such requirements, which could materially harm our future 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.

RELIANCE ON THIRD PARTIES

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. 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.

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 AV7909, BioThrax, ACAM2000, NARCAN Nasal Spray 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 AV7909. We also rely on single-source suppliers for 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.

We depend on third parties to conduct many of 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 rely on third parties to conduct many of our 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.

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 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, ACAM2000, and our other biological products and product candidates, including AV7909, 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 NARCAN® Nasal Spray marketed product to face future competition from other treatments.

Our marketed product NARCAN® Nasal Spray faces potentially substantial competition from other treatments, including injectable naloxone, auto-injectors, nasal sprays or improvised nasal spray 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, Abbreviated new Drug Applications with the FDA (ANDAs) which seek regulatory approval to market generic versions of NARCAN® Nasal Spray before the expiration of certain underlying patents and in April 2019, Teva received FDA approval to market its generic version of NARCAN® Nasal Spray. Teva may decide to sell its approved generic product in the market, although we have sued Teva and the litigation has not yet been resolved, so any market launch could subject Teva to the risk of damages for patent infringement.

Additionally, we are aware that other companies are developing other product candidates containing naloxone that, if successful, would compete with NARCAN Nasal Spray and reduce our market share. In January 2019, the FDA released new proposed template Drug Facts Labels to assist sponsors of investigational 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 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.

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.

Preclinical and clinical testing for certain of our product candidates addressing CBRNE threats may face additional difficulties and uncertainties because they cannot ethically or feasibly be tested in human subjects. We therefore 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 EUA. 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 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.

Changes to the U.S. patent system under the Leahy-Smith America Invents Act (the America Invents Act), affected the way patent applications are filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter parties review (IPR) post-grant review (PGR) and covered business methods review (CBM). These proceedings are conducted before the Patent Trial and Appeal Board (the PTAB) of the U.S. Patent and Trademark Office. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. In this regard, the IPR process permits any person (except a party who has been litigating the patent for more than a year) to challenge the validity of some patents on the grounds that it was anticipated or made obvious by prior art. As a result, non-practicing entities associated with hedge funds, pharmaceutical companies who may be our competitors and others have challenged certain valuable pharmaceutical U.S. patents based on prior art through the IPR process. A decision in such a proceeding adverse to our interests could result in the loss of valuable patent rights which would have a material adverse effect on our business, financial condition, results of operations and growth prospects. The America Invents Act and any other potential future changes to the U.S. patent system could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or

defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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 in which we have an interest and, although we may have the right to assume the maintenance and defense of such intellectual property rights if these third parties do not do so, our ability to maintain and defend such intellectual property rights may be compromised by the acts or omissions of these third parties. For example, we license from Opiant Pharmaceuticals, Inc. formulations of naloxone used in our NARCAN® Nasal Spray.

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.

One or more of our products could be subject to early competition from generic drugs and biosimilars.

One or more of our products is approved as a drug product under the provisions of the U.S. Food, Drug and Cosmetic Act (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 pharmacists 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 validity 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.

Further, the 2010 Patient Protection and Affordable Care Act, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA). That Act established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. As of January 15, 2020, the FDA has approved thirty six biosimilar products for use in the United States. No interchangeable biosimilars, have been approved. The FDA has issued several guidance documents outlining approaches for review and approval of biosimilars.

Further, the 2010 Patient Protection and Affordable Care Act, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA). That Act established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. As of January 15, 2020, the FDA has approved thirty six biosimilar products for use in the United States. No interchangeable biosimilars, have been approved. The FDA has issued several guidance documents outlining approaches for review and approval of biosimilars.

Under the Act, a manufacturer may apply for licensure of a biologic product that is ''biosimilar to'' or ''interchangeable with'' a previously approved biological product or ''reference product.'' In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed ''interchangeable'' by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

FINANCIAL RISKS

We have incurred significant indebtedness in connection with our acquisitions and servicing our debt requires a significant amount of cash. 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, to the extent we are unable to offset the risk of such increases through our hedging instruments;
- 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 senior secured credit facilities and other debt agreements could result in an event of default under those agreements. An event of default could result in the acceleration of amounts due under a particular debt agreement and a cross default and acceleration under other debt agreements, and we may not have sufficient funds to pay 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 $600 million with a revolving credit facility, of which we had outstanding borrowings of approximately $436 million and $373 million, respectively, as of December 31, 2019. 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 development and 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 a new 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 agreements 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 agreement and a cross default and acceleration under other debt agreements, 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 hedging program is subject to counterparty default risk.

We manage our interest rate risk in part by entering into interest rate swaps with a number of counterparties to swap a portion of our indebtedness that is based on variable interest rates to a fixed rate. As a result, we are subject to the risk that the counterparty to one or more of these contracts defaults on its performance under the contract. During an economic downturn, the counterparty's financial condition may deteriorate rapidly and with little notice and we may be unable to take action to protect our exposure. In the event of a counterparty default, we could incur losses, which may harm our business and financial condition. In the event that one or more of our counterparties becomes insolvent or files for bankruptcy, our ability to eventually recover any losses suffered as a result of that counterparty's default may be limited by the liquidity of the counterparty.

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. Our profitability has been substantially dependent on 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 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.

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 or for cases brought in non-U.S. tribunals or under non-U.S. law. We cannot predict whether the Secretary of HHS will renew the declarations when they expire, whether Congress will fund the relevant PREP Act compensation programs, or whether the necessary prerequisites for immunity would be triggered with respect to our products or product candidates.

Additionally, certain of our products, namely BioThrax and RSDL, are certified anti-terrorism products covered under the protections of the Support Anti-Terrorism by Fostering Effective Technology Act of 2002 (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, or the USG does not honor its obligations to us under the PREP Act or SAFETY Act, or if the liability protections under the PREP Act and SAFETY Act are 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 we may incur. 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 January 31, 2020, 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 14, 2020, our common stock has traded as high as $73.89 per share and as low as $4.17 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 December 31, 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 development and manufacturing, laboratories, fill/finish facility services, offices and warehouse space for the conduct of our businesses at 19 locations in North America and Europe. Properties that have been leased expire on various dates between 2020 to 2034. Principal locations include:

Location	Use	Approximate square feet	Owned/ leased
Bern, Switzerland	This location houses manufacturing operations for our Vaccines business unit and drug substance for our CDMO business unit, as well as office and laboratory space.	511,000	Owned
Lansing, Michigan	This location houses manufacturing operations, office space and laboratory space. The manufacturing capabilities are central to our Vaccines business unit and provide our CDMO business unit with capability for both small- and large- scale biologics bulk product manufacturing.	336,000	Owned
Winnipeg, Manitoba, Canada	This location houses manufacturing operations, office space and laboratory space. It is the primary location for product development and manufacturing for our Therapeutics business unit, supports our Devices business unit and is actively engaged in plasma-derived hyperimmune therapeutics manufacturing, chromatography-based plasma fractionation, downstream processing, aseptic filling, packaging and warehousing, quality assurance and control. It also supports our CDMO business unit.	315,000	Owned
Gaithersburg, Maryland	This location houses research operations and office space for our facilities and laboratory space for our CDMO business unit.	173,000	Owned

Baltimore, Maryland (Bayview)	This location houses manufacturing facilities, office and laboratory space. The facilities at this location are 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. It focuses primarily on disposable manufacturing for viral and non-viral products and is one of three centers designated by HHS as a CIADM facility to provide advanced development and manufacturing of MCMs to support the USG's national security and public health emergency needs. It has also been and will continue to be marketed to non-USG CDMO clients in need of bulk manufacturing services.	112,000	Owned
Baltimore, Maryland (Camden)	This location houses fill/finish manufacturing facilities for our CDMO business unit. It 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. It is an approved manufacturing facility under the regulatory regimes in the United States, Canada, Japan, Brazil, the Middle East and various other countries and has provided manufacturing services. The facility includes warehousing space used for cold-storage and freezer capacity to support contract manufacturing customers.	86,900 (Owned); 41,000 (Leased)	Owned/ Leased
Rockville, Maryland	This facility is a cGMP live viral fill/finish facility, which is an FDA-registered manufacturing facility under the regulatory regimes of the United States, Australia and Singapore, which supports our Therapeutics and CDMO business units. It also houses office and warehouse space.	59,000	Leased
Canton, Massachusetts	This location houses manufacturing operations for our Vaccines and CDMO business units.	57,000	Owned
San Diego, California	This location houses fill/finish manufacturing facilities for our Vaccines business unit.	30,000	Leased
Canton, Massachusetts	This location houses warehouse space.	27,000	Leased
Hattiesburg, Mississippi	This location houses a packaging facility for our Devices and CDMO business units.	8,900	Leased

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 operations.

ITEM 3. LEGAL PROCEEDINGS

ANDA Litigation - Perrigo 4mg

On September 14, 2018, Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd., (collectively, Adapt Pharma), and Opiant Pharmaceuticals, Inc. (Opiant), received notice from Perrigo UK FINCO Limited Partnership (Perrigo), that Perrigo had filed an Abbreviated New Drug Application, (ANDA), with the United States Food and Drug Administration, 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, (the '253 Patent), 9,468,747 (the '747 Patent), 9,561,177, (the '177 Patent), 9,629,965, (the '965 Patent) and 9,775,838 (the '838 Patent). On or about October 25, 2018, Perrigo sent a subsequent notice letter relating to U.S. Patent No. 10,085,937 (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 (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. On February 12, 2020, Adapt Pharma and Perrigo entered into a settlement agreement to resolve the ongoing litigation. Under the terms of the settlement, Perrigo has received a non-exclusive license under Adapt Phama's patents to make, have made, and market its generic naxolone hydrochloride nasal spray under its own ANDA. Perrigo's license will be effective as of January 5, 2033 or earlier under certain circumstances including circumstances related to the outcome of the current litigation against Teva (as defined below) or litigation against future ANDA filers. The Perrigo settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission, and entry of an order dismissing the litigation by the U.S. District Court for the District of New Jersey.

ANDA Litigation - Teva 2mg

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. (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, (the '644 Patent) and U.S. Patent No. 9,707,226, (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.

ANDA Litigation - Teva 4mg

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 (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 the date of this filing, Adapt Pharma Inc., Adapt Pharma Operations Limited, and Opiant, have not filed a complaint related to the '937 Patent. Closing arguments are scheduled for February 26, 2020.

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.

Nalox-1 Pharmaceuticals, a non-practicing entity, filed petitions with the United States Patent and Trademark Office Patent Trial and Appeal Board (''PTAB'') requesting inter parties review (IPR) of five of the six patents listed in the Orange Book related to NARCAN® Nasal Spray 4mg/spray. In a series of decisions, the PTAB agreed to institute a review of the '253 Patent, the '747 Patent and the '965 Patent but denied review of the '177 Patent and the '838 Patent. Nalox-1 did not request review of the '937 Patent.

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 14, 2020, the closing price per share of our common stock on the New York Stock Exchange was $63.17 and we had 25 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend Policy

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

Recent Sales of Unregistered Securities

Not applicable.

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, 2019. The Company previously had a share repurchase program, which expired as of December 31, 2019.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

(in millions, except per share data)	Year Ended December 31, 2019	2018	2017	2016	2015
Statements of operations data:					
Revenues:					
Product sales	$ 903.5	$ 606.5	$ 421.5	$ 296.3	$ 329.0
Contract development and manufacturing services	80.0	98.9	68.9	49.1	43.0
Contracts and grants	122.5	77.0	70.5	143.4	117.3
Total revenues	1,106.0	782.4	560.9	488.8	489.3
Operating expenses:					
Cost of product sales and contract development and manufacturing services	433.5	322.3	187.7	126.3	102.1
Research and development	226.2	142.8	97.4	106.9	117.8
Selling, general & administrative	273.5	202.5	142.9	143.1	120.6
Amortization of intangible assets	58.7	25.0	8.6	7.0	7.3
Total operating expenses	991.9	692.6	436.6	383.3	347.8
Income from operations	114.1	89.8	124.3	105.5	141.5
Other income (expense):					
Interest expense	(38.4)	(9.9)	(6.6)	(7.6)	(6.5)
Other income (expense), net	1.7	1.6	0.9	1.3	0.7
Total other income (expense), net	(36.7)	(8.3)	(5.7)	(6.3)	(5.8)
Income before provision for income taxes	77.4	81.5	118.6	99.2	135.7
Provision for income taxes	22.9	18.8	36.0	36.7	44.3
Net income	$ 54.5	$ 62.7	$ 82.6	$ 51.8	$ 62.9
Net income per share-basic	$ 1.06	$ 1.25	$ 1.98	$ 1.29	$ 1.63
Net income per share-diluted [1]	$ 1.04	$ 1.22	$ 1.71	$ 1.13	$ 1.41
Weighted average number of shares – basic	51.5	50.1	41.8	40.2	38.6
Weighted average number of shares – diluted	52.4	51.4	50.3	49.3	47.3

(in millions)	As of December 31, 2019	2018	2017	2016	2015
Balance Sheet Data:					
Cash and cash equivalents	$ 167.8	$ 112.2	$ 178.3	$ 271.5	$ 308.3
Working capital	469.9	420.4	385.3	404.4	425.9
Total assets	2,327.3	2,229.4	1,070.2	970.1	931.8
Total long-term liabilities	1,022.5	1,018.1	57.8	268.1	274.6
Total stockholders' equity	1,088.5	1,010.9	912.2	596.2	575.0

[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 PHTs.

We are currently focused on the following six distinct PHT categories: CBRNE; EID; travel health; emerging health crises; acute/emergency care; and CDMO. We have a product portfolio of ten products (vaccines, therapeutics, and drug-device combination products) that contribute a substantial portion of our revenue. We also have two product candidates that are not approved by the FDA or any other health agency that are procured by certain government agencies under special circumstances. Additionally, we have a development pipeline consisting of a diversified mix of both pre- clinical and clinical stage product candidates (vaccines, therapeutics, devices and combination products). Finally, we 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 and commercial (non-government) customers globally. The majority of revenue comes from the following products and product candidates:

Vaccines

- Anthrax Vaccines, including our AV7909 (Anthrax Vaccine Adsorbed with Adjuvant) product candidate being developed as a next-generation anthrax vaccine for post-exposure prophylaxis and BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the FDA for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), the only single-dose smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection;
- Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever; and
- Vaxchora®(Cholera Vaccine, Live, Oral), the only FDA-licensed vaccine for the prevention of cholera.

Devices

- NARCAN®(naloxone HCl) Nasal Spray, the first 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;
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only medical device cleared by the FDA to remove or neutralize the following chemical warfare agents from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin; and
- Trobigard®, a combination drug-device auto-injector product candidate that contains atropine sulfate and obidoxime chloride. It has not been approved by the FDA or any similar health regulatory body, but is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure.

Therapeutics

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

Contract Development and Manufacturing Services

We compete for CDMO service business with a number of biopharmaceutical product development organizations, contract manufacturers of biopharmaceutical products and university research laboratories. We also compete with in-house research, development and support service departments of other biopharmaceutical companies.

Highlights and Business Accomplishments for 2019

- On November 22, 2019, the Company announced updated results from the interim analysis of its Phase 2 clinical study evaluating the safety and immunogenicity of its chikungunya virus (CHIKV) virus-like particle (VLP) vaccine candidate, CHIKV VLP, across a series of dosing regimens. The interim analysis has shown that after the first dose is administered, up to 98% of study participants produced a neutralizing antibody response against CHIKV within seven days of vaccination and that the immune response persisted for at least one year for subjects who received a single dose.

- On November 21, 2019, we outlined our growth strategy over the next five years and announced our 2024 financial and operational goals during the Company's Analyst and Investor Day. Senior management shared their vision for continuing to build leadership positions in select public health threat markets and CDMO.
- On October 10, 2019, we announced that our CHIKV VLP was granted PRIME designation by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) during its September meeting.
- On September 30, 2019, we were awarded a letter contract for the continued supply of BAT® [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G)-(Equine)] into the SNS in support of botulism preparedness and response activity. The maximum value of this 10-year contract is $490 million, with approximately $90 million of deliverables agreed to and the potential value for the remaining deliverable to be negotiated and agreed upon within 180 days from the time of the award.
- On September 27, 2019, we announced the research grant awarded by the National Institute on Drug Abuse, a component of NIH, valued at approximately $6.3 million over two years, for the continued development of AP007, the Company's sustained-release nalmefene formulation for the treatment of addiction in opioid use disorder (OUD).
- On September 25, 2019, we announced our agreement with the Department of Defense (DoD) through the Medical CBRN Defense Consortium (MCDC) to develop and manufacture an auto-injector containing diazepam to treat nerve agent-induced seizures;
- On September 3, 2019, we announced the contract award by HHS valued at approximately $2 billion over 10 years for the continued supply of ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live) into SNS in support of smallpox preparedness.
- On June 3, 2019, we announced a contract award by HHS valued at approximately $535 million over 10 years for the continued supply of VIGIV into the SNS in support of smallpox preparedness.
- On May 15, 2019, we announced that BARDA informed the Company that it will begin procuring AV7909 (anthrax vaccine adsorbed with CPG 7909 adjuvant) for delivery into the SNS. On July 30, 2019, BARDA exercised its first contract option valued at $261 million to procure doses to be delivered to the SNS through June of 2020.
- On April 16, 2019, we announced results from an interim analysis of our Phase 2 clinical study evaluating the safety and immunogenicity of our CHIKV VLP product candidate across a series of dosing regimens. The interim analysis has shown that with a single dose administered, up to 98% of study participants produced a neutralizing antibody response against the chikungunya virus by day 7. Further, the immune response was shown to be persistent through the six-month visit, following the one-dose regimen.
- On March 19, 2019, we announced the initiation of a Phase 3 trial to evaluate the lot consistency, immunogenicity, and safety of AV7909 (anthrax vaccine adsorbed with adjuvant) following a two-dose schedule administered intramuscularly in healthy adults. AV7909 is being developed for post-exposure prophylaxis of disease resulting from suspected or confirmed Bacillus anthracis exposure.
- On February 28, 2019, we announced that we had signed an indefinite-delivery, indefinite-quantity contract with the U.S. Department of State to establish a long-term, reliable, and stable supply chain for MCMs intended to remove or neutralize chemical warfare agents and certain related toxins from the skin. The contract is comprised of a five-year base period of performance along with five one-year option periods with a total contract value of a minimum of approximately $7 million to a maximum of $100 million over the contract's period of performance. We will be supplying two of our current medical countermeasures addressing chemical threats.

Financial Operations Overview Revenues

We generate revenues from the sale of our marketed products and product candidates which include Vaccines, Therapeutics and Devices which have been described above. Additionally, revenue is generated from the performance of CDMO services, and our performance of research and development services under contracts and grants. 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. Our opioid overdose reversal product, NARCAN® Nasal Spray and our travel health products, comprising Vivotif and Vaxchora, are sold commercially through wholesalers and distributors, physician-directed or standing order prescriptions at retail pharmacies, as well as to other state and local community healthcare agencies, practitioners and hospitals.

We also generate revenue from the performance of CDMO 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 contracts and grants funding from the USG and other non-governmental organizations to perform research and development activities, particularly related to programs addressing certain CBRNE threats and EIDs.

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 Development and Manufacturing Services

The primary expenses that we incur to deliver our products and to perform CDMO services consist of fixed and variable costs. 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. Fixed manufacturing costs include facilities, utilities and amortization of intangible assets. 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. In addition to the fixed and variable manufacturing costs described above, the cost of product sales depends on utilization of available manufacturing capacity. For our commercial sales, other associated expenses include sales-based royalties (which include 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 generally 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 development and manufacturing or research and development expense.

Income Taxes

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.

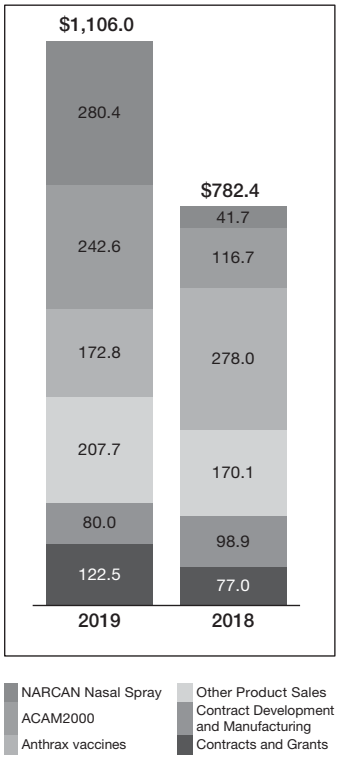
Management believes that the assumptions and estimates related to the provision for income taxes are critical to the Company's results of operations. For the year ended December 31, 2019, income tax expense totaled $22.9 million. For every 1% change in the 2019 effective rate, income tax expense would have changed by approximately $0.8 million.

For additional information on our uncertain tax positions and income tax expense, please see note 12, *Income taxes* to our consolidated financial statements included in this report.

Results of Operations

(in millions)	Year ended December 31, 2019	2018	$ Change	% Change
Product sales net:				
NARCAN Nasal Spray	$ 280.4	$ 41.7	$ 238.7	572%
ACAM2000	242.6	116.7	125.9	108%
Anthrax vaccines	172.8	278.0	(105.2)	(38)%
Other	207.7	170.1	37.6	22%
Total product sales, net	903.5	606.5	297.0	49%
Contract development and manufacturing services	80.0	98.9	(18.9)	(19)%
Contracts and grants	122.5	77.0	45.5	59%
Total revenues	1,106.0	782.4	323.6	41%
Operating expenses:				
Cost of product sales and contract development and manufacturing services	433.5	322.3	111.2	35%
Research and development	226.2	142.8	83.4	58%
Selling, general and administrative	273.5	202.5	71.0	35%
Amortization of intangible assets	58.7	25.0	33.7	135%
Total operating expenses	991.9	692.6	299.3	43%
Income from operations	114.1	89.8	24.3	27%
Other income (expense):				
Interest expense	(38.4)	(9.9)	(28.5)	288%
Other income (expense), net	1.7	1.6	0.1	6%
Total other expense, net	(36.7)	(8.3)	(28.4)	342%
Income before income taxes	77.4	81.5	(4.1)	(5)%
Income tax expense	22.9	18.8	4.1	22%
Net income	$ 54.5	$ 62.7	$ (8.2)	(13)%

Total Revenues



Product Sales, net

NARCAN Nasal Spray

NARCAN Nasal Spray was acquired in October 2018 in connection with the Company's acquisition of Adapt resulting in an increase in product sales in 2019 compared to 2018

ACAM2000

The increase in ACAM2000 sales for the year ended December 31, 2019 was primarily due to the volume and contractual per unit pricing increases of ACAM2000 delivered to the SNS as a result of the contract awarded by the USG in September 2019. Deliveries under this contract began in September.

Anthrax Vaccines (BioThrax® and AV7909®)

The decrease in anthrax vaccine sales for the year ended December 31, 2019 was primarily due to the lower number of BioThrax deliveries to the SNS during the period as compared to the prior comparable period partially offset by the unit deliveries of AV7909. The USG purchased fewer units of BioThrax during the year ended December 31, 2019, in connection with the transition to the next-generation anthrax vaccine, AV7909.

Deliveries of AV7909 to the USG began in September of 2019 under the base period and option

period executed by the USG in July 2019 and continued throughout the remainder of 2019.

Substantially all of the anthrax vaccine product sale revenues are made to the USG under long-term procurement contracts. The fluctuations in anthrax vaccine revenues is largely related to changes in volume depending on when the USG requests delivery, how much product the Company has ready in inventory to ship and the timing of funding available from the USG. The USG delivery schedule varies based on funding and management of the SNS inventory.

Volume is also contingent on the availability of product based on timing of manufacturing.

Other Product Sales

The increase in the Company's other product sales during the year ended December 31, 2019, was primarily due to the contribution of products associated with the PaxVax acquisition as well as increased sales of raxibacumab and BAT®, which were partially offset by a decrease in other sales, largely Trobigard, compared to the year ended December 31, 2018.

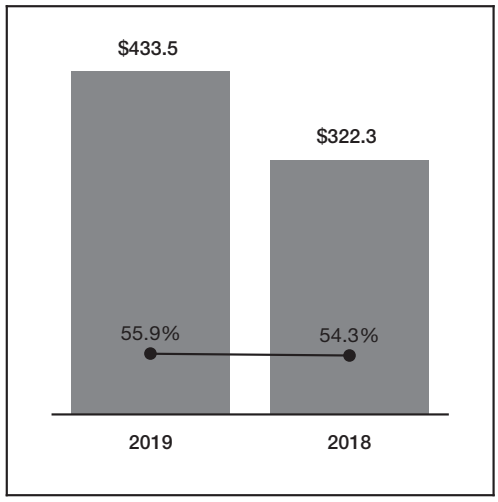
Contract Development and Manufacturing Services

The decrease in CDMO services revenue for the year ended December 31, 2019 is due to contract services performed during the year ended December 31, 2018 to design, construct and validate manufacturing capability at our Lansing, Michigan site and contract manufacturing activities at our Canton, Massachusetts site for which no similar services were provided during in the current year.

Contracts and Grants

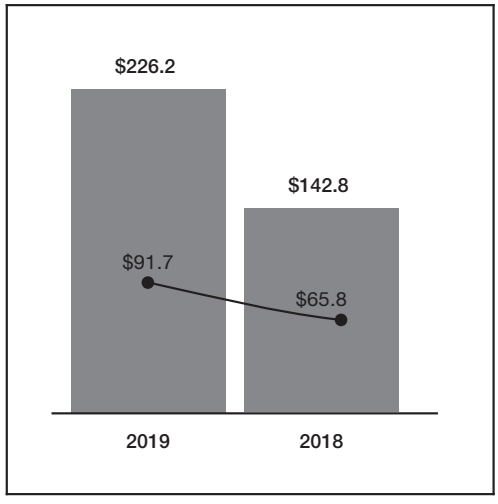
The increase in contracts and grants revenue for the year ended December 31, 2019 primarily reflects research and development activities related to clinical trial activities for AV7909. These increases were partially offset by a reduction in development funding for ACAM2000 stability testing which was performed during the year ended December 31, 2018 for which no similar services were provided in the current period.

Cost of Product Sales and Contract Manufacturing



Cost of product sales and contract development and manufacturing services increased for the year ended December 31, 2019 primarily due to the acquisitions of Adapt and PaxVax, both acquired in October 2018. The increases are proportional to the increase in product sales and contract development and manufacturing services revenues during the year ended December 31, 2019.

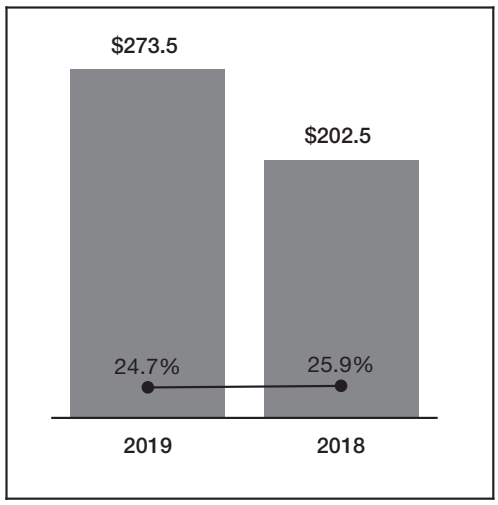
Research and Development Expenses (Gross and Net)



The increase in research and development expenses during the year ended December 31, 2019 is primarily due to expenses incurred at Adapt and PaxVax, costs associated with the development of the CHIK VLP vaccine candidate, timing of manufacturing development activities for our AV7909 product

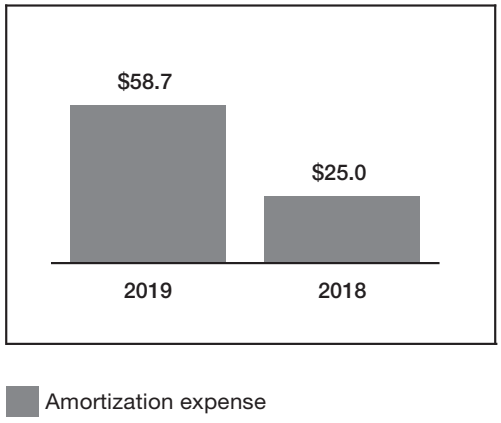
candidate and the impairment of our IPR&D intangible asset acquired as part of the Adapt acquisition. Both Adapt and PaxVax were acquired in October 2018.

Selling, General and Administrative Expenses



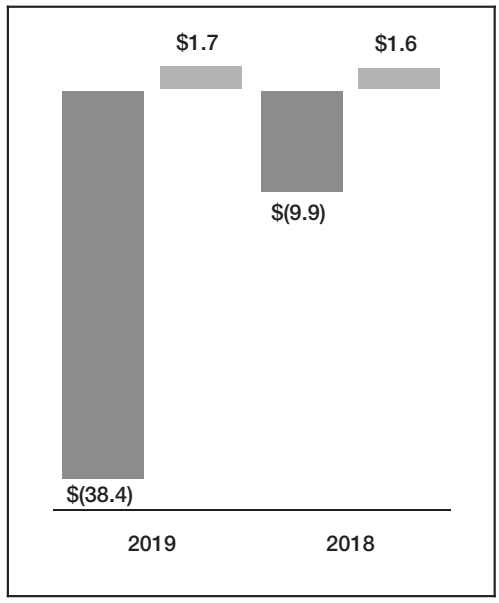
Selling, general and administrative expenses increased for the year ended December 31, 2019 primarily due to an increase of $62.8 million of expenses related to the consolidation of entities acquired in October 2018. The remaining increase is due to an increase in professional services and staffing to support the Company's growth.

Amortization of intangible Assets



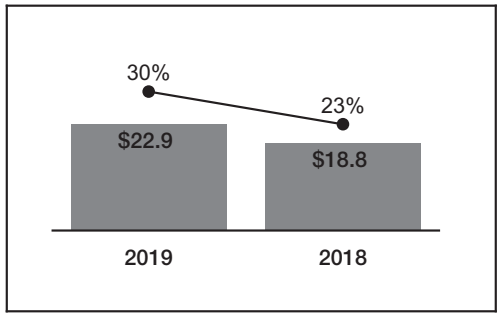
The increase in amortization of intangible assets to $58.7 million from $25.0 million for the year ended December 31, 2019 compared to 2018, was primarily due to the amortization of intangible assets resulting from the acquisitions of Adapt and PaxVax acquired in October 2018.

Total Other Income (Expense), Net



Total other expense, net increased due primarily to an increase in borrowings on our senior secured credit facilities established in October 2018 to fund our acquisitions of Adapt and PaxVax.

Income Tax Expense



The increase in income tax expense during the year ended December 31, 2019 is primarily due an increase in state taxes in 2019. The increase in the effective tax rate to 30% in 2019 is mainly due to the impact of non- deductible expenses. Excluding these non-deductible expenses, our effective tax rate would be approximately 23% in 2019.

Discussion and analysis of the year ended December 31, 2018 compared to the year ended December 31, 2017 is included under the heading ''Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations'' in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on February 21, 2019.

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 for the period ended December 31, 2019. As of December 31, 2019, we had cash and cash equivalents of $167.8 million. As of December 31, 2019, 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, 2019, 2018 and 2017.

	Year ended December 31,		
(in millions)	2019	2018	2017
Net cash provided by (used in):			
Operating activities	$188.0	$ 41.8	$ 208.1
Investing activities	(96.9)	(897.2)	(249.9)
Financing activities	(35.9)	788.7	(51.4)
Effect of exchange rate changes	$ 0.4	$ (0.2)	$ —
Net increase (decrease) in cash and cash equivalents	$ 55.6	$ (66.9)	$ (93.2)

Certain significant cash flows were as follows:

Operating Activities:

Net cash provided by operating activities of $188.0 million in 2019 was primarily due to net income excluding non-cash items of $230.4 million offset by working capital changes of $42.4 million.

Net cash provided by operating activities of $41.8 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.

Net cash provided by operating activities of $208.1 million in 2017 was primarily due to our net income excluding non-cash items of $154.4 million and changes in working capital which resulted in a net cash inflow of $53.7 million.

Investing Activities:

Net cash used in investing activities of $96.9 million in 2019 was primarily due to infrastructure and equipment investments.

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.

Financing Activities:

Net cash used in financing activities of $35.9 million in 2019 was primarily due to contingent consideration payments of $50.4 million mostly in relation to our recent acquisition of Adapt offset by $13.7 of net proceeds from debt.

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.

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 occurrence, plus $200 million and (vii) amended our debt covenant ratios as described below.

For the years ended December 31, 2019, 2018 and 2017, we capitalized $0, $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 financial covenants, which were amended in June 2019. The Amended Credit Agreement contains financial covenants which require the quarterly presentation of a minimum consolidated 12-month rolling debt service coverage ratio of 2.50 to 1.00, and an amended maximum consolidated net leverage ratio of 4.95 to 1.00 for the quarter ended June 30, 2019, 4.75 to 1.00 for the quarter ending September 30, 2019, 3.75 to 1.00 for the quarterly filing periods from October 1, 2019 through September 29, 2020 and 3.50 to 1.0, thereafter, which may be adjusted to 4.00 to 1.00 for a four quarter period in connection with a material permitted acquisition. The Amended Credit Agreement also contains affirmative and negative covenants, which were also amended in June 2019 to limit the amount of restricted payments as defined in the Amended Credit Agreement to $25 million until the filing of the Company's December 31, 2019 Form 10-K. Negative covenants in the Amended Credit Agreement, among other things, limit the ability of the Company to incur indebtedness and liens, dispose of assets, make investments and enter into certain merger or consolidation transactions. As of the date of these financial statements, the Company is in compliance with all affirmative and negative covenants.

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 development and 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 development and 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 adopt a share repurchase program and repurchase shares of our common stock 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.

Unused Credit Capacity

Available room under the revolving credit facility for the years ended December 31, 2019 and 2018 was:

(in millions)			
December 31, 2019			
Total Capacity	Outstanding Letters of Credit	Outstanding Indebtedness	Unused Capacity
$600.0	2.2	373.0	$224.8
December 31, 2018			
$600.0	1.4	348.0	$250.6

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2019:

	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	$822.5	$14.1	$69.6	$735.8	$3.0
Lease obligations	30.6	4.5	13.7	5.9	6.5
Purchase commitments	59.7	59.7	—	—	—
Total contractual obligations	$912.7	$78.2	$83.3	$741.7	$9.5

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 2019 Annual Report.

Market Risks

We have interest rate and foreign currency market risk. We manage our interest rate risk in part by entering into interest rate swaps to swap a portion of our indebtedness that is based on variable interest rates to a fixed rate. We currently do not hedge our 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. We manage the impact of interest rate changes on our variable debt through derivative instruments such as interest rate swap arrangements. For debt that we have not hedged through our interest rate swap arrangements increases in interest rates could therefore increase the associated interest payments that we are required to make on this debt. See Note 9, ''Long-term debt,'' to the Notes of our consolidated financial statements included in this 2019 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, 2019 would increase our interest expense by approximately $4.6 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 Shareholders 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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 24, 2020 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue recognition - identifying performance obligations and variable consideration

Description of the Matter

As described in Note 3 to the consolidated financial statements, the Company recognized revenues of $1,106.0 million for the year ended December 31, 2019. The Company enters into or periodically modifies revenue contracts whose terms are complex and require a significant level of judgment related to management's identification of performance obligations and determination of transaction price including variable consideration. At contract inception, management assesses the products or services promised in its contracts with customers and identifies a performance obligation for each promise to transfer to the customer a product or service that is distinct including evaluating whether the contract includes a customer option for additional goods or services which could represent a material right. In addition, the Company estimates the transaction price of the contract, including variable consideration that is subject to a constraint. The Company's estimation of variable consideration is subject to management's judgment and assumptions including returns, certain fees, discounts and rebates.

Auditing management's identification of the performance obligations and determination of the variable consideration in certain contracts involved judgment due to the subjective nature of the evaluation of customer options for additional goods or services as a material right and the estimation uncertainty in management's determination of the variable consideration and the related constraint (or lack thereof). For example, the estimated rebates and returns is subject to significant judgment because their expected value is based on assumptions including sales or invoice data, contractual terms, historical utilization rates and the related product program's regulations and guidelines. The estimated rebates and returns are forward-looking and could be affected by future economic conditions and the competitive environment.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of the Company's internal controls addressing revenue recognition including identification of performance obligations, and estimation of variable consideration. For example, we tested controls over management's review of the identification of performance obligations and management's review over the assumptions used in the estimation of the rebates and returns. We also tested management's controls over the completeness and accuracy of the data used in the underlying calculations.

To test management's identification of performance obligations, and variable consideration, our audit procedures included, among others, reading certain executed contracts, understanding the methodologies utilized and testing the completeness and accuracy of the information used in management's assessment. For example, in evaluating the estimate for rebates and returns, we reviewed the historical data available and compared to management's estimated rebates and returns related to current period sales. In addition, we recalculated the estimated rebates and returns, and we compared management's assumptions to industry standards and trends for comparable products.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2004.
Baltimore, Maryland
February 24, 2020

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

	December 31,	
	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 167.8	$ 112.2
Restricted cash	0.2	0.2
Accounts receivable, net	270.7	262.5
Inventories	222.5	205.8
Income tax receivable, net	4.6	8.6
Prepaid expenses and other current assets	20.4	31.5
Total current assets	686.2	620.8
Property, plant and equipment, net	542.3	510.2
Intangible assets, net	712.9	761.6
In-process research and development	29.0	50.0
Goodwill	266.6	259.7
Deferred tax assets, net	13.4	13.4
Other assets	76.9	13.7
Total assets	2,327.3	2,229.4
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 94.8	$ 80.7
Accrued expenses	39.5	30.7
Accrued compensation	62.4	58.2
Debt, current portion	12.9	10.1
Contingent consideration, current portion	3.2	5.6
Other current liabilities	3.5	15.1
Total current liabilities	216.3	200.4
Contingent consideration, net of current portion	26.0	54.4
Debt, net of current portion	798.4	784.5
Deferred tax liability	63.9	67.5
Contract liabilities, net of current portion	85.6	62.5
Other liabilities	48.6	49.2
Total liabilities	1,238.8	1,218.5
Stockholders' equity:		
Preferred stock, $0.001 par value; 15.0 shares authorized, 0 shares issued and outstanding at both December 31, 2019 and 2018	—	—
Common stock, $0.001 par value; 200.0 shares authorized, 52.9 shares issued and 51.7 shares outstanding at December 31, 2019; 52.4 shares issued and 51.2 shares outstanding at December 31, 2018	0.1	0.1
Treasury stock, at cost, 1.2 common shares at December 31, 2019 and 2018	(39.6)	(39.6)
Additional paid-in capital	716.1	688.6
Accumulated other comprehensive loss, net	(9.9)	(5.5)
Retained earnings	421.8	367.3
Total stockholders' equity	1,088.5	1,010.9
Total liabilities and stockholders' equity	$2,327.3	$2,229.4

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,		
	2019	2018	2017
Revenues:			
Product sales, net	$ 903.5	$606.5	$421.5
Contract development and manufacturing services	80.0	98.9	68.9
Contracts and grants	122.5	77.0	70.5
Total revenues	1,106.0	782.4	560.9
Operating expenses:			
Cost of product sales and contract development and manufacturing services	433.5	322.3	187.7
Research and development	226.2	142.8	97.4
Selling, general and administrative	273.5	202.5	142.9
Amortization of intangible assets	58.7	25.0	8.6
Total operating expenses	991.9	692.6	436.6
Income from operations	114.1	89.8	124.3
Other income (expense):			
Interest expense	(38.4)	(9.9)	(6.6)
Other income (expense), net	1.7	1.6	0.9
Total other income (expense), net	(36.7)	(8.3)	(5.7)
Income before provision for income taxes	77.4	81.5	118.6
Provision for income taxes	22.9	18.8	36.0
Net income	$ 54.5	$ 62.7	$ 82.6
Net income per share-basic	$ 1.06	$ 1.25	$ 1.98
Net income per share-diluted (Note 15)	$ 1.04	$ 1.22	$ 1.71
Weighted-average number of shares - basic	51.5	50.1	41.8
Weighted-average number of shares - diluted	52.4	51.4	50.3

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,		
	2019	2018	2017
Net income	$54.5	$62.7	$82.6
Other comprehensive income (loss), net of tax:			
Foreign currency translation	0.4	(1.6)	0.6
Unrealized losses on hedging activities, net of tax	(1.6)	—	—
Unrealized losses on pension benefit obligation, net of tax	(3.2)	(0.2)	—
Total other comprehensive income (loss), net of tax	(4.4)	(1.8)	0.6
Comprehensive income	$50.1	$60.9	$83.2

During 2019, there were tax benefits related to unrealized losses on hedging activities and the pension benefit obligation of $0.4 million and $0.5 million, respectively. During 2018 and 2017, the tax effect of the amounts presented was de minimus.

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,		
	2019	2018	2017
Cash flows from operating activities:			
Net income	$ 54.5	$ 62.7	$ 82.6
Adjustments to reconcile to net cash provided by operating activities:			
Share-based compensation	26.7	23.2	15.2
Depreciation and amortization	110.7	62.2	42.6
Deferred income taxes	(1.1)	8.6	3.3
Change in fair value of contingent consideration, net	24.8	3.1	7.8
Impairment of IPR&D intangible asset	12.0	—	—
Amortization of deferred financing costs	3.0	0.9	1.7
Other	(0.2)	0.2	1.2
Changes in operating assets and liabilities:			
Accounts receivable	(8.2)	(94.2)	(4.8)
Inventories	(16.7)	(1.9)	6.1
Income taxes	(11.7)	(5.1)	20.1
Prepaid expenses and other assets	(27.4)	(7.9)	(3.7)
Accounts payable	16.5	(7.0)	16.1
Accrued expenses and other liabilities	(15.1)	(11.6)	1.6
Accrued compensation	4.2	8.4	3.3
Deferred revenue	16.0	0.2	15.0
Net cash provided by operating activities:	188.0	41.8	208.1
Cash flows from investing activities:			
Purchases of property, plant and equipment and other	(86.9)	(72.1)	(54.8)
Milestone payment from asset acquisition	(10.0)	—	—
Asset acquisitions	—	—	(77.6)
Business acquisitions, net of cash acquired	—	(827.7)	(117.5)
Proceeds from sale of assets	—	2.6	—
Net cash used in investing activities:	(96.9)	(897.2)	(249.9)
Cash flows from financing activities:			
Proceeds from revolving credit facility	130.0	348.0	—
Proceeds from term loan facility	—	450.0	—
Principal payments on revolving credit facility	(105.0)	—	—
Principal payments on term loan facility	(11.3)	(2.8)	—
Proceeds from issuance of common stock upon exercise of stock options	8.2	15.9	19.3
Debt issuance costs	—	(13.4)	(1.4)
Taxes paid on behalf of employees for equity activity	(7.4)	(6.6)	(4.3)
Payment of notes payable to Aptevo	—	—	(20.0)
Contingent consideration payments	(50.4)	(3.4)	(10.9)
Receipts and payments of restricted cash	—	1.1	(1.0)
Purchase of treasury stock	—	(0.1)	(33.1)
Net cash (used in) provided by financing activities	(35.9)	788.7	(51.4)
Effect of exchange rate changes on cash and cash equivalents	0.4	(0.2)	—
Net increase (decrease) in cash and cash equivalents and restricted cash	55.6	(66.9)	(93.2)
Cash and cash equivalents and restricted cash at beginning of year	112.4	179.3	272.5
Cash and cash equivalents and restricted cash at end of year	$ 168.0	$ 112.4	$ 179.3
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ 34.5	$ 10.2	$ 8.4
Cash paid during the year for income taxes	$ 30.8	$ 14.0	$ 12.0
Supplemental information on non-cash investing and financing activities:			
Issuance of common stock to acquire Adapt Pharma	$ —	$ 37.7	$ —
Purchases of property, plant and equipment unpaid at year end	$ 12.3	$ 14.7	$ 4.6
Reconciliation of cash and cash equivalents and restricted cash:			
Cash and cash equivalents	$ 167.8	$ 112.2	$ 178.3
Restricted cash	0.2	0.2	1.0
Total	$ 168.0	$ 112.4	$ 179.3

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

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

	$0.001 Par Value Common Stock		Additional Paid-In	Treasury Stock		Accumulated Other Comprehensive	Retained	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	Loss	Earnings	Equity
Balance at December 31, 2016	41.0	$ —	$ 352.4	(0.4)	$ (6.4)	$ (4.3)	$ 254.5	$ 596.2
Employee equity plans activity	1.1	—	28.0	—	—	—	—	28.0
Shares issued to extinguish convertible notes	8.5	0.1	237.9	—	—	—	—	238.0
Treasury stock	—	—	—	(0.8)	(33.1)	—	—	(33.1)
Net income	—	—	—	—	—	—	82.6	82.6
Other comprehensive income	—	—	—	—	—	0.6	—	0.6
Balance at December 31, 2017	50.6	$ 0.1	$ 618.3	(1.2)	$ (39.5)	$ (3.7)	$ 337.1	$ 912.3
Adoption of new accounting standard (ASC 606), net of tax	—	—	—	—	—	—	(32.5)	(32.5)
Balance at January 1, 2018	50.6	0.1	618.3	(1.2)	(39.5)	(3.7)	304.6	879.8
Employee equity plans activity	1.1	—	32.6	—	—	—	—	32.6
Issuance of common stock in acquisition	0.7	—	37.7	—	—	—	—	37.7
Treasury stock	—	—	—	—	(0.1)	—	—	(0.1)
Net income	—	—	—	—	—	—	62.7	62.7
Other comprehensive loss	—	—	—	—	—	(1.8)	—	(1.8)
Balance at December 31, 2018	52.4	$ 0.1	$ 688.6	(1.2)	$ (39.6)	$ (5.5)	$ 367.3	$ 1,010.9
Employee equity plans activity	0.6	—	27.5	—	—	—	—	27.5
Net income	—	—	—	—	—	—	54.5	54.5
Other comprehensive loss	—	—	—	—	—	(4.4)	—	(4.4)
Balance at December 31, 2019	53.0	$ 0.1	$ 716.1	(1.2)	$ (39.6)	$ (9.9)	$ 421.8	$ 1,088.5

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

1. Nature of the business and organization

Organization and business

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

The Company is focused on innovative preparedness and response products and solutions addressing the following six distinct PHT categories: Chemical, Biological, Radiological, Nuclear and Explosives (''CBRNE''); emerging infectious diseases (''EID''); travel health; emerging health crises, acute/emergency care, and contract development and manufacturing (''CDMO''). The Company has a product portfolio of twelve products and product candidates (vaccines, therapeutics, and drug-device combination products) that generate a majority of our revenue. The U.S. government (the ''USG') is the Company's largest customer and provides us with substantial funding for the development of a number of its product candidates.

The Company's product portfolio includes:

Vaccines

- ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), the only single-dose smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection;
- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration (''FDA''), for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- Vaxchora® (Cholera Vaccine, Live, Oral), the only FDA-licensed vaccine for the prevention of cholera, it is orally delivered; and
- Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever.

Devices

- NARCAN® (naloxone HCl) Nasal Spray, 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;
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only medical device cleared by the FDA to remove or neutralize the following chemical warfare agents from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin; and

Therapeutics

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

Product Candidates

- AV7909® (Anthrax Vaccine Absorbed with Adjuvant), is a product candidate being developed as a next generation anthrax vaccine for post-exposure prophylaxis of disease resulting from suspected or confirmed Bacillus antracis exposure. The USG has started procuring AV7909 for the SNS prior to its approval by the FDA and has been reducing its purchases of BioThrax as a result;
- Trobigard® is a combination drug-device auto-injector product candidate that contains atropine sulfate and obidoxime chloride. It has not been approved by the FDA or any similar health regulatory body, but is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure.

The Company also generates revenue from contract development and manufacturing services on a clinical and commercial (small and large) scale by providing such services to the pharmaceutical and biotechnology industry. These services include process development and bulk drug substance and drug product manufacturing of biologics, fill/finish formulation and analytical development services for injectable and other sterile products, inclusive of process design, technical transfer, manufacturing validations, aseptic filling, lyophilization, final packaging and stability studies, as well as manufacturing of vial and pre-filled syringe formats across bacterial, viral and mammalian therapy technology platforms.

We operate as one operating segment.

2. Summary of significant accounting policies

Basis of presentation and consolidation

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

Use of estimates

The preparation of financial statements in accordance with U.S. generally accepted accounting principles (''GAAP'') requires management to make estimates, judgments and assumptions that affect the amounts and disclosures reported in the consolidated financial statements and accompanying notes. Management continually re-evaluates its estimates, judgments and assumptions, and management's evaluations could change. These estimates are sometimes complex, sensitive to changes in assumptions and require fair value determinations using Level 3 fair value measurements. Actual results may differ materially from those estimates.

Estimates and judgments inherent in the preparation of the consolidated financial statements include accounting for asset impairments, revenue recognition, allowances for doubtful accounts, inventory, depreciation and amortization, business combinations, contingent consideration, stock-based compensation, income taxes, and other contingencies.

Cash, cash equivalents and restricted cash

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions. Also, the Company maintains cash balances with financial institutions in excess of insured limits. The Company does not anticipate any losses with such cash balances. Restricted cash includes cash that is not readily available for use in the Company's operating activities. Restricted cash is primarily comprised of cash pledged under letters of credit.

Fair value measurements

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

Level 1 — Observable inputs for identical assets or liabilities such as quoted prices in active markets;

Level 2 — Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3 — Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

On a recurring basis, the Company measures and records money market funds (level 1), contingent purchase considerations (level 3) and interest-rate swap arrangements (level 2) using fair value measurements in the accompanying financial statements. On a non-recurring basis, the Company measures its IPR&D assets (level 3) using fair value measurements. The carrying amounts of the Company's short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair values due to their short maturities. The carrying amounts of the Company's long-term debt arrangements approximates their fair values due to variable interest rates which fluctuate with changes in market rates.

Significant customers and accounts receivable

Billed accounts receivable are stated at invoice amounts and consist mostly of amounts due from the USG, as well as amounts due under reimbursement contracts with other government entities and non-government organizations. Our opioid overdose reversal product is sold commercially through physician-directed or standing order prescriptions at retail pharmacies, as well as state health departments, law enforcement agencies, state and local community based organizations, substance abuse centers and federal agencies. If necessary, the Company records a provision for doubtful receivables to allow for amounts which may be unrecoverable. This provision is based upon an analysis of the Company's prior collection experience, customer creditworthiness and current economic trends. Unbilled accounts receivable relates to various service contracts for which work has been performed, though invoicing has not yet occurred.

Concentration Risk

Customers

The Company has long-term contracts with the USG that expire at various times from 2020 through 2029. The Company has derived a significant portion of its revenue from sales of ACAM2000 and Anthrax

Vaccines under contracts with the USG. The Company's current USG contracts do not necessarily increase the likelihood that it will secure future comparable contracts with the USG. The Company expects that a significant portion of the business will continue to be under government contracts that present a number of risks that are not typically present in the commercial contracting process. USG contracts for ACAM 2000 and Anthrax Vaccines are subject to unilateral termination or modification by the government. The Company may fail to achieve significant sales of ACAM 2000 and Anthrax Vaccines to customers in addition to the USG, which would harm its growth opportunities. The Company may not be able to manufacture Anthrax Vaccines consistently in accordance with FDA specifications. The Company's other product sales are largely sold commercially through physician-directed or standing order prescriptions at retail pharmacies, as well as to state health departments, local law enforcement agencies, community-based organizations, substance abuse centers and other federal agencies.

Although the Company seeks expand its customer base and to renew its agreements with its customers prior to expiration of a contract, a delay in securing a renewal or a failure to secure a renewal or a renewal on less favorable terms may have a material adverse effect on the Company's financial condition and results of operations.

The Company's trade receivables do not represent a significant concentration of credit risk. The USG accounted for approximately 61%, 76% and 78% of total revenues for 2019, 2018 and 2017, respectively, and approximately 69% and 76% of total accounts receivable as of December 31, 2019 and 2018, respectively. Because accounts receivable consists primarily of amounts due from the USG for product sales and from government agencies under government grants and development contracts, management does not deem the credit risk to be significant.

Financial Institutions

Cash and cash equivalents are maintained with several financial institutions. The Company has deposits held with banks that exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and are maintained with financial institutions of reputable credit and, therefore, bear minimal credit risk.

Lender Counterparties

There is lender counterparty risk associated with the Company's revolving credit facility and derivatives instruments. There is risk that the Company's revolving credit facility investors and derivative counterparties will not be available to fund as obligated. If funding under the revolving credit facility is unavailable, the Company may have to acquire a replacement credit facility from different counterparties at a higher cost or may be unable to find a suitable replacement. The Company seeks to manage risks from its revolving credit facility and derivative instruments by contracting with experienced large financial institutions and monitoring the credit quality of its lenders. As of December 31, 2019, the Company did not anticipate nonperformance by any of its counterparties.

Inventories

Inventories are stated at the lower of cost or net realizable value with cost being determined using a standard cost method, which approximates average cost. Average cost consists primarily of material, labor and manufacturing overhead expenses (including fixed production-overhead costs) and includes the services and products of third-party suppliers.

The Company analyzes its inventory levels quarterly and writes down, in the applicable period, inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand. The Company also writes off, in the applicable period, the costs related to expired inventory. Costs of purchased inventories are recorded using weighted-average costing. The Company determines normal capacity for each production facility and allocates fixed production-overhead costs on that basis.

The Company records inventory acquired in business acquisitions utilizing the comparative sales method, which estimates the expected sales price reduced for all costs expected to be incurred to complete/dispose of the inventory with a profit on those costs.

Property, plant and equipment

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

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

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

The Company capitalizes internal-use software when both (a) the software is internally developed, acquired, or modified solely to meet the entity's internal needs and (b) during the software's development or modification, no substantive plan

either exists or is being developed to market the software externally. Capitalization of qualifying internal-use software costs begins when the preliminary project stage is completed, management with the relevant authority, implicitly or explicitly, authorizes and commits to the funding of the software project, and it is probable that the project will be completed and the software will be used to perform the function intended.

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

Income taxes

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

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

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

Under sections 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a ''loss corporation'', as defined therein, there are annual limitations on the amount of net operating losses and deductions that are available. The Company has recognized the portion of net operating losses and research and development tax credits acquired that will not be limited and are more likely than not to be realized.

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

Acquisitions

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

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the merger or acquisition at their respective fair values with limited exceptions and generally use Level 3 fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair

values that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the merger or acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an asset acquisition and recorded at cost rather than a business combination and, therefore, no goodwill will be recorded.

The fair values of intangible assets, including acquired in-process research and development (''IPR&D''), are determined utilizing information available at or near the merger or acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, the Company typically obtains assistance from third-party valuation specialists for significant items. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets. Upon successful completion of each project, the Company will make a separate determination as to the remaining useful life of the asset and begin amortization. The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect the Company's results of operations.

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

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

Assets acquired and liabilities assumed in a business combination that arise from contingencies are recognized at fair value if fair value can reasonably be estimated. If the acquisition date fair value of an asset acquired or liability assumed that arises from a contingency cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized.

Asset Impairment Analysis

Goodwill and Indefinite-lived Intangible Assets

Goodwill is allocated to the Company's reporting units, which are one level below its operating segment. The Company evaluates goodwill and other indefinite-lived intangible assets for impairment annually as of October 1 and earlier if an event or other circumstance indicates that we may not recover the carrying value of the asset. If the Company believes that as a result of its qualitative assessment it is more likely than not that the fair value of a reporting unit or other indefinite-lived intangible asset is greater than its carrying amount, the quantitative impairment test is not required. If however it is determined that it is not more likely than not that the fair value of a reporting unit or other indefinite-lived intangible asset is greater than its carrying amount, a quantitative test is required.

The quantitative goodwill impairment test is performed using a two-step process. The first step of the process is to compare the fair value of a reporting unit with its carrying amount, including goodwill. If the fair value of a reporting unit exceeds its carrying amount, goodwill of the reporting unit is not impaired and the second step of the quantitative impairment test is not necessary. If the carrying amount of a reporting unit exceeds its fair value, the second step of the quantitative goodwill impairment test is required to be performed to measure the amount of impairment loss, if any. The second step of the quantitative goodwill impairment test compares the implied fair value of the reporting unit's goodwill with the carrying amount of that goodwill. The implied fair value of goodwill is determined in the same manner as the amount of goodwill recognized in a business combination. In other words, the estimated fair value of the reporting unit's identifiable net assets excluding goodwill is compared to the fair value of the

reporting unit as if the reporting unit had been acquired in a business combination and the fair value of the reporting unit was the purchase price paid. If the carrying amount of the reporting unit's goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess. The Company used a qualitative assessment for our goodwill impairment testing for 2019 and 2018. The qualitative evaluation completed during the years ended December 31, 2019 and 2018 indicated no impairment losses.

The Company has material indefinite lived intangible assets associated with in-process research and development (IPR&D) which were acquired as part of the acquisitions completed in the fourth quarter of 2018. Following a qualitative assessment indicating that it is not more likely than not that the fair value of the indefinite lived intangible asset exceeds its carrying amount, impairment of other intangible assets not subject to amortization involves a comparison of the estimated fair value of the intangible asset with its carrying value. If the carrying value of the intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. Determining fair value requires the exercise of judgment about appropriate discount rates, perpetual growth rates and the amount and timing of expected future cash flows. The Company used a quantitative assessment for our IPR&D impairment testing for 2019 and determined there was an impairment loss of $12.0 million, which was recorded as a component of R&D expense (see Notes 4 Acquisitions and 5 Fair value measurements).

Long-lived Assets

Long-lived assets such as intangible assets and property, plant and equipment are not required to be tested for impairment annually. Instead, long-lived assets are tested for impairment whenever circumstances indicate that the carrying amount of the asset may not be recoverable, such as when the disposal of such assets is likely or there is an adverse change in the market involving the business employing the related assets. If an impairment analysis is required, the impairment test employed is based on whether the Company's intent is to hold the asset for continued use or to hold the asset for sale. If the intent is to hold the asset for continued use, the impairment test first requires a comparison of undiscounted future cash flows to the carrying value of the asset. If the carrying value of the asset exceeds the undiscounted cash flows, the asset would not be deemed to be recoverable. Impairment would then be measured as the excess of the asset's carrying value over its fair value. Fair value is typically determined by discounting the future cash flows associated with that asset. If the intent is to hold the asset for sale and certain other criteria are met, the impairment test involves comparing the asset's carrying value to its fair value less costs to sell. To the extent the carrying value is greater than the asset's fair value less costs to sell, an impairment loss is recognized in an amount equal to the difference. Significant judgments used for long-lived asset impairment assessments include identifying the appropriate asset groupings and primary assets within those groupings, determining whether events or circumstances indicate that the carrying amount of the asset may not be recoverable, determining the future cash flows for the assets involved and assumptions applied in determining fair value, which include, reasonable discount rates, growth rates, market risk premiums and other assumptions about the economic environment.

Contingent Consideration

In connection with the Company's acquisitions accounted for as business combinations, the Company records contingent consideration associated with sales-based royalties, sales-based milestones and development and regulatory milestones at fair value. The fair value model used to calculate these obligations is based on the income approach (a discounted cash flow model) that has been risk adjusted based on the probability of achievement of net sales and achievement of the milestones. The inputs the Company uses for determining the fair value of the contingent consideration associated with sales-based royalties, sales-based milestones and development and regulatory milestones are Level 3 fair value measurements. The Company re-evaluates the fair value on a quarterly basis. Changes in the fair value can result from adjustments to the discount rates and updates in the assumed timing of or achievement of net sales and/or the achievement of development and regulatory milestones. Any future increase in the fair value of the contingent consideration associated with sales-based royalties and sales-based milestones along with development and regulatory milestones are based on an increased likelihood that the underlying net sales or milestones will be achieved.

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

The associated payment or payments which will become due and payable for development and regulatory milestones will result in a charge to research and development expense in the period in

which the increase is determined. Similarly, any future decrease in the fair value for development and regulatory milestones will result in a reduction in research and development expense.

Revenue recognition

On January 1, 2018 the Company adopted ASC topic 606 using the modified retrospective approach applied to those contracts in effect as of January 1, 2018. Under this transition method, results for reporting periods beginning after January 1, 2018 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported in accordance with historical accounting under Topic 605. See further discussion of the adoption of Topic 606, including the impact to our 2018 financial statements within the recently issued accounting standards section below.

The Company recognizes revenue when the Company's customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services by analyzing the following five steps: (1) identify the contract with a customer(s); (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. To indicate the transfer of control for the Company's product sales and contract development and manufacturing services, it must have a present right to payment, legal title must have passed to the customer, and the customer must have the significant risks and rewards of ownership. Revenue for long-term development contracts is generally recognized based upon the cost-to-cost measure of progress, provided that the Company meets the criteria associated with transferring control of the good or service over time.

Multiple performance obligations

A performance obligation is a promise in a contract to transfer a distinct product or service to a customer and is the unit of account under ASC 606. Contracts sometimes include options for customers to purchase additional products or services in the future. Customer options that provide a material right to the customer, such as free or discounted products or services, give rise to a separate performance obligation. For contracts with multiple performance obligations, the Company allocates the contract price to each performance obligation on a relative standalone selling price basis using the Company's best estimate of the standalone selling price of each distinct product or service in the contract. The primary method used to estimate standalone selling price is the price observed in standalone sales to customers, however when prices in standalone sales are not available the Company may use third-party pricing for similar products or services or estimate the standalone selling price. Allocation of the transaction price is determined at the contracts' inception.

Transaction price and variable consideration

Once the performance obligations in the contract have been identified, the Company estimates the transaction price of the contract. The estimate includes amounts that are fixed as well as those that can vary based on expected outcomes of the activities or contractual terms. The Company's variable consideration includes for example consideration transferred under its development contracts with the USG as consideration received can vary based on developmental progression of the product candidate(s). When a contract's transaction price includes variable consideration, the Company evaluates the variable consideration to determine whether the estimate needs to be constrained; therefore, the Company includes the variable consideration in the transaction price only to the extent that it is probable that a significant reversal of the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration estimates are updated at each reporting date. There were no significant constraints or material changes to the Company's variable consideration estimates as of or during the twelve months ended December 31, 2019.

Contract financing

In determining the transaction price, the Company adjusts the promised amount of consideration for the effects of the time value of money if the timing of payments agreed to by the parties to the contract (either explicitly or implicitly) provides the customer with a significant benefit of financing the transfer of goods or services to the customer, which is called a significant financing component. The Company does not adjust transaction price for the effects of a significant financing component when the period between the transfer of the promised good or service to the customer and payment for that good or service by the customer is expected to be one year or less.

Product sales

CBRNE

The primary customer for the Company's CBRNE products and the primary source of funding for the development of its CBNRE product candidate portfolio is the USG. The Company's contracts for the sale of CBRNE products generally have a single performance obligation. Certain product sales contracts with the USG include multiple performance obligations, which generally include the marketed product, stability testing associated with that product, expiry extensions and plasma collection. The USG contracts for the sale of the Company's CBRNE products are normally multi-year contracts. AV7909 and Trobigard are product candidates that are not approved by the FDA or any other health agency, but are procured by certain government agencies under special circumstances.

The transaction price for product sales are based on a cost build-up model with a mark-up. For our product sales, we recognize revenue at a ''point in time'' when the Company's performance obligations have been satisfied and control of the products transfer to the customer. This ''point in time'' depends on several factors, including delivery, transfer of legal title, transition of risk and rewards of the product to the customer and the Company's right to payment. The USG contracts for the sale of the Company's CBRNE products also include certain acceptance criteria before title passes to the USG.

Opioid and travel health products

Revenues are recognized when control of the goods are transferred to our customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Allowances for returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, chargebacks and rebates under managed care plans are considered in determining the variable consideration. Revenues from sales of products is recognized to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with such variable consideration is subsequently resolved. Product sales revenue is recognized when control has transferred to the customer, which occurs at a point in time, which is typically upon delivery to the customer. Provisions for variable consideration revenues from sales of products are recorded at the net sales price, which includes estimates of variable consideration for which provisions are established and which relate to returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, chargebacks and rebates under managed care plans. Calculating certain of these provisions involves estimates and judgments and the Company determines their expected value based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates, the Company's expectations regarding future utilization rates for these programs and channel inventory data. These provisions reflect the Company's best estimate of the amount of consideration to which the Company is entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. The Company reassesses the Company's provisions for variable consideration at each reporting date. Historically, adjustments to estimates for these provisions have not been material.

Provisions for returns, specialty distributor fees, wholesaler fees, government rebates and rebates under managed care plans are included within current liabilities in the Company's consolidated balance sheets. Provisions for chargebacks and prompt payment discounts are shown as a reduction in accounts receivable.

Contract development and manufacturing services

The Company performs contract development and manufacturing services for third parties. Under these contracts, activities can 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. These contracts, with a duration that is less than one year, generally include a single performance obligation as the customer benefits from our performance upon full completion of our services. The performance obligation is satisfied when the Company must have a present right to payment because legal title has passed to the customer, the goods are in the customer's possession with all the risks and rewards of ownership, and the efficacy of the goods has been confirmed. The Company recognizes revenue at a ''point in time'' based on when the performance obligation to the customer is satisfied.

Contracts and grants

The Company generates contract and grant revenue primarily from cost-plus-fee contracts associated with development of certain product candidates. Revenues from reimbursable contracts are recognized as costs are incurred, generally based on allowable costs incurred during the period, plus any recognizable earned fee. The Company uses this input method to measure progress as the customer has the benefit of access to the development research under these projects and therefore benefits from the Company's performance incrementally as research and development activities occur under each project. We consider fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. We analyze costs for contracts and reimbursable grants to ensure reporting of revenues gross versus net is appropriate. Revenue for long-term development contracts is considered variable consideration, because the deliverable is dependent on the successful completion of development and is generally recognized based upon the cost-to-cost measure of progress, provided that the Company meets the criteria associated with satisfying the performance obligation over time. The USG contracts for the development of the Company's CBRNE product candidates are normally multi-year contracts.

Research and development

We expense research and development costs as incurred. The Company's 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 the Company's clinical trials and obtaining and evaluating data from the Company's clinical trials and non-clinical studies;
- costs of contract development and manufacturing services for clinical trial material; and
- costs of materials used in clinical trials and research and development.

Comprehensive income

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

Translation of Foreign Currencies

For our non-U.S. subsidiaries that transact in a functional currency other than the U.S. dollar, assets and liabilities are translated at current rates of exchange at the balance sheet date. Income and expense items are translated at the average foreign currency exchange rates for the period. Adjustments resulting from the translation of the financial statements of our foreign operations into U.S. dollars are excluded from the determination of net income and are recorded in accumulated other comprehensive income, a separate component of equity. For subsidiaries where the functional currency of the assets and liabilities differ from the local currency, non-monetary assets and liabilities are translated at the rate of exchange in effect on the date assets were acquired while monetary assets and liabilities are translated at current rates of exchange as of the balance sheet date. Income and expense items are translated at the average foreign currency rates for the period. Translation adjustments of these subsidiaries are included in other income (expense), net in our consolidated statements of income.

Earnings per share

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

For the years ended December 31, 2019 and 2018, the Company calculated diluted earnings per share using the treasury method by dividing net income by the weighted average number of shares of common stock outstanding during the period. For the year ended December 31, 2017, the Company calculated diluted earnings per share using the if-converted method by dividing the adjusted net income by the adjusted weighted average number of shares of common stock outstanding during the period. The adjusted net income was adjusted for interest expense and amortization of debt issuance cost, both net of tax, associated with the Company's 2.875% Convertible Senior Notes due 2021 (the ''Notes''). The weighted average number of diluted shares was adjusted for the potential dilutive effect of the exercise of stock options and the vesting of restricted stock units along with the assumption of the conversion of the Notes, each at the beginning of the period. During the fourth quarter of 2017, the Company issued a notice of termination of conversion rights related to the Notes and issued 8.5 million shares of common stock due to conversions that occurred in 2017. After the date of conversion and during the years ended December 31, 2019 and 2018, the Notes are strictly debt instruments and, therefore, no longer impact the diluted earnings per share calculation.

Accounting for stock-based compensation

The Company has one stock-based employee compensation plan, the Emergent BioSolutions Inc. Stock Incentive Plan (the ''Emergent Plan''), under which the Company may grant various types of equity awards including stock options, restricted stock units and performance stock units.

The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Emergent Plan is determined by the compensation committee of the Company's board of directors, which administers the Emergent Plan. Each equity award granted under the Emergent Plan vests as specified in the relevant agreement with the award recipient and no option can be exercised after either seven or ten years from the date of grant depending on the grant date. The Company charges the estimated fair value of awards against income on a straight-line basis over the requisite service period, which is generally the vesting period. Where awards are made with non-substantive vesting periods (for instance, where a portion of the award vests upon retirement eligibility), the Company estimate and recognize expense based on the period from the grant date to the date the employee becomes retirement eligible.

The Company determines the fair value of restricted stock units using the closing market price of the Company's common stock on the day prior to the date of grant. The Company's performance stock units settle in stock. The fair value is determined on the date of the grant using the number of shares expected to be earned and the ending market value of the stock on the grant date. The number of shares expected to vest is

determined by assessing the probability that the performance criteria will be met and the associated targeted payout level that is forecasted will be achieved.

The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. Set forth below is a discussion of the Company's methodology for developing each of the assumptions used:

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

Pension plans

The Company maintains defined benefit plans for employees in certain countries outside the U.S., including retirement benefit plans required by applicable local law. The plans are valued by independent actuaries using the projected unit credit method. The liabilities correspond to the projected benefit obligations of which the discounted net present value is calculated based on years of employment, expected salary increase, and pension adjustments. The Company reviews its actuarial assumptions on an annual basis and makes modifications to the assumptions based on current rates and trends. Actuarial gains and losses are deferred in accumulated other comprehensive income, net of tax and are amortized over the remaining service attribution periods of the employees under the corridor method. Differences between the expected long-term return on plan assets and the actual annual return are amortized to net periodic benefit cost over the estimated remaining life as a component of selling, general and administrative expenses in the consolidated statements of operations.

Derivative Instruments and Hedging Activities

The Company's interest rate swaps qualify for hedge accounting as cash flow hedges. All derivatives are recorded on the balance sheet at fair value. Hedge accounting provides for the matching of the timing of gain or loss recognition on these interest rate swaps with the recognition of the changes in interest expense on the Company's variable rate debt. For derivatives designated as cash flow hedges of interest rate risk, the gain or loss on the derivative is recorded in accumulated other comprehensive income and subsequently reclassified into interest expense in the same period during which the hedged transaction affects earnings. Amounts reported in accumulated other comprehensive income related to derivatives will be reclassified to interest expense as interest payments are made on the Company's variable- rate debt. The cash flows from the designated interest rate swaps are classified as a component of operating cash flows, similar to interest expense.

Recently issued accounting standards

Recently Adopted

ASU 2016-2, *Leases (Topic 842)* (''ASU 2016-2'')

In February 2016, the FASB issued ASU 2016-2. ASU 2016-2 increased transparency and comparability among organizations by requiring the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements for both lessees and lessors. The Company adopted the new standard effective January 1, 2019 using the modified retrospective approach. An entity that applies the transition provisions at the beginning of the period of adoption records its cumulative adjustment to the opening balance of retained earnings in the period of adoption rather than in the earliest period presented (i.e., January 1, 2019). In this case, an entity continues to apply the legacy guidance in ASC 840, including its disclosure requirements, in the comparative periods presented in the year it adopts the standard.

The Company utilized the transition package of certain practical expedients permitted: ASC 842-10-65-1(f) and ASC 842-10-65-1(g). The Company made an accounting policy election that kept leases with an initial term of 12 months or less off of the balance sheet which resulted in recognizing those lease payments in the consolidated statements of operations on a straight-line basis over the lease term. In addition, the Company has made an accounting policy election, by class of underlying asset, to not separate non-lease components from lease components and instead to account for each separate lease component, and the non-lease components associated with that lease component, as a single lease component.

As of January 1, 2019 the total right of use assets increased $13.4 million, while total operating lease liabilities increased $14.0 million. There was no adjustment to the opening balance of retained earnings as of January 1, 2019. The standard has not materially affect the Company's consolidated net

earnings. The Company continues to apply the legacy guidance from the old lease accounting standard, including its disclosure requirements, in the comparative periods presented (see Note 14).

ASU No. 2014-9, *Revenue from Contracts with Customers (Topic 606)* (''ASU 2014-9'')

In May 2014, the Financial Accounting Standards Board (''FASB'') issued ASU No. 2014-9. ASU No. 2014-9 (known as ASC 606) supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, as well as most industry-specific guidance, and significantly enhances comparability of revenue recognition practices across entities and industries by providing a principles-based, comprehensive framework for addressing revenue recognition issues. The Company adopted ASC 606 as of January 1, 2018 using the modified retrospective method resulting in an adjustment to opening retained earnings of $32.5 million for the cumulative effect of initially applying the new standard.

Under ASC 606, the Company finalized the review of its portfolio of revenue contracts that were not complete as of the adoption date and made its determination of its revenue streams as well as completed extensive contract specific reviews to determine the impact of the new standard on its historical and prospective revenue recognition. Because many of the Company's significant contracts with customers have unique contract terms, the Company reviewed all its non-standard agreements in order to determine the effect of adoption. The Company tested a sample of remaining agreements to verify that there were no changes in accounting based on the assumption that these contracts had similar characteristics and that the effects on the financial statements would not differ materially from applying this guidance to the individual contracts. To estimate the financial impacts of the adoption, the Company did not apply the contract modification practical expedient and retrospectively restated long-term contracts for any contract modifications.

The opening balance sheet adjustment as of January 1, 2018, was the result of the Centers for Innovation in Advanced Development and Manufacturing (''CIADM'') contract with the Biomedical Advanced Research and Development Authority (''BARDA''). Under ASC 606 at January 1, 2018, the Company determined that the performance obligation under the arrangement is to provide ongoing manufacturing capability to the USG and would recognize the consideration received in the initial 7 years year base period on a straight-line basis over a 24-year period as the capability being created during the base period of the contract is being provided to the customer over both the base period contract term as well as 17 additional option periods. As the Company's performance obligation is providing the USG with continuous access to its production capabilities throughout the contract duration, a time-based measure resulting in straight-line revenue recognition is proportionate to the Company's progress in satisfying the performance obligation when compared to the total progress. This measure of progress is most reflective of the Company satisfying the performance obligation over time. Beginning in June 2013, the Company was expected to be able to stand ready and be available to respond to the USG and importantly to respond to any task orders that may be issued during the base period and additional option periods. Being able to stand ready to perform in the event of an outbreak is of importance to the USG and by entering into this arrangement with the Company, the USG expected to receive the benefit of having access to Company's readiness and its capability to immediately respond to public health threats. The Company concluded the identified stand-ready performance obligations represent a series of distinct services that are substantially the same and have the same pattern of transfer to the customer.

In addition, the Company determined the CIADM contract includes a significant financing component which is included in the transaction price. The Company calculated the financing component using an interest rate the Company had on its other debt obligations at inception of the contract. The difference in revenue recognized under ASC 605 vs. ASC 606, as of the adoption date, was primarily attributable to the difference in the overall consideration or transaction price resulting from different accounting treatment related to options within the contract and the inclusion of a significant financing component under ASC 606.

Prior to the adoption of ASC 606, the Company recognized revenue under the CIADM contract on a straight-line basis, based upon its estimate of the total payments to be received under the contract. The Company analyzes the estimated payments to be received on a quarterly basis to determine if an adjustment to revenue was required. As a result of the adoption of ASC 606, as of January 1, 2018, there was an increase in the deferred revenue liability of

$42.4 million and an increase in deferred tax assets of $9.9 million with an offsetting reduction to retained earnings of $32.5 million.

ASU 2018-2, *Income Statement — Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* (''ASU 2018-2'')

In February 2018, the FASB issued ASU 2018-2. ASU 2018-2 provides the option to reclassify certain income tax effects related to the Tax Cuts and Jobs Act passed in December of 2017 between accumulated other comprehensive income and retained earnings and also requires additional disclosures. ASU 2018-2 is effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. Adoption of ASU 2018-2 is to be applied either in the period of adoption or

retrospectively to each period in which the effect of the change in the tax laws or rates were recognized. The adoption of ASU 2018-2 did not have a material impact on the Company's consolidated financial statements.

Not Yet Adopted

ASU 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (''ASU 2016-13'')

In June 2016, the FASB issued ASU 2016-13. ASU 2016-13 provides guidance on measurement of credit losses on financial instruments that changes the impairment model for most financial assets and certain other instruments, including trade and other receivables, held-to-maturity debt securities and loans, and that requires entities to use a new, forward-looking ''expected loss'' model that is expected to generally result in the earlier recognition of allowances for losses. The guidance became effective for annual periods beginning after December 15, 2019, including interim periods within those years, but early adoption is permitted. The Company has evaluated the effects of this standard and determined that the adoption will not have a material impact on the Company's consolidated financial statements.

ASU 2017-4, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* (''ASU 2017-4'')

In January 2017, the FASB issued ASU 2017-4. ASU 2017-4 simplifies the subsequent measurement of goodwill and eliminates Step 2 from the goodwill impairment test. ASU 2017-4 is effective for annual and interim goodwill tests beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates on or after January 1, 2017. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

ASU 2018-13, *Fair Value Measurement — Disclosure Framework (Topic 820)* (''ASU 2018-13'')

In August 2018, the FASB issued ASU 2018-13. ASU 2018-13 improves the disclosure requirements on fair value measurements. The updated guidance if effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted for any removed or modified disclosures. The Company is currently assessing the timing and impact of adopting the updated provisions.

ASU 2018-14, *Compensation — Retirement Benefits — Defined Benefit Plans — General (Topic 715-20): Disclosure Framework — Changes to the Disclosure Requirements for Defined Benefit Plans* (''ASU 2018-14'')

In August 2018, the FASB issued ASU 2018-14. ASU 2018-14 modifies the disclosure requirements for defined benefit pension plans and other post-retirement plans. ASU 2018-14 is effective for all entities for fiscal years ending after December 15, 2020, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2018-14 on its consolidated financial statements.

ASU 2018-15, *Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* (''ASU 2018-15'')

In August 2018, the FASB issued ASU 2018-15. ASU 2018-15 clarifies the accounting for implementation costs in cloud computing arrangements. ASU 2018-15 is effective for all entities for fiscal years beginning after December 15, 2019, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2018-15 on its consolidated financial statements.

ASU 2019-12, *Simplifications to Accounting for Income Taxes* (''ASU 2019-12'')

In December 2019, the FASB issued ASU 2019-12. ASU 2019-12 removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including deferred taxes for goodwill and allocating taxes for members of a consolidated group. ASU 2019-12 is effective for all entities for fiscal years beginning after December 15, 2020, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2019-12 on its consolidated financial statements.

3. Revenue recognition

The Company operates in one business segment. Therefore, results of the Company's operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting.

For the years ended December 31, 2019, 2018 and 2017 the Company's revenues disaggregated by the major sources was as follows:

(in millions)	Year Ended December 31,								
	2019			2018			2017		
	U.S Government	Non-U.S. Government	Total	U.S Government	Non-U.S. Government	Total	U.S Government	Non-U.S. Government	Total
Product sales	$568.8	$334.7	$ 903.5	$526.1	$ 80.4	$606.5	$374.8	$ 46.7	$421.5
Contract development and manufacturing services	—	80.0	80.0	—	98.9	98.9	—	68.9	68.9
Contracts and grants	105.9	16.6	122.5	71.5	5.5	77.0	65.1	5.4	70.5
Total revenues	$674.7	$431.3	$1,106.0	$597.6	$184.8	$782.4	$439.9	$121.0	$560.9

Contract liabilities

When performance obligations are not transferred to a customer at the end of a reporting period, the amount allocated to those performance obligations are reflected as contract liabilities on the consolidated balance sheets and are deferred until control of these performance obligations is transferred to the customer. The following table presents the rollforward of contract liabilities:

(in millions)	
December 31, 2017	$ 30.5
Adoption of new accounting standard (ASC 606)	42.4
January 1, 2018	72.9
Deferral of revenue	29.3
Revenue recognized	(29.1)
Balance at December 31, 2018	73.1
Deferral of revenue	46.7
Revenue recognized	(30.9)
Balance at December 31, 2019	$ 88.9

Transaction price allocated to remaining performance obligations

As of December 31, 2019, the Company had expected future revenues of approximately $600 million associated with performance obligations that have not been satisfied. The Company expects to recognize a majority of these revenues within the next 24 months, with the remainder recognized thereafter. However, the amount and timing of revenue recognition for unsatisfied performance obligations can materially change due to timing of funding appropriations from the USG and the overall success of the Company's development activities associated with its PHT product candidates that are then receiving development funding support from the USG under development contracts. In addition, the amount of future revenues associated with unsatisfied performance obligations excludes the value associated with unexercised option periods in the Company's contracts (which are not performance obligations as of December 31, 2019).

Contract assets

The Company considers unbilled accounts receivables and deferred costs associated with revenue generating contracts, which are not included in inventory or property, plant and equipments, as contract assets. As of December 31, 2019 and 2018, the Company had contract assets associated with deferred costs of $34.0 million and $1.2 million, respectively, which is included in prepaid expenses and other current assets and other assets on the Company's consolidated balance sheets.

Accounts receivable

Accounts receivable including unbilled accounts receivable contract assets consist of the following:

	December 31,	
(in millions)	2019	2018
Billed, net	$227.3	$234.0
Unbilled	43.4	28.5
Total, net	$270.7	$262.5

As of December 31, 2019 and 2018, the Company's accounts receivable balances were comprised of 69% and 76%, respectively, from the USG. As of December 31, 2019 and 2018 allowance for doubtful accounts were de minimis.

4. Acquisitions

Adapt

On October 15, 2018, the Company acquired Adapt, a company focused on developing new treatment options and commercializing products addressing opioid overdose and addiction. Adapt's NARCAN® (naloxone HCl) Nasal Spray marketed product is the first 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. This acquisition included 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. The

products and product candidates within Adapt's portfolio are consistent with the Company's mission and expand the Company's core business of addressing public health threats.

The total purchase price revised for adjustments is summarized below:

(in millions)	October 15, 2018
Cash	$581.5
Equity	37.7
Fair value of contingent purchase consideration	48.0
Preliminary purchase consideration	667.2
Adjustments	1.5
Final purchase consideration	$668.7

The Company issued 733,309 shares of Common Stock at $60.44 per share, the closing price of Emergent's share price on October 15, 2018, for a total of $44.3 million (inclusive of adjustments). The $44.3 million value of the common stock shares issued has been adjusted to a fair value of $37.7 million considering a discount for lack of marketability due to a two-year lock-up period beginning on October 15, 2018. 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 which the Company has determined the fair value of to be $48.0 million as of the acquisition date. The fair value of the contingent purchase consideration is based on management's assessment of the potential future realization of the contingent purchase consideration payments. This assessment is based on inputs that have no observable market (Level 3). The obligation is measured using a discounted cash flow model.

This transaction was accounted for by the Company under the acquisition method of accounting, with the Company as the acquirer. Under the acquisition method of accounting, the assets and liabilities of Adapt were recorded as of October 15, 2018, the acquisition date, at their respective fair values, and combined with those of the Company. The Company reflects measurement period adjustments in the period in which the adjustments occur. The adjustments during the measurement period resulted from receipt of additional financial information associated with certain acquired contract assets and the value of associated contingent purchase consideration. These adjustments did not impact the Company's statements of operations.

The table below summarizes the final allocation of the purchase price based upon fair values of assets acquired and liabilities assumed at October 15, 2018.

(in millions)	October 15, 2018	Measurement Period Adjustments	Updated October 15, 2018
Fair value of tangible assets acquired and liabilities assumed:			
Cash	$ 17.7	$ —	$ 17.7
Accounts receivable	21.3	—	21.3
Inventory	41.4	—	41.4
Prepaid expenses and other assets	7.8	3.0	10.8
Accounts payable	(32.2)	—	(32.2)
Accrued expenses and other liabilities	(50.4)	—	(50.4)
Deferred tax liability, net	(62.4)	(0.5)	(62.9)
Total fair value of tangible assets acquired and liabilities assumed	(56.8)	2.5	(54.3)
Acquired in-process research and development	41.0	—	41.0
Acquired intangible asset	534.0	—	534.0
Goodwill	149.0	(1.0)	148.0
Total purchase price	$667.2	$ 1.5	$668.7

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

The fair value of the intangible asset acquired for Adapt's marketed product NARCAN®Nasal Spray was valued at $534.0 million. The Company has determined the useful life of the NARCAN® Nasal Spray intangible asset to be 15 years. The Company calculated the fair value of the NARCAN®Nasal Spray intangible asset using the income approach with a present value discount rate of 10.5%, which is based on the weighted-average cost of capital for companies with profiles substantially similar to that of Adapt. This is comparable to the internal rate of return for the acquisition and represents the rate that market participants would use to value these intangible assets. The projected cash flows from the NARCAN® Nasal Spray intangible asset were based on key assumptions including: estimates of revenues and operating profits; and risks related to the viability of and potential alternative treatments in any future target markets.

The intangible asset associated with IPR&D acquired from Adapt is related to a product candidate. Management determined that the acquisition-date fair value of intangible assets related to IPR&D was $41.0 million. The fair value was determined using the income approach, which discounts expected future cash flows to present value. The Company calculated the fair value using a present value discount rate of 11%, which is based on the weighted-average cost of capital for companies with that profiles substantially similar to that of Adapt and IPR&D assets at a similar stage of development as the product candidate. This is comparable to the internal rate of return for the acquisition and represents the rate that market participants would use to value the IPR&D. The projected cash flows for the product candidate were based on key assumptions including: estimates of revenues and operating profits, considering its stage of development on the acquisition date; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate, such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential for alternative treatments in any future target markets. Non-amortizing IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development effort and are evaluated for impairment annually. During the year ended December 31, 2019, the Company recorded an impairment charge of $12.0 million to the IPR&D asset. The fair value of the IPR&D intangible asset is $29.0 million at December 31, 2019 (see Note 8).

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

The Company recorded approximately $148.0 million in goodwill related to the Adapt acquisition, which is calculated as the purchase price paid in excess of the fair value of the tangible and intangible assets acquired representing the future economic benefits the Company expects to receive as a result of the acquisition. The goodwill created from the Adapt acquisition is associated with early stage pipeline products. The goodwill generated from the Adapt acquisition is not expected to be deductible for tax purposes.

PaxVax

On October 4, 2018, the Company 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, adenovirus 4/7 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 sales force in the U.S. and in select European countries. The products and product candidates within PaxVax's portfolio are consistent with the Company's mission and will expand the Company's core business of addressing PHTs. In addition, the acquisition expands the Company's manufacturing capabilities.

At the closing, the Company paid a cash consideration of $273.1 million (inclusive of closing adjustments). This transaction was accounted for by the Company under the acquisition method of accounting, with the Company as the acquirer. Under the acquisition method of accounting, the assets and liabilities of PaxVax were recorded as of October 4, 2018, the acquisition date, at their respective fair values, and combined with those of the Company.

The table below summarizes the final allocation of the purchase consideration based upon the fair values of assets acquired and liabilities assumed at October 4, 2018.

(in millions)	October 4, 2018	Measurement Period Adjustments	Updated October 4, 2018
Fair value of tangible assets acquired and liabilities assumed:			
Cash	$ 9.0	$ —	$ 9.0
Accounts receivable	4.1	—	4.1
Inventory	19.7	—	19.7
Prepaid expenses and other assets	12.2	(0.3)	11.9
Property, plant and equipment	57.8	—	57.8
Deferred tax assets, net	3.8	1.8	5.6
Accounts payable	(3.5)	—	(3.5)
Accrued expenses and other liabilities	(33.6)	(0.4)	(34.0)
Total fair value of tangible assets acquired and liabilities assumed	69.5	1.1	70.6
Acquired in-process research and development	9.0	(9.0)	—
Acquired intangible assets	133.0	—	133.0
Goodwill	61.6	7.9	69.5
Total purchase consideration	$273.1	$ —	$273.1

The fair value of the intangible assets acquired for PaxVax's marketed products are valued at a total of $133.0 million. The Company has determined that the weighted average useful lives of the intangible assets to be 19 years.

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

The Company calculated the fair value of the Vivotif and Vaxchora intangible assets using the income approach with a present value discount rate of 14.5% and 15%, respectively, which is based on the weighted-average cost of capital for companies with profiles substantially similar to that of PaxVax. This is comparable to the internal rate of return for the acquisition and represents the rate that market participants would use to value these intangible assets. The projected cash flows from these intangible assets were based on key assumptions including: estimates of revenues and operating profits; and risks related to the viability of and potential alternative treatments in any future target markets.

The intangible asset associated with IPR&D acquired from PaxVax is related to a product candidate. The Company has adjusted the provisional amounts recognized at the acquisition date to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the measurement of the amounts recognized as of that date. The Company estimates the fair value based on the income approach.

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

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

The Company recorded approximately $69.5 million in goodwill related to the PaxVax acquisition, calculated as the purchase price paid in the acquisition that was in excess of the fair value of the tangible and intangible assets acquired representing the future economic benefits the Company expects to receive as a result of the acquisition. The goodwill created from the PaxVax acquisition is associated with early stage pipeline products along with potential contract development and manufacturing services. The majority of the goodwill generated from the PaxVax acquisition is expected to be deductible for tax purposes.

The Company has incurred transaction costs related to the PaxVax acquisition of approximately $4.5 million for the year ended December 31, 2018, which have been recorded in selling, general and administrative expenses.

Acquisition of ACAM2000 business

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

At the closing, the Company paid $97.5 million in an upfront payment and $20 million in milestone payments earned as of the closing date tied to the achievement of certain regulatory and manufacturing-related milestones, for a total payment in cash of $117.5 million. The agreement includes an additional milestone payment of up to $7.5 million upon achievement of a regulatory milestone, which was achieved in November 2017. The $7.5 million milestone payment was made during the fourth quarter of 2018 and is reflected as a component of financing activities in the consolidated statement of cash flows. This transaction was accounted for by the Company under the acquisition method of accounting, with the Company as the acquirer. Under the acquisition method of accounting, the assets and liabilities of the ACAM2000 business were recorded as of October 6, 2017, the acquisition date, at their respective fair values, and combined with those of the Company.

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

The total purchase price is summarized below:

(in millions)	Purchase Price
Amount of cash paid	$117.5
Fair value of contingent purchase consideration	2.2
Total purchase price	$119.7

The table below summarizes the allocation of the purchase price based upon the fair values of assets acquired at October 6, 2017. The Company did not assume any liabilities in the acquisition. The Company has finalized the purchase price allocation related to this acquisition.

(in millions)	Purchase Price
Fair value of tangible assets acquired:	
Inventory	$ 74.9
Property, plant and equipment	20.0
Total fair value of tangible assets acquired	94.9
Acquired intangible asset	16.7
Goodwill	8.1
Total purchase price	$119.7

The fair value measurements are based on significant unobservable inputs that are developed by the Company using estimates and assumptions of the respective market and market penetration of the Company's products. The Company determined the fair value of the ACAM2000 intangible asset using the income approach, which is based on the present value of future cash flows, with a present value discount rate of 15.50%, based on the weighted-average cost of capital for substantially similar companies. This is comparable to the internal rate of return for the acquisition and represents the rate that market participants would use to value these intangible assets. The projected cash flows from ACAM2000 intangible asset were based on key assumptions, including: estimates of revenues and operating profits, the life of the potential commercialized product and associated risks, and risks related to the viability of and potential alternative treatments in any future target markets. The Company has determined the ACAM2000 intangible asset will be amortized over 10 years.

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

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

The Company recorded approximately $8.1 million in goodwill related to the ACAM2000 acquisition, calculated as the purchase price paid in the acquisition that was in excess of the fair value of the tangible and intangible assets acquired and represents the future economic benefits the Company expects to receive as a result of the acquisition. Goodwill generated from the ACAM2000 acquisition is not expected to be deductible for tax purposes.

Acquisition of raxibacumab asset

On October 2, 2017, the Company completed the acquisition of raxibacumab, a fully human monoclonal antibody therapeutic product approved by the U.S. Food and Drug Administration (''FDA'') for the treatment and prophylaxis of inhalational anthrax, from Human Genome Sciences, Inc. and GlaxoSmithKline LLC (collectively referred to as ''GSK''). The all-cash transaction consists of a $76 million upfront payment and up to $20 million in product sale and manufacturing-related milestone payments. The Company recorded an asset (including transaction costs) of $77.6 million, at date of acquisition, which is recorded within intangible assets, net line item of the consolidated balance sheets. The Company has determined that substantially all of the value of raxibacumab is attributed to the raxibacumab asset and therefore the raxibacumab acquisition is considered an asset acquisition. During the twelve months ended December 31, 2019, a contingent milestone was achieved which resulted in a payment of $10.0 million with a corresponding increase in intangible assets.

5. Fair value measurements

The Company's recurring fair value measurement items recorded on a recurring basis primarily consist of contingent consideration liabilities, interest rate swaps and investments in money market funds.

Contingent consideration

The contingent consideration liabilities have been generated from our acquisitions. These liabilities represent an obligation of the Company to transfer additional assets to the selling shareholders if future events occur or conditions are met. The Company's contingent consideration is measured initially and subsequently at each reporting date at fair value. The changes in the fair value of contingent consideration obligations are primarily due to the expected amount and timing of future net sales and achieving regulatory milestones, which are inputs that have no observable market (Level 3). Any changes in expectations for the Company's products are classified in the Company's statement of operations as cost of product sales and contract development and manufacturing. Any changes in expectations for the Company's product candidates are recorded in research and development expense for regulatory and development milestones.

The following table is a reconciliation of the beginning and ending balance of the contingent consideration liabilities measured at fair value using significant unobservable inputs (Level 3) during the years ended December 31, 2019 and 2018.

(in millions)	
Balance at December 31, 2017	$ 12.3
Expense included in earnings	3.1
Settlements	(3.4)
Additions due to acquisition	48.0
Balance at December 31, 2018	$ 60.0
Expense included in earnings	24.8
Milestone achievement - asset acquisition	10.0
Measurement period adjustment	1.5
Settlements	(67.1)
Balance at December 31, 2019	$ 29.2

Interest rate swaps

The valuation of the interest rate swaps is determined using widely accepted valuation techniques, including discounted cash flow analysis on the expected cash flows of each interest rate swap. This analysis reflects the contractual terms of the interest rate swaps, including the period to maturity, and uses observable market-based inputs, including interest rate curves and implied volatilities. The fair values of interest rate swaps are determined using the market standard methodology of netting the discounted future fixed cash payments (or receipts) and the discounted expected variable cash receipts (or payments). The variable cash payments (or receipts) are based on an expectation of future interest rates (forward curves) derived from observable market interest rate curves. To comply with the provisions of ASC 820, Fair Value Measurement, we incorporate credit valuation adjustments in the fair value measurements to appropriately reflect both our own nonperformance risk and the respective counterparty's nonperformance risk. These credit valuation adjustments were concluded to not be significant inputs for the fair value calculations for the periods presented. In adjusting the fair value of our derivative contracts for the effect of nonperformance risk, we have considered the impact of netting and any applicable credit enhancements, such as the posting of collateral, thresholds, mutual puts and guarantees. The valuation of interest rate swaps fall into Level 2 in the fair value hierarchy. See note 10 ''Derivative Instruments ''for further details on the interest rate swaps.

Money market funds

The fair values of the Company's money market funds are based on quoted prices in active markets for identical assets (level 1). As of December 31, 2019 and 2018, the Company held cash in money market accounts of $52.2 million and $0 million, respectively. These amounts are included in cash and cash equivalents in the consolidated balance sheets.

Non-recurring fair value measurements

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a non-recurring basis. As of December 31, 2019 and 2018, there were no assets or liabilities measured at fair value on a non-recurring basis, except for the IPR&D assets acquired with the Adapt acquisition and the assets acquired from PaxVax, Adapt. See Note 4. ''Acquisitions'' and Note 8. ''Intangible assets and goodwill'' for further details on the IPR&D assets.

6. Inventories

Inventories consist of the following:

	December 31,	
(in millions)	2019	2018
Raw materials and supplies	$ 70.5	$ 51.8
Work-in-process	89.7	103.2
Finished goods	62.3	50.8
Total inventories	$222.5	$205.8

7. Property, plant and equipment

Property, plant and equipment consist of the following:

	December 31,	
(in millions)	2019	2018
Land and improvements	$ 46.5	$ 44.6
Buildings, building improvements and leasehold improvements	234.8	216.2
Furniture and equipment	334.2	293.9
Software	55.7	55.2
Construction-in-progress	81.5	71.8
	752.7	681.7
Less: Accumulated depreciation and amortization	(210.4)	(171.5)
Total property, plant and equipment, net	$ 542.3	$ 510.2

For the years ended December 31, 2019 and 2018, construction-in-progress primarily includes costs related to construction of manufacturing capabilities.

Depreciation and amortization expense associated with property, plant and equipment was $49.5 million, $36.3 million and $32.2 million for the years ended December 31, 2019, 2018, and 2017, respectively.

8. Intangible assets and goodwill

The Company's intangible assets were acquired via business combinations or asset acquisitions. Changes in the Company's intangible assets, excluding IPR&D and goodwill, consisted of the following:

		December 31, 2019			
(in millions)	Estimated Life	Cost	Additions	Accumulated Amortization	Net
Products	9-22 years	$778.0	$10.0	$ 82.2	$705.8
Corporate trade name	5 years	2.8	—	2.8	—
Customer relationships	8 years	28.6	—	23.0	5.7
Contract development and manufacturing	8 years	5.5	—	4.0	1.5
Total intangible assets		$814.9	$10.0	$112.0	$712.9

		December 31, 2018			
(in millions)	Estimated Life	Cost	Additions	Accumulated Amortization	Net
Products	9-22 years	$111.0	$667.0	$27.9	$750.1
Corporate trade name	5 years	2.8	—	2.7	0.1
Customer relationships	8 years	28.6	—	19.4	9.2
Contract development and manufacturing	8 years	5.5	—	3.3	2.2
Total intangible assets		$147.9	$667.0	$53.3	$761.6

For the years ended December 31, 2019, 2018, and 2017, the Company recorded amortization expense for intangible assets of $58.7 million, $25.0 million and $8.6 million, respectively, which is

included in the amortization of intangible assets line item of the consolidated statements of operations. As of December 31, 2019, the weighted average amortization period remaining for intangible assets is 13.6 years.

Future amortization expense as of December 31, 2019 is as follows:

(in millions)	
2020	$ 58.7
2021	57.3
2022	54.6
2023	54.4
2024 and beyond	487.9
Total remaining amortization	$712.9

During the year ended December 31, 2019, the Company recorded the impact of an impairment charge of $12.0 million related to our intangible assets associated with the IPR&D acquired as part of our acquisition of Adapt. The $12.0 million impairment charge is reflected as a component of research and development expense on the consolidated statement of operations. The IPR&D intangible asset balance on the consolidated balance sheet at December 31, 2019 was $29.0 million.

The following table is a summary of changes in goodwill:

	Year Ended December 31,	
(in millions)	2019	2018
Balance at beginning of the year	$259.7	$ 49.1
Measurement period adjustments	6.9	—
Additions	—	210.6
Balance at end of the year	$266.6	$259.7

9. Long-term debt

The components of debt are as follows:

	December 31,	
(in millions)	2019	2018
Senior secured credit agreement - Term loan due 2023	$435.9	$447.2
Senior secured credit agreement - Revolver loan due 2023	373.0	348.0
2.875% Convertible Senior Notes due 2021	10.6	10.6
Other	3.0	3.0
Total debt	$822.5	$808.8
Current portion of debt, net of debt issuance costs	(12.9)	(10.1)
Unamortized debt issuance costs	(11.2)	(14.2)
Debt, net of current portion	$798.4	$784.5

Senior secured credit agreement

On September 29, 2017, the Company entered into a senior secured credit agreement (the ''2017 Credit Agreement'') with four lending financial institutions, which replaced the Company's prior senior secured credit agreement (the ''2013 Credit Agreement'').

On October 15, 2018, the Company entered into an Amended and Restated Credit Agreement (the ''Amended Credit Agreement''), which modified the 2018 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 the Company 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, the Company's 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, the Company borrowed $318.0 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 year ended December 31, 2019, we did not capitalize debt issuance costs. For the year ended December 31, 2018 we capitalized $13.4 million, as a direct reduction to the Term Loan and the revolver.

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 the Company's consolidated net leverage ratio or (b) a base rate (which is the highest of the prime rate, the federal funds rate plus 0.50%, and a eurocurrency rate for an interest period of one month plus 1%) plus a margin ranging from 0.25% to 1.00%, depending on the Company's consolidated net leverage ratio. The Company is 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, the Company is required to pay commitment fees ranging from 0.15% to 0.30% per annum, depending on the Company's consolidated net leverage ratio, in respect of the average daily unused commitments under the Revolving Credit Facility. The Company is 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. The Company has 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 the Company or its Subsidiaries (a) incur indebtedness not otherwise permitted under the Amended Credit Agreement or (a) 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 financial covenants, which were then further amended in June 2019. The financial covenants require the quarterly presentation of a minimum consolidated 12-month rolling debt service coverage ratio of 2.50 to 1.00, and an amended maximum consolidated net leverage ratio of 4.95 to 1.00 for the quarter ended June 30, 2019, 4.75 to 1.00 for the quarter ended September 30, 2019, and 3.75 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. The Amended Credit Agreement also contains affirmative and negative covenants, which were also amended in June 2019 to limit the amount of restricted payments as defined in the Amended Credit agreement to $25 million until the filing of the Company's December 31, 2019 Form 10-K. Negative covenants in the Amended Credit Agreement, among other things, limit the ability of the Company to incur indebtedness and liens, dispose of assets, make investments and enter into certain merger or consolidation transactions. As of the date of these financial statements, the Company is in compliance with affirmative and negative covenants.

2.875% Convertible senior notes due 2021

On November 14, 2017, the Company issued a notice of termination of conversion rights for its outstanding Notes, of which $250.0 million was outstanding as of the notice date. In connection with the notice of termination, bondholders were given the option to convert their notes into the Company's stock at a rate of 32.386 per $1,000 of principal outstanding, plus a make-whole of an additional 3.1556 shares per $1,000 principal outstanding, in accordance with the terms of the indenture. The Company was not obligated to pay accrued or unpaid interest on converted notes, and bondholders who did not convert by the deadline of December 28, 2017 would retain their bonds but lose the conversion rights associated with the Notes and be paid interest of 2.875% until the earlier of maturity of the Notes in 2021 or the bonds being called and repaid in full by the Company. Between July 15, 2017 and the notification of termination of conversion rights, the Company accrued interest on the converted Notes of $2.4 million which was recorded as an increase in additional paid-in-capital on the balance sheet. Between November 14, 2017 and December 28, 2017 (the ''conversion period''), approximately $239.4 million of bonds were converted into 8.5 million shares of the Company's common stock, inclusive of shares issued as part of the make-whole provision. In addition, the Company recorded a reduction in additional paid-in-capital on the Company's balance sheet of $3.6 million associated with debt issuance costs attributable to the converted notes. After giving effect to the converted bonds, the outstanding principal balance of the Notes as of December 31, 2019 was $10.6 million.

Future debt payments of long-term indebtedness are as follows:

(in millions)	December 31, 2019
2020	$ 14.1
2021	35.9
2022	33.7
2023	735.8
2024 and thereafter	3.0
Total debt	$822.5

10. Derivative Instruments

The Company is exposed to certain risk arising from both its business operations and economic conditions. The Company principally manages its exposures to a wide variety of business and operational risks through management of its core business activities. The Company manages economic risks, including interest rate, liquidity, and credit risk primarily by managing the amount, sources, and duration of its assets and liabilities and the use of derivative financial instruments. Specifically, the Company has entered into interest rate swaps to manage exposures that arise from the Company's senior secured credit agreement's payments of variable interest rate debt. All outstanding cash flow hedges mature in October 2023.

As of December 31, 2019, the Company had the following outstanding interest rate swap derivatives that were designated as cash flow hedges of interest rate risk:

	Number of Instruments	Notional amount (in millions)
Interest Rate Swaps	7	350

The table below presents the fair value of the Company's derivative financial instruments designated as hedges as well as their classification on the balance sheet. If current fair values of designated interest rate swaps remained static over the next twelve months, the Company would reclassify $0.5 million of net deferred losses from accumulated other comprehensive loss to the statement of operations over the next twelve months.

	Asset Derivatives				Liability Derivatives			
	December 31, 2019		December 31, 2018		December 31, 2019		December 31, 2018	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Interest Rate Swaps	Other Assets	$ —	Other Assets	—	Other Liabilities	$2.0	Other Liabilities	—

The table below presents the effect of cash flow hedge accounting on accumulated other comprehensive income.

Hedging derivatives	Amount of Gain/(Loss) Recognized in OCI on Derivative		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain or (Loss) Reclassified from Accumulated OCI into Income	
	December 31, 2019	December 31, 2018		December 31, 2019	December 31, 2018
Interest Rate Swaps	$2.0	—	Interest expense	$0.6	$ —

11. Stockholders' equity

Preferred stock

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

Common stock

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

Accounting for stock-based compensation

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

As of December 31, 2019, an aggregate of 21.9 million shares of common stock were authorized for issuance under the Emergent Plan, of which a total of approximately 5.8 million shares of common stock remain available for future awards to be made to plan participants. The exercise price of each option must be not less than 100% of the fair market value of the shares underlying such option on the date of grant. Awards granted under the Emergent Plan have a contractual life of no more than 10 years.

The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted.

Set forth below are the assumptions used in valuing the stock options granted:

	Year Ended December 31, 2019	2018	2017
Expected dividend yield	0%	0%	0%
Expected volatility	37-39%	38-39%	37-40%
Risk-free interest rate	1.57-2.48%	2.54-3.03%	1.66-1.88%
Expected average life of options	4.5 years	4.5 years	4.3 years

Stock options, restricted and performance stock units

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

(in millions, except share and per share data)	Number of Shares	Emergent Plan Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2018	1,871,468	$32.59	$50.1
Granted	295,770	60.16	
Exercised	(199,352)	25.98	
Forfeited	(84,011)	52.26	
Outstanding at December 31, 2019	1,883,875	$36.74	$34.5
Exercisable at December 31, 2019	1,253,658	$29.46	$30.8

The weighted average remaining contractual term of options outstanding as of December 31, 2019 and 2018 was 3.3 years and 4.0 years, respectively. The weighted average remaining contractual term of options exercisable as of December 31, 2019 and 2018 was 2.3 years and 3.0 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2019, 2018, and 2017 was $21.13, $18.48 and $10.53 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2019, 2018, and 2017 was $5.3 million, $24.4 million and $13.9 million, respectively. The total fair value of awards vested during 2019, 2018 and 2017 was $16.9 million, $16.9 million and $17.9 million, respectively. As of the year ended December 31, 2019, the total compensation cost and weighted average period over which total compensation is expected to be recognized related to unvested equity awards was $37.0 million and 1.5 years, respectively.

The following is a summary of performance stock and restricted stock unit award activity under the Emergent Plan. Performance stock units of approximately 0.1 million shares were granted and remain outstanding the year ended December 31, 2019, and are included in the table below.

(in millions, except share and per share data)	Number of Shares	Weighted-Average Grant Price	Aggregate Intrinsic Value
Outstanding at December 31, 2018	921,093	$42.82	$ 54.6
Granted	594,752	57.94	
Vested	(434,629)	38.81	
Forfeited	(128,364)	53.17	
Outstanding at December 31, 2019	952,852	$ 52.77	$51.5

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

(in millions)	Year Ended December 31, 2019	2018	2017
Cost of product sales	$ 3.1	$ 1.7	$ 1.1
Research and development	4.0	3.1	2.5
Selling, general and administrative	19.6	18.4	11.6
Total stock-based compensation expense	$26.7	$23.2	$15.2

Accumulated Other Comprehensive Loss

The following table includes changes in accumulated other comprehensive loss by component, net of tax:

(in millions)	Defined Benefit Pension Plan	Derivative Instruments	Foreign Currency Translation Losses	Total
Balance, January 1, 2018	$ —	$ —	$(3.7)	$(3.7)
Other comprehensive loss	(0.2)	—	(1.6)	(1.8)
Balance, December 31, 2018	$(0.2)	$ —	$(5.3)	(5.5)
Other comprehensive (loss) income before reclassifications	$(3.2)	$(2.2)	$ 0.4	$(5.0)
Amounts reclassified from accumulated other comprehensive income	—	0.6	—	0.6
Net current period other comprehensive loss	$(3.2)	$(1.6)	$ 0.4	$(4.4)
Balance, December 31, 2019	$(3.4)	$(1.6)	$(4.9)	$(9.9)

12. Income taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. Valuation allowances are recorded as appropriate to reduce deferred tax assets to the amount considered likely to be realized. As a result of the reduction in the U.S. corporate income tax rate from 35% to 21% under the Tax Reform Act, the Company revalued its ending net deferred tax liabilities in the United States at December 31, 2017 and recognized a provisional $13.4 million tax benefit in the Company's consolidated statement of income for the year ended December 31, 2017. During 2018, we adjusted the provisional estimate by approximately $4.5 million, bringing the total tax benefit recorded to date to $17.9 million related to the revaluation of our deferred tax assets and liabilities.

The Tax Reform Act provided for a one-time deemed mandatory repatriation of post-1986 undistributed foreign subsidiary earnings and profits (''E&P'') through the year ended December 31, 2017. The Company had an estimated $95.4 million of undistributed foreign E&P subject to the deemed mandatory repatriation and recognized a provisional transition tax of $13.6 million of income tax expense in the Company's consolidated statement of income for the year ended December 31, 2017. During 2018 we reduced the provisional transition tax by $0.3 million, bringing the total transition tax to $13.3 million.

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

The GILTI provisions require the Company to include in its U.S. income tax return foreign subsidiary earnings in excess of an allowable return on the foreign subsidiary's tangible assets. The Company is subject to incremental U.S. tax on GILTI income. The Company has elected to account for GILTI tax in the period in which it is incurred, and therefore has not provided any deferred tax impacts of GILTI in its consolidated financial statements for the year ended December 31, 2019.

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

	December 31,		
(in millions)	2019	2018	2017
Current			
Federal	$ 1.4	$ 1.8	$29.4
State	11.6	2.4	3.0
International	11.0	6.0	0.3
Total current	24.0	10.2	32.7
Deferred			
Federal	1.9	7.5	(6.0)
State	1.1	3.0	(0.6)
International	(4.1)	(1.9)	9.9
Total deferred	(1.1)	8.6	3.3
Total provision for income taxes	$22.9	$18.8	$36.0

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

(in millions)	December 31, 2019	2018
Federal losses carryforward	$ 8.5	$ 10.7
State losses carryforward	17.4	18.1
Research and development carryforward	9.0	10.1
State research and development carryforward	5.0	5.0
Scientific research and experimental development credit carryforward	11.0	13.1
Stock compensation	7.6	7.5
Foreign NOLs	36.9	35.4
Deferred revenue	18.1	11.6
Inventory reserves	1.8	3.4
Lease liability	6.0	—
Other	7.5	4.9
Deferred tax asset	128.8	119.8
Fixed assets	(51.2)	(46.4)
Intangible assets	(54.5)	(60.4)
Right-of-use asset	(5.9)	—
Other	(3.2)	(0.7)
Deferred tax liability	(114.8)	(107.5)
Valuation allowance	(64.5)	(66.4)
Net deferred tax asset (liability)	$ (50.5)	$ (54.1)

As of December 31, 2019, the Company has a net U.S. deferred tax liability in the amount of $7.7 million and a foreign net deferred tax liability in the amount of $42.8 million. The Company had a net U.S. deferred tax liability in the amount of $4.8 million and a foreign net deferred tax asset in the amount of $49.3 million as of December 31, 2018.

As of December 31, 2019, the Company currently has approximately $40.5 million ($8.5 million tax effected) in U.S. federal net operating loss carryforwards along with $14.0 million in research and development tax credit carryforwards for U.S. federal and state tax purposes that will begin to expire in 2027 and 2024, respectively. The U.S. federal net operating loss carryforwards are recorded with a $4.7 million valuation allowance. The research and development tax credit carryforwards have a valuation allowance in the amount of $9.1 million. The Company has $280.7 million ($17.4 million tax effected) in state net operating loss carryforwards, primarily in Maryland and California, that will begin to expire in 2025. The U.S. state tax loss carryforwards are recorded with a valuation allowance of $245.0 million ($16.4 million tax effected). The Company has approximately $199.0 million ($37.0 million tax effected) in net operating losses from foreign jurisdictions, some of which have an indefinite life (unless the foreign entities have a change in the nature or conduct of the business in the three years following a change in ownership), and some of which begin to expire in 2022. A valuation allowance in respect to these foreign losses has been recorded in the tax effected amount of $34.3 million. The Company currently has approximately $11.0 million in Manitoba scientific research and experimental development credit carryforwards that will begin to expire in 2027. The use of any of these net operating losses and research and development tax credit carryforwards may be restricted due to future changes in the Company's ownership.

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

(in millions)	December 31, 2019	2018	2017
US	$63.9	$71.0	$ 80.7
International	13.5	10.5	37.9
Earnings before taxes on income	77.4	81.5	118.6
Federal tax at statutory rates	$16.3	$17.1	$ 41.5
State taxes, net of federal benefit	10.3	4.3	1.3
Impact of foreign operations	(6.9)	2.8	(2.2)
Change in valuation allowance	(1.0)	(0.1)	0.3
Tax credits	(3.6)	(1.8)	(1.9)
Transition tax	—	(0.2)	13.6
Change in U.S. tax rate	—	(4.5)	(13.4)
Stock compensation	(2.4)	(5.8)	(4.0)
Other differences	—	(1.3)	(0.7)
Return to provision true-ups	(2.3)	1.1	—
Transaction costs	—	5.4	—
Contingent consideration	4.7	—	—
Compensation limitation	1.3	1.1	1.3
FIN 48	1.1	0.3	0.5
GILTI, net	3.6	0.4	—
Permanent differences	1.8	—	(0.3)
Provision for income taxes	$22.9	$18.8	$ 36.0

The effective annual tax rate for the years ended December 31, 2019, 2018, and 2017 was 30%, 23% and 30%, respectively.

The effective annual tax rate of 30% in 2019 is higher than the statutory rate primarily due to the impact of state taxes, GILTI, contingent consideration and other non-deductible items. This is partially offset

by stock option deduction benefits, tax credits, and favorable rates in foreign jurisdictions.

The effective annual tax rate of 23% in 2018 is higher than the statutory rate primarily due to the impact of state taxes, GILTI, acquisition transaction costs and other non-deductible items, and the jurisdictional mix of earnings. This is partially offset by the impact of the SAB 118 benefit and the stock option deduction benefit.

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

The Company recognizes interest in interest expense and recognizes potential penalties related to unrecognized tax benefits in selling, general and administrative expense. Of the total unrecognized tax benefits recorded at December 31, 2019 and 2018, $0.0 million and $0.4 million, respectively, is classified as a current liability and $10.4 million and $8.4 million, respectively, is classified as a non-current liability on the balance sheet.

The table below presents the gross unrecognized tax benefits activity for 2019, 2018 and 2017:

(in millions)	
Gross unrecognized tax benefits at December 31, 2016	$ 1.8
Increases for tax positions for prior years	—
Decreases for tax positions for prior years	—
Increases for tax positions for current year	0.5
Settlements	(0.3)
Lapse of statute of limitations	—
Gross unrecognized tax benefits at December 31, 2017	$ 2.0
Unrecognized tax benefits acquired in business combinations	6.5
Increases for tax positions for prior years	—
Decreases for tax positions for prior years	—
Increases for tax positions for current year	0.3
Settlements	—
Lapse of statute of limitations	—
Gross unrecognized tax benefits at December 31, 2018	$ 8.8
Increases for tax positions for prior years	0.5
Unrecognized tax benefits acquired in business combinations	—
Decreases for tax positions for prior years	—
Increases for tax positions for current year	1.5
Settlements	(0.4)
Lapse of statute of limitations	—
Gross unrecognized tax benefits at December 31, 2019	$10.4

The total gross unrecognized tax benefit of $10.4 million of which $7.0 million relates to the acquisition of PaxVax is entirely offset by a receivable pursuant to a Tax Indemnity Agreement that became effective as at the close of the acquisition.

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

The Company's federal and state income tax returns for the tax years 2016 to 2018 remain open to examination. The Company's tax returns in the United Kingdom remain open to examination for the tax years 2012 to 2018, and tax returns in Germany remain open indefinitely. The Company's tax returns for Canada remain open to examination for the tax years 2012 to 2018. The Company's Swiss tax returns remain open to federal examination for 2018. The Company's Irish tax returns remain open to examination for the tax years 2013 to 2018.

As of December 31, 2019, the Company's Canadian 2017 Scientific Research and Experimental Development Claim is under audit. As of December 31, 2019, the Company's 2017 Canadian and US federal income tax returns for the Adapt entities prior to acquisition are under audit.

13. Defined benefit and 401(k) savings plan

The Company sponsors a defined benefit pension plan covering eligible employees in Switzerland (the

''Swiss Plan''). Under the Swiss Plan, the Company and certain of its employees with annual earnings in excess of government determined amounts are required to make contributions into a fund managed by an independent investment fiduciary. Employer contributions must be in an amount at least equal to the employee's contribution. The Swiss Plan assets are comprised of an insurance contract that has a fair value consistent with its contract value based on the practicability exception using level 3 inputs. The entire liability is listed as non-current, because plan assets are greater than the expected benefit payments over the next year. The Company recognizes pension expense as a component of selling, general and administrative expense. The Company recognized pension expense related to the Swiss Plan of $1.0 million reflected as a component of selling, general and administrative for the year ended December 31, 2019.

The funded status of the Swiss Plan is as follows:

(in millions)	December 31, 2019	December 31, 2018
Fair value of plan assets, beginning of year	$ 18.2	$ —
Acquisitions	—	18.2
Employer contributions	1.0	0.2
Employee contributions	0.7	0.1
Net benefits received (paid)	1.7	0.3
Actual return on plan assets	1.7	—
Settlements	(3.0)	(0.6)
Currency impact	0.3	—
Fair value of plan assets, end of year	$ 20.6	$ 18.2
Projected benefit obligation, beginning of year	$ 28.6	$ —
Acquisitions	—	28.3
Service cost	1.3	0.3
Interest Cost	0.2	0.1
Employee contributions	0.7	0.1
Actuarial loss	7.0	0.3
Net benefits received (paid)	1.7	(0.1)
Plan amendment	(1.7)	0.1
Settlements	(3.0)	(0.6)
Currency impact	0.4	0.1
Projected benefit obligation, end of year	$ 35.3	$ 28.6
Funded status, end of year	$(14.7)	$(10.4)
Accumulated benefit obligation, end of year	$ 31.0	$ 25.6

Since assets exceed the present value of expected benefit payments for the next twelve months, all of the liability is classified as non-current.

Components of net periodic pension cost incurred during the year are as follows:

(in millions)	December 31, 2019	December 31, 2018
Service cost	$ 1.3	$ 0.3
Interest cost	0.2	0.1
Expected return on plan assets	(0.5)	(0.1)
Net periodic benefit cost	$ 1.0	$ 0.3

The weighted average assumptions used to calculate the projected benefit obligations are as follows:

	December 31, 2019	December 31, 2018
Discount rate	0.2%	0.9%
Expected rate of return	3.0%	3.0%
Rate of future compensation increases	1.5%	1.5%

The overall expected long-term rate of return on assets assumption considers historical returns, as well as expected future returns based on the fact that investment returns are insured, and the legal minimum interest crediting rate as applicable. Total contributions expected to be made into the plan for the year-ended December 31, 2020 is $1.1 million.

The following table presents losses recognized in accumulated other comprehensive loss before income tax related to the Company's defined benefit pension plans:

(in millions)	Year Ended December 31, 2019	Year Ended December 31, 2018
Net actuarial loss	$ 5.4	$0.1
Prior service cost	(1.7)	0.1
Total recognized in accumulated other comprehensive loss	$ 3.7	$0.2

Actuarial losses in accumulated other comprehensive loss related to the Company's defined benefit pension plans expected to be recognized as components of net periodic benefit cost over the year ending December 31, 2020 are de minimis.

Future benefits expected to be paid as of December 31, 2019 are as follows:

(in millions)	December 31, 2019
2020	$ 1.0
2021	1.0
2022	1.5
2023	1.0
2024	1.0
Thereafter	6.6
Total	$12.1

401(k) savings plan

The Company has established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers substantially all U.S. employees. Under the 401(k) Plan, employees may make elective salary deferrals. During the years ended December 31, 2019, 2018 and 2017, the Company made matching contributions of approximately $5.1 million, $3.1 million and $2.7 million, respectively.

14. Leases

The Company has operating leases for corporate offices, research and development facilities and manufacturing facilities. We determine if an arrangement is a lease at inception. Operating leases are included in right-of-use (''ROU'') assets and liabilities.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The Company uses an implicit rate when readily determinable. At the beginning of a lease, the operating lease ROU asset also includes any concentrated lease payments expected to be paid and excludes lease incentives. The Company's lease ROU asset may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise those options.

Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company has lease agreements with lease and non-lease components, which are accounted for separately. The Company's leases have remaining lease terms of 1 year to 14 years, some of which include options to extend the leases for up to 5 years, and some of which include options to terminate the leases within 1 year.

The components of lease expense were as follows:

	December 31, 2019
Operating lease cost:	
Amortization of right-of-use assets	$2.7
Interest on lease liabilities	0.6
Total operating lease cost	$3.3

For the years ended December 31, 2018 and 2017 total lease expense was $3.3 million and $1.6 million, respectively.

Supplemental balance sheet information related to leases was as follows as of December 31, 2019:

(In millions, except lease term and discount rate)	Balance Sheet Location	December 31, 2019
Operating lease right-of-use assets	Other assets	$24.7
Operating lease liabilities, current portion	Other current liabilities	3.6
Operating lease liabilities	Other liabilities	22.1
Total operating lease liabilities		25.7
Operating leases:		
Weighted average remaining lease term (years)		8.0
Weighted average discount rate		4.2%

15. Earnings per share

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

	Year Ended December 31,		
(in millions, except per share data)	2019	2018	2017
Numerator:			
Net earnings	$54.5	$62.7	$82.6
Interest expense, net of tax	—	—	2.6
Amortization of debt issuance costs, net of tax	—	—	0.7
Net income, adjusted	$54.5	$62.7	$85.9
Denominator:			
Weighted-average number of shares-basic	51.5	50.1	41.8
Dilutive securities-equity awards	0.9	1.3	1.1
Dilutive securities-convertible debt	—	—	7.4
Weighted-average number of shares-diluted	52.4	51.4	50.3
Net income per share-basic	$1.06	$1.25	$1.98
Net income per share-diluted	$1.04	$1.22	$1.71

For the year ending December 31, 2019 approximately 0.9 million shares of common stock are not considered in the diluted earnings per share calculation because the exercise price of these options is greater than the average per share closing price during the year and their effect would be anti-dilutive. For the years ending December 31, 2018, and 2017, substantially all of the outstanding stock options to purchase shares of common stock were included in the calculation of diluted earnings per share.

16. Purchase commitments

As of December 31, 2019 the Company has approximately $59.7 million of purchase commitments associated with raw materials and contract development and manufacturing services that will be purchased in the next three years. For the years ended December 31, 2019, 2018, and 2017, the Company purchased $51.3 million, $12.1 million and $3.0 million, respectively, of materials under this commitment.

17. Segment information

For financial reporting purposes, the Company reports financial information for one reportable segment. This reportable segment engages in business activities based on financial information that is provided to and resources which are allocated by the Chief Operating Decision Maker. The accounting policies of the reportable segment is the same as those described in the summary of significant accounting policies.

For the years ended December 31, 2019, 2018, and 2017, the Company's revenues within the United States comprised 90%, 91% and 89%, respectively, of total revenues. For the years ended December 31, 2019, 2018, and 2017, product sales from ACAM 2000 and Anthrax Vaccines to the USG comprised approximately 43%, 65% and 68%, respectively, of total product sales.

The Company's product sales from Anthrax Vaccines, ACAM2000, NARCAN Nasal Spray and Other comprised approximately:

	2019	2018	2017
% of product sales:			
Anthrax Vaccines	19%	46%	68%
ACAM2000	27%	19%	—%
NARCAN Nasal Spray	31%	7%	—%
Other	23%	28%	32%

As of December 31, 2019, 2018 and 2017, aside from Anthrax Vaccines and ACAM2000, there were no other product sales to an individual customer or for an individual product in excess of 10% of total revenues.

For years ended December 31, 2019 and 2018, the Company had long-lived assets outside of the United States of approximately $90.6 million and $82.9 million, respectively, which are primarily located within Canada and Switzerland.

18. Quarterly financial data (unaudited)

Quarterly financial information for the years ended December 31, 2019 and 2018 is presented in the following tables:

	Quarter Ended			
(in millions, except per share data)	March 31,	June 30,	September 30,	December 31,
2019:				
Revenue	$190.6	$243.2	$311.8	$360.4
Income (loss) from operations	(27.4)	(7.0)	70.7	77.8
Net income (loss)	(26.1)	(9.5)	43.2	46.9
Net income (loss) per share-basic	$ (0.51)	$ (0.18)	$ 0.84	$ 0.91
Net income (loss) per share-diluted	$ (0.51)	$ (0.18)	$ 0.83	$ 0.90
2018:				
Revenue	$117.8	$220.2	$173.7	$270.7
Income (loss) from operations	(9.5)	66.8	21.3	11.2
Net income (loss)	(4.9)	50.1	20.9	(3.4)
Net income (loss) per share-basic	$ (0.10)	$ 1.00	$ 0.42	$ (0.07)
Net income (loss) per share-diluted	$ (0.10)	$ 0.98	$ 0.41	$ (0.07)

19. Litigation

ANDA Litigation

On September 14, 2018, Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd. (collectively, ''Adapt Pharma''), and Opiant Pharmaceuticals, Inc. (''Opiant''), received notice from Perrigo UK FINCO Limited Partnership (''Perrigo''), that Perrigo had filed an Abbreviated New Drug Application (''ANDA''), with the United States Food and Drug Administration 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, (the '''253 Patent''), 9,468,747 (the '''747 Patent''), 9,561,177, (the '''177 Patent''), 9,629,965, (the '''965 Patent'') and 9,775,838 (the '''838 Patent''). On or about October 25, 2018, Perrigo sent a subsequent notice letter relating to U.S. Patent No. 10,085,937 (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, (collectively, the ''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. On February 12, 2020, Adapt Pharma and Perrigo entered into a settlement agreement to resolve the ongoing litigation. Under the terms of the settlement, Perrigo has received a non-exclusive license under Adapt's patents to make, have made and market its generic naloxone hydrochloride nasal spray under its own ANDA. Perrigo's license will be effective as of January 5, 2033 or earlier under certain circumstances including circumstances related to the outcome of the current litigation against Teva (as defined below) or litigation against future ANDA filers. The Perrigo settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission, and entry of an order dismissing the litigation by the U.S. District Court for the District of New Jersey.

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. (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, (the '''644 Patent''), and

U.S. Patent No. 9,707,226, (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 (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 the date of this filing, Adapt Pharma Inc., Adapt Pharma Operations Limited, and Opiant, have not filed a complaint related to the '937 Patent. Closing arguments are scheduled for February 26, 2020.

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.

Nalox-1 Pharmaceuticals, a non-practicing entity, filed petitions with the United States Patent and Trademark Office Patent Trial and Appeal Board (the ''PTAB'') requesting inter parties review (''IPR'') of five of the six patents listed in the Orange Book related to NARCAN®Nasal Spray 4mg/spray. In a series of decisions, the PTAB agreed to institute a review of the '253 Patent, the '747 Patent and the '965 Patent but denied review of the '177 Patent and the '838 Patent. Nalox-1 did not request review of the '937 Patent.

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

Not applicable.

ITEM 9 A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019. The term ''disclosure controls and procedures,'' as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2019, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework* (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2019, our internal control over financial reporting was effective based on those criteria.

Ernst & Young LLP, the independent registered public accounting firm that has audited our consolidated financial statements included herein, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2019, a copy of which is included in this annual report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There have been changes in our internal control over financial reporting (as defined in Rule 13a-15(f)) identified in connection with the evaluation required by Rule 13a-15(d) of the Exchange Act that occurred during the period covered by this report that have materially affected our internal control over financial reporting. These changes pertained to the integration of the acquired companies in 2018, Adapt and PaxVax, onto the Company's information technology platforms during the fourth quarter of 2019.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited Emergent BioSolutions Inc. and subsidiaries' internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Emergent BioSolutions Inc. and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019 based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, 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 and our report dated February 24, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

Baltimore, Maryland
February 24, 2020

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Code of Ethics

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

The remaining information required by Item 10 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2020 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2020 annual meeting of stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

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

The information required by Item 12 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2020 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

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

The information required by Item 13 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2020 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2020 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statements

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2019 and 2018

Consolidated Statements of Operations for the years ended December 31, 2019, 2018 and 2017

Consolidated Statements of Comprehensive Income for the years ended December 31, 2019, 2018 and 2017

Consolidated Statements of Cash Flows for the years ended December 31, 2019, 2018 and 2017

Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2019, 2018 and 2017

Notes to Consolidated Financial Statements

Financial Statement Schedules

Schedule II – Valuation and Qualifying Accounts for the years ended December 31, 2019, 2018 and 2017 has been filed as part of this annual report on Form 10-K. All other financial statement schedules are omitted because they are not applicable or the required information is included in the financial statements or notes thereto.

Exhibits

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

SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS

(in millions)	Beginning Balance	Additions from Acquisition	Charged to costs and expenses	Deductions	Ending Balance
Year Ended December 31, 2019					
Inventory allowance	$ 14.0	$ –	$ 23.0	$ (19.1)	$ 17.9
Prepaid expenses and other current assets allowance	4.3	–	–	(0.3)	4.0
Year Ended December 31, 2018					
Inventory allowance	$ 3.8	$ 4.4	$ 14.6	$ (8.8)	$ 14.0
Prepaid expenses and other current assets allowance	5.3	–	–	(1.0)	4.3
Year Ended December 31, 2017					
Inventory allowance	$ 3.5	$ –	$ 8.8	$ (8.5)	$ 3.8
Prepaid expenses and other current assets allowance	4.9	–	0.4	–	5.3

Exhibit Index

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

Exhibit Number		Description
2.1	†	Merger Agreement, dated August 8, 2018, by and among Emergent BioSolutions Inc., PaxVax Holding Company Ltd., Panama Merger Sub Ltd., and PaxVax SH Representative LLC (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on October 5, 2018).
2.2	†	Share Purchase Agreement, dated August 28, 2018, by and among Emergent BioSolutions Inc., the Sellers identified therein, Seamus Mulligan and Adapt Pharma Limited (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on October 15, 2018).
3.1		Third Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3 to the Company's Quarterly Report on Form 10-Q filed on August 5, 2016).
3.2		Amended and Restated By-laws of the Company (incorporated by reference to Exhibit 3 to the Company's Current Report on Form 8-K filed on August 16, 2012).
4.1		Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 3 to the Company's Registration Statement on Form S-1 filed on October 20, 2006) (Registration No. 333-136622).
4.2		Registration Rights Agreement, dated as of September 22, 2006, among the Company and the stockholders listed on Schedule 1 thereto (incorporated by reference to Exhibit 4.3 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on September 25, 2006) (Registration No. 333-136622).
4.3		Indenture, dated as of January 29, 2014, between the Company and Wells Fargo Bank, National Association, including the form of 2.875% Convertible Senior Notes due 2021 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 29, 2014).
4.4		Description of the Company's Securities.
9.1		Voting and Right of First Refusal Agreement, dated as of October 21, 2005, between the William J. Crowe, Jr. Revocable Living Trust and Fuad El-Hibri (incorporated by reference to Exhibit 9.1 to the Company's Registration Statement on Form S-1 filed on August 14, 2006) (Registration No. 333-136622).
10.1		Amended and Restated Credit Agreement, dated October 15, 2018, by and among Emergent BioSolutions Inc., the lenders party thereto from time to time, and Wells Fargo Bank, National Association, as the Administrative Agent (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K, filed on October 15, 2018).
10.2	*	Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 5 to the Company's Registration Statement on Form S-1 filed on October 30, 2006) (Registration No. 001-33137).
10.3	*	Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 7, 2009).
10.4	*	Second Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Appendix A to the Company's definitive proxy statement on Schedule 14A filed on April 6, 2012).
10.5	*	Third Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Appendix A to the Company's definitive proxy statement on Schedule 14A filed on April 7, 2014).
10.6	*	Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 5, 2016).

10.7	*	Emergent BioSolutions Inc. Stock Incentive Plan (incorporated by reference to Exhibit 99 to Registration Statement on Form S-8, filed on May 30, 2018.)
10.8	*	Form of Director Nonstatutory Stock Option Agreement (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.9	*	Form of Director Restricted Stock Unit Agreement (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.10	#*	Global Form of Restricted Stock Unit Award Agreement.
10.11	#*	Global Form of Non-Qualified Stock Option Agreement.
10.12	*	Form of 2017-2019 Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 21, 2017).
10.13	*	Form of 2018-2020 Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 14, 2018).
10.14	*	Form of 2019-2021 Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 12, 2019).
10.15	#*	Form of 2020-2022 Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 18, 2020).
10.16	*	Form of Indemnity Agreement for directors and senior officers (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on January 18, 2013).
10.17	*	Director Compensation Program (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K filed on March 8, 2013).
10.18	*	Annual Bonus Plan for Executive Officers (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on March 5, 2010).
10.19	*	Amended and Restated Senior Management Severance Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 22, 2011).
10.20	*	Second Amended and Restated Senior Management Severance Plan (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on July 16, 2015).
10.21	†	Solicitation/Contract/Order for Commercial Items (the CDC BioThrax Procurement Contract), effective December 8, 2016, from the Centers for Disease Control and Prevention to Emergent Biodefense Operations Lansing LLC (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K, filed on February 28, 2017).
10.22	†	Modification No. 1, effective January 27, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.23	†	Modification No. 2, effective February 23,2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.24		Modification No. 3, effective March 22, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.25	†	Modification No. 4, effective April 5, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.26	†	Modification No. 5, effective September 8, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.26 to the Company's Quarterly Report on Form 10-Q filed on November 3, 2017).
10.27	†	Modification No. 6, effective September 21, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.27 the Company's Annual Report on Form 10-K filed on February 23, 2018).

10.28	†	Modification No. 7, effective February 26, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 4, 2018).
10.29		Modification No. 8, effective March 6, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 4, 2018).
10.30	†	Modification No. 9, effective June 6, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.31	†	Modification No. 10, effective June 18, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.32	†	Modification No. 11, effective June 20, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.33	†	Modification No. 12, effective June 21, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.34	†	Modification No. 13, effective December 6, 2018 to the CDC BioThrax Procurement (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 2, 2018).
10.35	†	Modification No. 14, effective October 1, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.45 the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.36	†	Modification No. 15, effective December 7, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.46 the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.37		Modification No. 16, effective December 8, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.47 the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.38	† † †	Modification No. 17, effective June 13, 2019, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q filed on August 2, 2019).
10.39	#† † †	Modification No. 18, effective September 11, 2019, to the CDC BioThrax Procurement Contract
10.40	#† † †	Modification No. 19, effective January 6, 2020, to the CDC BioThrax Procurement Contract.
10.41	#† † †	Modification No. 20, effective January 7, 2020, to the CDC BioThrax Procurement Contract.
10.42	†	Award/Contract (the BARDA AV7909 Contract), effective September 30, 2016, from the BioMedical Advanced Research and Development Authority to Emergent Product Development Gaithersburg Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2016).
10.43	†	Modification No. 1, effective March 16, 2017, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2016) (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 5, 2017).
10.44	†	Modification No. 2, effective August 29, 2018, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on November 2, 2018).
10.45	† † †	Modification #3, effective July 30, 2019, to the BARDA AV7909 contract (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2019).

10.46	#† †	License Agreement, dated as of December 15, 2014, by and between Opiant Pharmaceuticals, Inc. (formerly known as Lightlake Therapeutics Inc.) and Adapt Pharma Operations Limited. (incorporated by reference to Exhibit 10.51 the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.47	#† †	Amendment No. 1 to License Agreement, dated as of December 13, 2016, by and between Opiant Pharmaceuticals, Inc. and Adapt Pharma Operations Limited. (incorporated by reference to Exhibit 10.52 the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.48	#† † †	Award/Contract, effective August 30, 2019 (ACAM 2000 Contract), from the Assistant Secretary, U.S. Department of Health and Human Services (ASPR/OPM) to Emergent Product Development Gaithersburg Inc.
21	#	Subsidiaries of the Company.
23	#	Consent of Independent Registered Public Accounting Firm.
31.1	#	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).
31.2	#	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).
32.1	#	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	#	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	#	The following financial information related to the Company's Annual Report on Form 10-K for the year ended December 31, 2019, formatted in iXBRL (Inline Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Income, (iv) the Consolidated Statements of Cash Flows, (v) the Consolidated Statement of Changes in Stockholders' Equity; and (vi) the related Notes to Consolidated Financial Statements.
104	#	Cover Page Interactive Data File, formatted in iXBRL and contained in Exhibit 101.

#	Filed herewith
†	Confidential treatment granted by the Securities and Exchange Commission as to certain portions. Confidential materials omitted and filed separately with the Securities and Exchange Commission.
† †	Confidential treatment requested by the Securities and Exchange Commission as to certain portions. Confidential materials omitted and filed separately with the Securities and Exchange Commission.
† † †	Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.
*	Management contract or compensatory plan or arrangement filed herewith in response to Item 15(a) of Form 10-K.

Attached as Exhibit 101 to this Annual Report on Form 10-K are the following formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2019 and 2018, (ii) Consolidated Statements of Operations for the Years Ended December 31, 2019, 2018 and 2017, (iii) Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2019, 2018 and 2017 (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2019, 2018 and 2017, (v) Consolidated Statements of Changes in Stockholders' Equity for the Years ended December 31, 2019, 2018 and 2017, and (vi) Notes to Consolidated Financial Statements.

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

By: /s/ RICHARD S. LINDAHL
Richard S. Lindahl

Executive Vice President, Chief Financial Officer and Treasurer

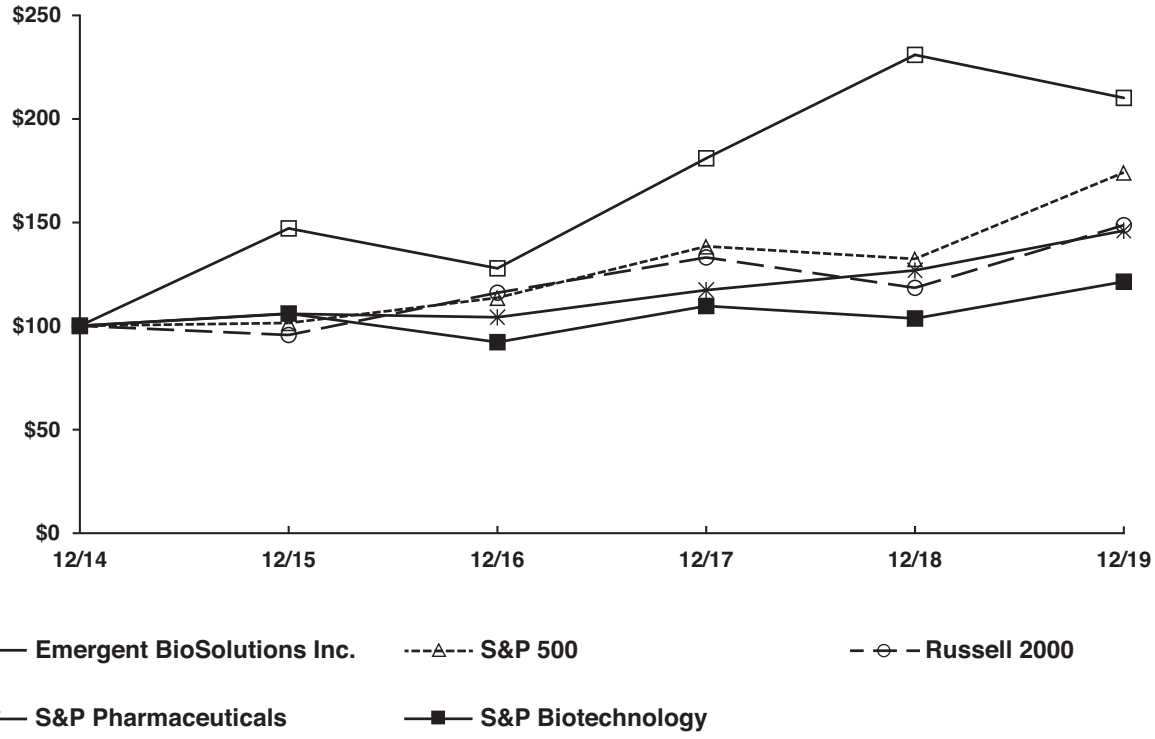
Date: February 24, 2020

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

Signature	Title	Date
/s/ Robert G. Kramer Sr. Robert G. Kramer Sr.	President, Chief Executive Officer and Director (Principal Executive Officer)	February 24, 2020
/s/ Richard S. Lindahl Richard S. Lindahl	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 24, 2020
/s/ Fuad El-Hibri Fuad El-Hibri	Executive Chairman of the Board of Directors	February 24, 2020
/s/ Zsolt Harsanyi, Ph.D. Zsolt Harsanyi, Ph.D.	Director	February 24, 2020
/s/ Kathryn Zoon, Ph.D. Kathryn Zoon, Ph.D.	Director	February 24, 2020
/s/ Ronald B. Richard Ronald B. Richard	Director	February 24, 2020
/s/ Louis W. Sullivan, M.D. Louis W. Sullivan, M.D.	Director	February 24, 2020
/s/ Dr. Sue Bailey Dr. Sue Bailey	Director	February 24, 2020
/s/ George Joulwan George Joulwan	Director	February 24, 2020
/s/ Jerome Hauer, Ph.D. Jerome Hauer, Ph.D.	Director	February 24, 2020
/s/ Seamus Mulligan Seamus Mulligan	Director	February 24, 2020

The graph below matches Emergent BioSolutions Inc.'s cumulative 5-Year total shareholder return on common stock with the cumulative total returns of the S&P 500 index, the Russell 2000 index, the S&P Pharmaceuticals index, and the S&P Biotechnology index. The graph tracks the performance of a $100 investment in our common stock and in each index (with the reinvestment of all dividends) from 12/31/2014 to 12/31/2019.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Emergent BioSolutions Inc., the S&P 500 Index,
the Russell 2000 Index, the S&P Pharmaceuticals Index and the S&P Biotechnology Index



* $100 invested on 12/31/14 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

	12/14	12/15	12/16	12/17	12/18	12/19
Emergent BioSolutions Inc.	**100.00**	**146.93**	**127.70**	**180.70**	**230.51**	**209.78**
S&P 500	**100.00**	**101.38**	**113.51**	**138.29**	**132.23**	**173.86**
Russell 2000	**100.00**	**95.59**	**115.95**	**132.94**	**118.30**	**148.49**
S&P Pharmaceuticals	**100.00**	**105.79**	**104.13**	**117.22**	**126.71**	**145.83**
S&P Biotechnology	**100.00**	**105.92**	**92.13**	**109.56**	**103.54**	**121.25**

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

Directors, Officers and Senior Management

BOARD OF DIRECTORS

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

Robert G. Kramer (5)
President and Chief Executive Officer, Emergent BioSolutions Inc.

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

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

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

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

Seamus Mulligan (4,5)
Former Chairman and Chief Executive Officer,
Adapt Pharma Limited

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

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

Kathryn C. Zoon, Ph.D. (3,4,5)
Scientist Emeritus, National Institute of Allergy and Infectious Diseases at the National Institutes of Health

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

CORPORATE OFFICERS AND SENIOR MANAGEMENT

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

Robert G. Kramer*
President, Chief Executive Officer and Director

Adam R. Havey*
Executive Vice President, Business Operations

Sean Kirk*
Executive Vice President, Manufacturing and Technical Operations

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

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

Katy Strei*
Executive Vice President, Human Resources and Chief Human Resources Officer

Nina DeLorenzo
Senior Vice President, Public Affairs

John H. Ducote
Senior Vice President, Global Quality

Jennifer Fox
Senior Vice President, Legal Affairs and Deputy General Counsel

Christopher W. Frech
Senior Vice President, Global Government Affairs

Syed T. Husain
Senior Vice President, CDMO Business Unit Head

Abigail Jenkins
Senior Vice President, Vaccines Business Unit Head

Laura Kennedy
Senior Vice President, Chief Ethics and Compliance Officer

Brian Millard
Senior Vice President, Corporate Controller

Dino Muzzin
Senior Vice President, Manufacturing Operations

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

Sharon Solomon
Senior Vice President, Chief Information Officer

Doug White
Senior Vice President, Devices Business Unit Head

* Executive Officer

Corporate Information

CORPORATE HEADQUARTERS

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

Additional copies of the company's Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission, and copies of the exhibits thereto, are available without charge upon written request to Investor Relations, Emergent BioSolutions, 400 Professional Drive, Suite 400, Gaithersburg, MD 20879, by calling (240) 631-3200 or by accessing the company's website at www.emergentbiosolutions.com.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young LLP, McLean, VA, United States

STOCK TRANSFER AGENT AND REGISTRAR

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

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

INVESTOR RELATIONS

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

MARKET INFORMATION

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

ANNUAL MEETING

The annual meeting of Emergent BioSolutions will be in virtual format via live audio webcast on May 21, 2020, at 9:00 a.m. Eastern Time. Stockholders can attend the meeting via the internet at www.virtualshareholdermeeting.com/EBS2020

CORPORATE GOVERNANCE

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

emergent
biosolutions®

400 Professional Drive, Suite 400,
Gaithersburg, Maryland 20879 USA

www.emergentbiosolutions.com