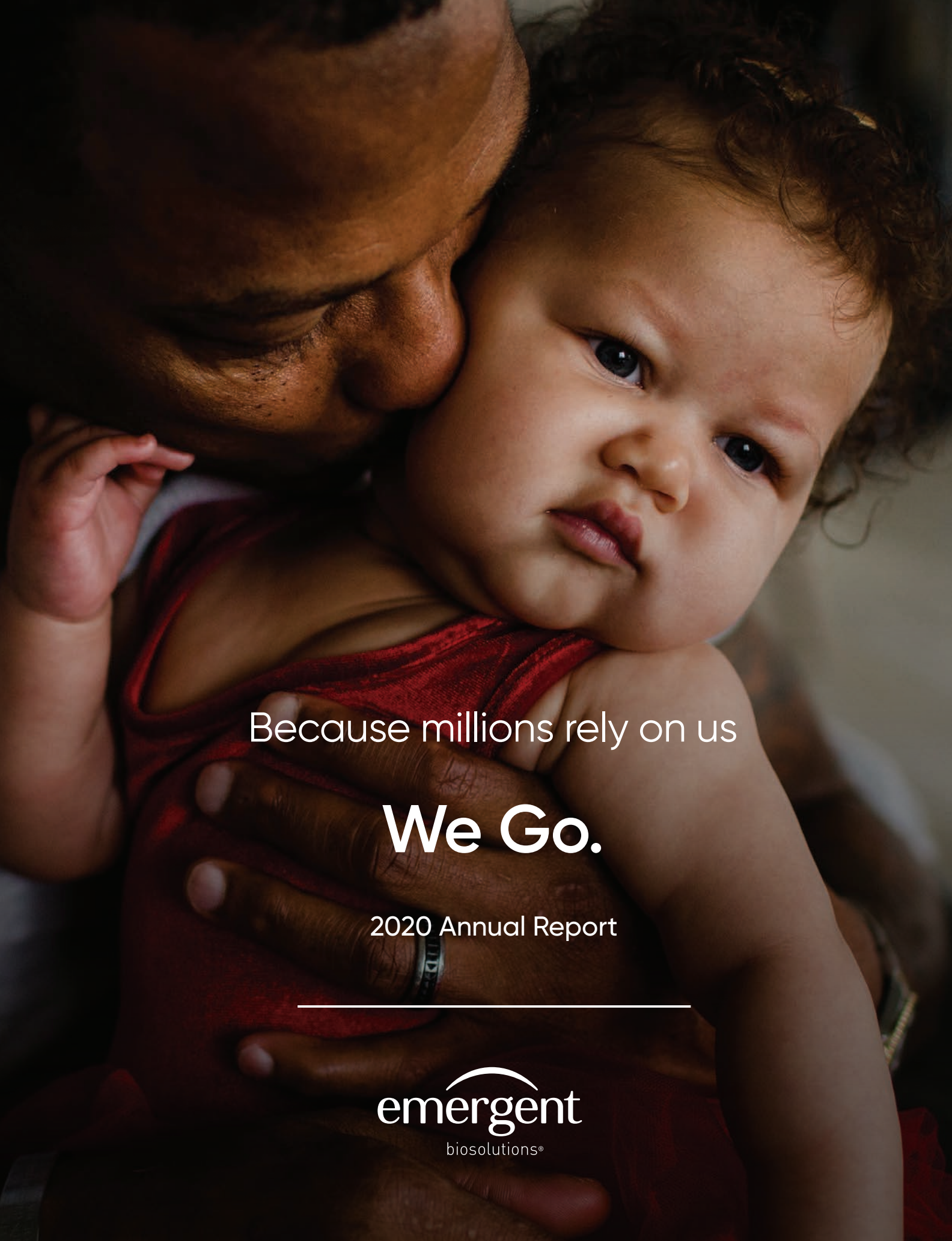
Because millions rely on us
We Go.
2020 Annual Report
emergent
biosolutions®

Dear Fellow Shareholders,

In 2020, Emergent employees rallied to face the challenge of successfully delivering on new and existing commitments with the dedication, passion and agility that are ingrained in our culture. Public health emergencies require strategic planning and standing shoulder-to-shoulder with innovators, regulators, governments and countless other stakeholders in order to respond. Every day at Emergent – We Go – living our mission to protect and enhance life.

Our 2020 achievements are significant on their own, but even more so in light of the complexities we navigated to achieve them. We joined the U.S. government's program to provide an expedited pathway for COVID-19 vaccine and therapeutic development and manufacturing, and simultaneously ramped up manufacturing processes for multiple vaccine candidates including those for Johnson & Johnson and AstraZeneca.

Additionally, we partnered with the Biomedical Advanced Research and Development Authority to develop COVID-Human Immune Globulin (COVID-HIG), a human plasma-derived therapeutic product candidate as a potential treatment in severe hospitalized patients as part of a National Institutes of Health-sponsored clinical trial. COVID-HIG is also being evaluated for potential post-exposure prophylaxis in populations at high risk of exposure to SARS-CoV-2 in partnership with the U.S. Department of Defense, Mount Sinai Health System and ImmunoTek Bio Centers.

The pandemic deepened the opioid crisis. Our team navigated new ways of reaching customers to ensure that NARCAN® (naloxone HCl) Nasal Spray continued to make it into the hands of first responders and loved ones to reverse the effects of opioid overdose.

Other milestones included the manufacture and steady supply of critical medical countermeasures supporting governments' preparedness needs against biological and chemical threats. We invested in the expansion of our CDMO capabilities and capacities in viral vector development and manufacturing and gene therapy.

Most importantly, my Emergent colleagues showed unwavering commitment to our mission. Through it all, their well-being was our top priority. We launched new programs to help support their safety, mental health and need for work flexibility. Because of the Emergent team, we were able to play a crucial role in the fight against the pandemic.

Over the course of the last year, our business demonstrated its strength and durability. We are proud of the contributions we have made to global public health, which we expect to continue well into the future.

Stay safe and my best wishes to you and your families.

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, 2020

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 share	**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 (§ 232.405 of this chapter) 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 the 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No ☐

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, 2020 was approximately $4.2 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 12, 2021, the registrant had 53.3 million shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2021 annual meeting of stockholders scheduled to be held in May 2021, 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, 2020, 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 2021 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, 2020

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K and the documents we incorporate by reference include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding 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 and the continued impact of the COVID-19 pandemic, 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 full impact of the novel strain of coronavirus (SARS-CoV-2) causing COVID-19 disease (COVID-19), on our markets, operations and employees as well as those of our customers and suppliers;
- the availability of U.S. government (USG) funding for procurement of our products and certain product candidates;
- our ability to perform under our contracts with the USG including the timing of and specifications relating to deliveries;
- our ability to provide contract development and manufacturing (CDMO) services for the development and/or manufacture of product candidates of our customers at required levels;
- 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 obtain and maintain regulatory approvals for our product candidates and the timing of any such approvals;
- 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);
- the exercise of all remaining options under our contract for the procurement of ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) and other government procurement contracts;
- the negotiation of further commitments or contracts related to the collaboration and deployment of capacity toward future commercial manufacturing under our CDMO contracts;
- the timing of our submission of an application for and 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 to successfully appeal the patent litigation decision related to NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray;
- our ability and the ability of our collaborators to enforce patents related to NARCAN Nasal Spray against potential generic entrants;
- our ability to develop safe and effective treatments for COVID-19 and obtain authorization for emergency use for or approval of such treatments by the FDA;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- our ability to comply with the operating and financial covenants required by our senior secured credit facilities and our 3.875% Senior Unsecured Notes due 2028;
- 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 impact on our revenues from declines in sales of our vaccine products that target travelers due to the reduction of international travel caused by the COVID-19 pandemic;
- 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 sections entitled ''Risk Factor Summary'' and ''Risk Factors'' in this annual report on Form 10-K and the risk factors identified in our other periodic reports filed with the Securities and Exchange Commission (SEC) when evaluating our forward-looking statements.

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.

PART I

ITEM 1. BUSINESS

OVERVIEW

We are a global life sciences company focused on providing innovative preparedness and response solutions addressing accidental, deliberate and naturally occurring public health threats (PHTs). Our solutions include a product portfolio, a product development pipeline portfolio, and a portfolio of CDMO services. The types of PHTs we are currently addressing are focused on the following five categories:

- chemical, biological, radiological, nuclear and explosives (CBRNE);
- emerging infectious diseases (EID);
- travel health;
- emerging health crises; and
- acute/emergency care.

Our product portfolio comprises ten marketed products (vaccines, therapeutics, and drug-device combination products) that are sold to government and commercial customers. Our product portfolio also includes two product candidates, designated AV7909 (vaccine) and Trobigard Auto-Injector (drug-device combination), that are not approved by the FDA or any other regulatory health authority, but which are procured under special circumstances by certain government agencies.

Our product development pipeline portfolio consists of a diversified mix of both pre-clinical and clinical-stage product candidates, encompassing a mix of vaccines, therapeutics and drug-device combination products. In some cases, certain candidates are supported by external, non-dilutive funding sources (government agencies, non-governmental organizations, pharma/biotech innovators). Certain other candidates are supported solely by internal funding sources.

Our portfolio of CDMO services consists of three distinct but interrelated service pillars: development services (process and analytical development); drug substance manufacturing; and drug product manufacturing (fill/finish) and packaging. These services, which we refer to as ''molecule-to-market'' offerings, employ five technology platforms (mammalian, microbial, viral, plasma and gene therapy) across a network of nine geographically distinct development and manufacturing sites operated by us for our internal products and pipeline and CDMO services, for both clinical-stage projects and commercial-stage projects. We direct these CDMO services for a variety of third-party customers, including innovative pharmaceutical companies, government agencies and non-government organizations.

Our revenues are derived from a combination of the sale and procurement of our product portfolio and the provision of our CDMO services to external customers.

STRATEGY

Our current five-year strategic plan, 2020-2024, is focused on leveraging core competencies, relationships and operating systems we have developed over the last 22 years and driving growth across various segments of the PHT market. The strategic plan includes achievement of the following financial goals by the end of 2024:

- Total revenue of at least $2 billion; and
- Adjusted EBITDA margin of 27%-30%.

In pursuit of these goals, the strategic plan specifies employing five core strategies. They are:

Execute Core Business—We are focused on continuing to build our leadership positions across several markets in the PHT space. These include, but are not limited to, medical countermeasures (MCMs), opioid rescue and travel health. Additionally, our Core Business includes our growing CDMO services. We believe our diversified portfolio of products and services, combined with our quality development and manufacturing services across a spectrum of differentiated and complex manufacturing processes position us for continued growth across the PHT landscape. Additionally, we will continue to leverage our specialized government relations and contracting operations to negotiate long-term, profitable procurement and development agreements that enable us to protect and enhance lives around the world and that help ensure sustainability of our business.

Grow Through Mergers and Acquisitions (M&A)—We have successfully executed and integrated several product and facility acquisitions that have increased our diversification, allowed expansion into new markets, and provided a differentiated research and development (R&D) pipeline. We plan to continue to leverage our M&A and partnering strengths not only to solidify our leadership positions in the MCM market, but also to expand our businesses in PHT markets where the government is not the primary customer. We aim to accomplish this goal through a disciplined approach to acquiring accretive or clinical-stage assets and to forming partnerships that help us to achieve our strategic objectives.

Strengthen R&D Portfolio—We continue to focus on expanding and advancing our pipeline of drug and device product candidates across several categories, with the aim to launch and/or sell differentiated products that address unmet needs in the PHT space. We fund our pipeline by investing our own funds and

through securing government contracts, grants, or other non-dilutive funding. We plan to grow our R&D pipeline to expand our portfolio of marketed and procured PHT products.

Build Scalable Capabilities—Achieving our 2024 strategic objectives requires an investment in infrastructure, internal governance and capabilities that help us realize the benefits of scale. This includes investing new capital into our development and manufacturing facilities, strengthening our global sales and procurement models, upgrading our technology and growing our commercial infrastructure. These, and other capabilities, are intended to help us operate in a more efficient, customer-focused manner, while better serving both government and non- government customers.

Evolve the Culture—We are proud of our heritage and organization we have built, and further believe that the growth we are striving for requires continued improvement and refinement of the culture of the organization. We anticipate continuing to invest in development of our people and our culture consistent with our values. We are committed to attracting, developing, and retaining the best talent reflecting a diversity of ideas, backgrounds, and perspectives and seek to demonstrate that commitment through our talent development strategy, processes and company-wide programs.

OUR BUSINESS UNITS

We are organized into four business units:

- Three product business units: Vaccines, Devices, Therapeutics, and
- One services business unit: CDMO.

Vaccines

Vaccine Products

Our Vaccines business unit contains a portfolio of specialty vaccines that address existing and emerging PHTs consisting of the following products:

APPROVED VACCINES BUSINESS UNIT PRODUCTS		
Product	**Indication(s)**	**Primary Regulatory Approvals**
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
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, Canada, France (where it is known as BaciThrax®), Germany, Italy, the Netherlands, Poland, Singapore and UK
Vaxchora® (Cholera Vaccine Live Oral)	Vaccine indicated for active immunization against disease caused by Vibrio cholerae serogroup 01 in persons 2 through 64 years of age traveling to cholera-affected areas.	United States, EU
Vivotif® (Typhoid Vaccine Live Oral Ty21a)	For immunization of adults and children greater than 6 years of age against disease caused by Salmonella typhi.	United States Argentina, Austria, Australia, Belgium, Canada, Czech Republic, Denmark, France, Finland, Germany, Hong Kong, Italy, Luxembourg, Malaysia, the Netherlands, New Zealand, Nigeria, Norway, Poland, Portugal, Singapore, South Korea, Slovakia, Spain, Sweden, Switzerland and UK

***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. According to the Centers for Disease Control and Prevention (CDC), it is one of the most devastating diseases with a mortality rate as high as 30%. 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.

On September 3, 2019, we announced the award by the USG of a contract valued at up to approximately $2 billion over 10 years for the continued supply of ACAM2000 into the Strategic National Stockpile (SNS), assuming all contract options are exercised. 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. On May 28, 2020, we announced the exercise by the U.S. Department of Health and Human Services (HHS) of the first contract option, valued at $176 million, to procure doses of ACAM2000. The number of doses under the first contract option were delivered by year end 2020. The actual number of ACAM2000 doses to be procured in the future is dependent on certain timing and tiered-pricing terms that are subject to the discretion of HHS.

***BioThrax*® (Anthrax Vaccine Adsorbed).** BioThrax is the only vaccine licensed by the FDA for pre-exposure prophylaxis of anthrax disease in persons at high risk of exposure. BioThrax was granted orphan drug designation (market exclusivity) through 2022 (see ''Regulation—Marketing Approval—Biologics, Drugs and Vaccines—Orphan Drugs''). BioThrax is also approved by the FDA for post-exposure prophylaxis 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. In the United States, BioThrax is administered in a pre-exposure prophylaxis setting by intramuscular injection as a three-dose primary series over a six-month period. Per the U.S. 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 post-exposure prophylaxis setting in conjunction with recommended antibacterial drugs following suspected or confirmed *Bacillus anthracis* exposure. When we report the revenue associated with ''anthrax vaccines'', it reflects the combined revenue from the procurement and sale of BioThrax as well as the product candidate AV7909 (described below).

In December 2016, we signed a follow-on contract with the CDC 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.

***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 is a potentially life-threatening bacterial infection that occurs in the intestines and causes severe diarrhea and dehydration. It has a low incidence in the United States and Europe, but a high incidence in Africa, Southeast Asia, and other locations around the world. These areas have historically drawn travelers from the United States and Europe, so cholera can occur in patients who return to the United States or Europe from visits to these regions. Vaxchora is indicated for active immunization against cholera caused by the bacterium *V. cholerae serogroup 01*.

We have generally marketed Vaxchora to a subset of travelers primarily from the United States. Our sales of Vaxchora were disrupted in 2020 due to the broader disruption to travel caused by the COVID-19 pandemic, and we expect limited sales in 2021 due to that continuing disruption.

***Vivotif*® (Typhoid Vaccine Live Oral Ty21a).** Vivotif is a live attenuated vaccine for oral administration to prevent typhoid fever. 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. Travelers from North America and Europe going to Asia, Africa, and Latin America have historically been particularly at risk.

We have generally marketed Vivotif to a subset of travelers primarily from the United States and the European Union. Our sales of Vivotif were disrupted in 2020 due to the broader disruption to travel caused by the COVID-19 pandemic, and we expect limited sales in 2021 due to that continuing disruption.

Vaccine Product Candidates

The chart below highlights two of our leading vaccine pipeline product candidates:

Product Candidate	Target Indication
AV7909* (anthrax vaccine adsorbed with adjuvant)	Procured vaccine candidate for post-exposure prophylaxis of disease resulting from suspected or confirmed *Bacillus anthracis* exposure.
CHIKV VLP Chikungunya virus VLP vaccine	Vaccine candidate being developed for active immunization to prevent disease caused by Chikungunya virus.
** 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.*	

Description of Procured Vaccine Product Candidate

AV7909 (anthrax vaccine adsorbed with adjuvant). We are developing AV7909, an anthrax vaccine product candidate based on anthrax vaccine adsorbed combined with an adjuvant. Studies have shown that AV7909 elicits a more rapid onset of immune response using fewer doses than BioThrax while still providing protective immunity in patients. AV7909 is expected to provide protection with a two-dose regimen (versus the BioThrax three-dose regimen) for post-exposure prophylaxis of anthrax disease. In September 2016, we signed a combination development and procurement contract with BARDA, which included a five-year base period of performance 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 and options for an additional clinical study and post marketing commitments. In 2019, we initiated and completed enrollment of a Phase 3 study; the 3,850 subject trial evaluating safety, immunogenicity and lot consistency was completed in 2020. In collaboration with us, the CDC filed with the FDA a pre-Emergency Use Authorization (EUA) 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. On July 14, 2020, we announced the exercise by BARDA of another contract option, valued at $258 million, to procure additional doses of AV7909 for delivery into the SNS over 12 months. We currently anticipate the submission of a biologics license application (BLA) for AV7909 to the FDA in 2021, although there can be no assurance it will be approved by the FDA.

When we report the revenue associated with ''anthrax vaccines,'' it reflects the combined revenue from the procurement and sale of AV7909 as well as BioThrax (described above).

Devices

Device Products

Our Devices business unit contains a portfolio of device and drug-device combination products that address PHTs. The current portfolio consists of the following products:

APPROVED DEVICES BUSINESS UNIT PRODUCTS		
Product	**Indication(s)**	**Primary Regulatory Approvals**
NARCAN® (naloxone HCl) Nasal Spray	Emergency treatment of known or suspected opioid overdose as demonstrated 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), Australia, Canada, European Union, Israel

NARCAN® (naloxone HCl) Nasal Spray. NARCAN® (naloxone HCl) Nasal Spray, a product we obtained in connection with our acquisition of Adapt Pharma Inc. in 2018, is an intranasal formulation of naloxone approved by the FDA and Health Canada for the emergency treatment of known or suspected opioid overdose as demonstrated 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. Recently, we completed two important product life cycle improvements that we expect will provide meaningful value for our customers. First, we launched the Generation II NARCAN Nasal Spray device, which has a claim for enhanced temperature excursions and storage below 25° C. Second, we gained FDA approval for an extension of the shelf life of NARCAN from 24 months to 36 months.

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, is a five-year contract valued at up to approximately $171 million to supply RSDL for use by all branches of the U.S. military. In addition to the DoD and other USG agencies, beginning in 2017, we made RSDL available for the first time for purchase by civilians in the United States. We have also sold RSDL to 35 foreign countries outside the United States since the device was cleared in 2003.

Device Product Candidates

The chart below highlights several of our pipeline product candidates in our Devices business unit.

Product Candidate	Target Indication
AP003 (Naloxone multidose nasal spray)	A nasal delivery device candidate designed to deliver multiple 4mg doses to treat acute opioid overdose.
AP007 (Sustained release nalmefene injectable)	A slow release injectable candidate designed to release an effective dose of nalmefene over an extended time period that is intended to treat addiction and reduce the potential for relapse in patients undergoing treatment for opioid use disorder.
SIAN (stabilized isoamyl nitrite)	A single-use intranasal spray device candidate being developed to deliver a stabilized form of isoamyl nitrite (SIAN) that is intended to be developed for use by first responders and medical personnel following a cyanide incident.
Trobigard Auto-Injector®* (atropine sulfate, obidoxime chloride)	Combination drug-device auto-injector procured product candidate for potential use as a nerve agent countermeasure.
** 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.*	

We have also 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.

Therapeutics

Therapeutics Products

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

APPROVED THERAPEUTICS BUSINESS UNIT PRODUCTS		
Product	**Indication(s)**	**Primary Regulatory Approvals**
Anthrasil® [Anthrax Immune Globulin Intravenous (Human)]	Treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs.	United States, Canada
BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)]	Treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients.	United States, Canada, 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
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; and • Aberrant infections induced by vaccinia virus (except in cases of isolated keratitis).	United States, Canada

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 licensed by the FDA for the treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs. Anthrasil also received orphan drug designation for that indication, resulting in market exclusivity in the United States until March 2022. We currently have two 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. This contract covers extended plasma storage, and the options for manufacturing and product delivery, which are available to be exercised by HHS through September 2023. In addition to domestic government sales, Anthrasil has been sold to several foreign governments, including the Canadian government.

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 licensed by the FDA 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 is also licensed in Canada pursuant to Health Canada's EUND regulations. BAT is also approved in Singapore and Ukraine. BAT is the only heptavalent botulism antitoxin available in the United States and 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. On May 8, 2020, we

announced the finalization of a previously announced contract with HHS, valued at up to $550 million, if all options under the contract are exercised. The contract has two deliverables. The first deliverable, negotiated in September 2019 and valued at up to approximately $90 million, is to supply annual doses of BAT into the SNS for 10 years by converting existing bulk drug substance into final drug product. This deliverable also includes options for additional doses valued at up to approximately $94 million over 10 years. The second deliverable, valued at up to approximately $366 million, is for the production of additional doses of bulk drug substance over 10 years to maintain the plasma collection and production capability for botulism response planning. In addition to domestic government sales, BAT continues to be sold internationally, with deliveries to over 10 foreign governments in 2020.

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*. 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 appropriate. We assumed responsibility for a multi-year contract with BARDA from Human Genome Sciences, Inc. and GlaxoSmithKline LLC (collectively referred to as GSK) 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. In addition, we have initiated the process of transferring raxibacumab manufacturing from GSK to our facilities.

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 being procured by the USG 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 is licensed by the FDA and Health Canada for counteracting 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.

Therapeutics Product Candidates

The chart below highlights several of our Therapeutics business unit pipeline product candidates:

Product Candidate	Target Indication
COVID-EIG (Equine-derived polyclonal hyperimmune with antibodies to SARS-CoV-2)	Potential treatment of severe COVID-19 disease.
COVID-HIG (Human polyclonal hyperimmune with antibodies to SARS-CoV2)	Potential treatment of COVID-19 disease in severe hospitalized patients and post-exposure prophylaxis in individuals at high risk of exposure, such as front-line workers and military personnel.
FLU-IGIV (Human polyclonal hyperimmune with antibodies to Influenza A)	Treatment of Influenza A infection in hospitalized patients.

Contract Development and Manufacturing

Our CDMO business unit is based on our established development and manufacturing infrastructure, technology platforms and expertise, as well as continuing capital expenditure projects to expand our capabilities.

Our CDMO portfolio consists of development services, bulk drug substance manufacturing, fill, finish, and packaging of final drug product, or ''molecule-to-market'' offerings. These services are provided for innovator biopharmaceutical companies, government agencies and non-government organizations. The biologics technology platforms consist of mammalian, microbial, viral, plasma and gene therapy.

We have nine development and manufacturing sites spread across multiple locations in the United States, Canada and Switzerland. Five of these sites currently provide CDMO services to customers and the others are either ready now or in various stages of investment to advance them for servicing CDMO customers.

- Our Winnipeg and Gaithersburg sites house our development services expertise;
- Our Bayview, Lansing, Winnipeg, Bern and Canton sites house our drug substance expertise; and
- Our Camden, Winnipeg, Rockville and Hattiesburg sites house our drug product expertise.

We currently have over 50 CDMO customers. Below is a description of the largest CDMO arrangements awarded during 2020.

BARDA COVID-19 Public-Private Partnership. On June 1, 2020, we announced that we had been issued a task order under our existing Center for Innovation in Advanced Development and Manufacturing (CIADM) agreement with BARDA for COVID-19 vaccine development and manufacturing. The task order has a contract value of up to $628 million and includes the reservation of manufacturing capacity valued at $542.7 million and $85.5 million for accelerating the planned expansion of viral and non-viral drug product fill/finish capacity.

Johnson & Johnson COVID-19 Vaccine Arrangement. On July 2, 2020, we executed a large scale drug substance manufacturing agreement related to Johnson & Johnson's lead COVID-19 vaccine candidate for up to five years beginning in 2021. The first two years are valued at approximately $480 million, with the remaining three years providing optional flexible capacity to support volume commitments. This agreement was preceded by an agreement executed in April 2020 valued at approximately $135 million to provide CDMO services and capacity reservation to Johnson & Johnson.

AstraZeneca COVID-19 Vaccine Arrangement. On July 26, 2020, following BARDA direction to release capacity to AstraZeneca, we executed a large-scale drug substance manufacturing agreement related to AstraZeneca's COVID-19 vaccine candidate, valued at approximately $174 million through 2021, which followed an initial agreement, also executed in 2020, valued at approximately $87 million to provide CDMO services and capacity reservation to AstraZeneca.

We also have three capital investment projects in support of the growth of our CDMO business unit. First, we are nearing completion of a $50 million expansion at our Baltimore, Maryland – Camden drug product site, which was announced in 2018 of which approximately $7.5 million is funded by BARDA. Second, we are broadening our drug product capabilities at our Rockville, Maryland site, with $75 million in funding from BARDA. Third, we will be investing $75 million in our Canton, Massachusetts facility, to expand our viral-based service offering to include viral vector and gene therapy capabilities. Together, this represents a $200 million expansion of our manufacturing capability and capacity adding strength, diversity and durability to our network.

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. In addition to U.S. sales, we sell our products to governments and non-governmental organizations outside of the United States, primarily to those governments and organizations with which the United States enjoys positive diplomatic relations. For our non-U.S. sales, we use a combination of our employees as well as third-party distributors and representatives to sell our products.

Commercial Sales

In addition to direct sales primarily to state and local governments as described above, NARCAN® Nasal Spray is sold commercially through physician-directed or standing order prescriptions at retail pharmacies and to first responders including police, firefighters 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. Sales of these products were significantly reduced beginning in 2020 due to a sustained decline in international travel resulting from COVID-19 and we expect limited sales of these products in 2021 due to continuing travel disruptions.

Our CDMO business unit is supported by a dedicated group of sales and business development, marketing and customer experience, and commercial operations professionals qualified to represent our full breadth of service offerings to the global pharmaceutical and biotechnology industry and governments/non-government organizations.

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®.*** AV7909 and BioThrax are currently procured, primarily by the USG, for prevention of anthrax disease. While there are no vaccines, other than BioThrax, approved by the FDA for prevention of anthrax disease, and none other than AV7909 and BioThrax that are currently procured by the SNS, we face potential future competition for the supply of anthrax vaccines if the USG chooses to procure products or product candidates for any programs currently in development. Altimmune, Inc., GC Pharma, Blue Willow Biologics, and Greffex are each currently developing anthrax vaccine product candidates, which are in various stages of clinical development. Of the product candidates, Altimmune announced completion of enrollment of a Phase 1 trial in August, 2020 and Blue Willow Biologics announced FDA clearance to begin Phase 1 study in October 2019.
- ***NARCAN®* (naloxone HCl) Nasal Spray.** NARCAN®Nasal Spray is the first FDA-approved intranasal naloxone spray for the emergency reversal of opioid overdoses. Teva Pharmaceuticals Industries Ltd. and its Canadian affiliate (collectively, Teva) have filed applications for generic versions of an intranasal naloxone spray based on NARCAN®Nasal Spray with the FDA and Health Canada. Teva has not launched its generic product in either jurisdiction, but may launch at risk, despite our patent infringement litigation (described in more detail below) that is currently proceeding against them. NARCAN®Nasal Spray also faces branded competition from other injectable naloxone, auto-injectors and improvised nasal kits, including Amphastar Pharmaceuticals, Inc's. naloxone injection product and Kaléo's EVZIO™ (naloxone HCl injection) Auto-Injector and Teleflex Medical Inc's Intranasal Mucosal Atomization Device. NARCAN®Nasal Spray may face additional generic and branded competition in the future.
- ***ACAM2000®.*** ACAM2000® faces competition from JYNNEOS™, which is licensed by the FDA for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. JYNNEOS is also approved in Canada and in the European Union under the trade names IMVAMUNE and IMVANEX, respectively. ACAM2000 remains the primary smallpox vaccine stockpiled by the USG and offers key features for public health mass vaccination programs that are critical, including a single dose vaccination schedule and multi-dose vial presentation.

  While therapeutics generally do not compete directly with vaccines, our sales to the USG are dependent upon U.S. policy of stockpiling vaccines for emergency use. There is an approved smallpox therapeutic in the United States made by SIGA Technologies, Inc. (Siga) and in the event USG policy regarding smallpox vaccine and therapeutic stockpiling was to change, our sales could be adversely affected.
- ***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 chimeric (or ''partially human'') antibody indicated for the treatment and prophylaxis of inhalational anthrax. Obiltoxaximab is also approved in Canada and the EU.
- ***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. 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. While direct competition in terms of the treatment of smallpox vaccination side effects is limited, SIGA has obtained FDA approval for TPOXX® (tecovirimat), an oral therapy for the treatment of smallpox disease TPOXX® is currently procured by the SNS. 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 primarily 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. Vaxchora is subject to competition by Valneva's Dukoral® cholera vaccine in the EU.

We also compete for CDMO services with a number of biopharmaceutical product development organizations, contract manufacturers of biopharmaceutical products and university research laboratories.

- ***CDMO Services Business.*** Companies with which we compete for CDMO services include, among others: Lonza Group Ltd., Catalent, Inc., Thermo Fisher Scientific, FUJIFILM Dionsynth Biotechnologies. We also compete with in-house research, development and support service departments of other biopharmaceutical companies.

Geographical Reliance

For the years ended December 31, 2020, 2019 and 2018, the Company's revenue from U.S. customers as a percentage of total revenues were 93%, 90% and 91%, respectively.

MANUFACTURING OPERATIONS

Our development and manufacturing network allows us to deploy capabilities and capacity for clinical and commercial supply needs.

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 AV7909 and BioThrax, from a single-source supplier for which we have no alternative source of supply. However, we maintain stored supplies of this adjuvant in quantities believed to be sufficient to meet our expected manufacturing needs. 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 Anthrasil, 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.

The rapid demand for COVID-19 vaccines and therapeutics in light of the current pandemic has caused significant demand for raw materials for the vaccine and therapeutics we are manufacturing. The USG has invoked the Defense Production Act to prioritize our ability to obtain some of these raw materials, but there is still competition from other manufacturers of COVID-19 vaccines and therapeutics that may limit our ability to manufacture on a timely basis.

INTELLECTUAL PROPERTY

We actively seek to protect intellectual property related to our Company's assets, including patent rights, trademark rights, trade secrets and proprietary confidential information, through defense and enforcement of existing rights and pursuit of protection on new and arising innovations. The duration of and the type of protection for patent rights 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. We are a party to various license agreements, including those under which we license patents, patent applications, trademarks, and other intellectual property rights. It is our policy to ethically consider the enforcement and defense of our intellectual property rights, and to respect the intellectual property rights of others. We are currently in litigation with Teva to enforce our patents related to NARCAN® Nasal Spray as described in greater detail below.

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.

The Project BioShield Act of 2004. The Project BioShield Act of 2004 (Project BioShield) was enacted to augment market incentives for companies pursuing the development of MCMs of which the government is the only significant market. Project BioShield provided $5.6 billion over 10 years to develop, purchase, and stockpile MCMs for use in a public health emergency against Chemical, Biological, Radiological and Nuclear agents.

The Pandemic and All Hazards Preparedness Act of 2006 and Reauthorization Acts. The Pandemic and All Hazards Preparedness Act of 2006 (PAHPA) established a new, Assistant Secretary for Preparedness and Response (ASPR) within HHS; provided new authorities for a number of programs, including the creation of BARDA for the advanced research and development and procurement of MCMs for CBRN threats and emerging infectious diseases. The Pandemic All Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) continued BARDA's role and reauthorized Project BioShield funding through fiscal year 2018 and provided BARDA with additional appropriations to support advanced research and development. The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA) reauthorized Project BioShield's special reserve fund and authorized 10-year funding for product development. BARDA has used the incentives under Project BioShield and subsequent reauthorizations of it to build a robust pipeline of MCMs for multiple CBRN threat agents. It has also procured and stockpiled many of our related products for potential use in the event of a public health threat emergency, including BioThrax, ACAM2000, Anthrasil, BAT, VIGIV and raxibacumab.

Funding for BARDA is provided by annual appropriations by Congress. Congress appropriates annual funding for procurements of MCMs for the SNS (currently managed by ASPR) and for the National Institute of Allergy and Infectious Diseases (NIAID) to conduct biodefense research. This appropriation funding supplements amounts available under Project BioShield.

Emergency Use Authorization

As amended by Project BioShield and subsequent legislation, including 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, 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.

Under PAHPRA, the USG may also, at its discretion, purchase critical biodefense products for the SNS prior to FDA approval after the filing of a pre-EUA application with the FDA. BARDA is currently procuring AV7909 from us pursuant to this authority, a product candidate which has not yet been approved by the FDA.

Public Readiness and Emergency Preparedness Act. The Public Readiness and Emergency Preparedness Act (PREP Act) creates liability immunity for manufacturers of MCMs when the Secretary of HHS

issues a declaration for their manufacture, administration or use. A PREP Act declaration is intended to provide liability immunity from claims under federal or state law for loss arising out of the administration or use of a covered MCM under a government contract. The Secretary of HHS has issued PREP Act declarations identifying BioThrax, ACAM2000, raxibacumab, Anthrasil, BAT and VIGIV, as covered MCMs.

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

Product Development for Therapeutics and Vaccines

Pre-Clinical Testing. We generally perform pre-clinical safety and efficacy testing on our product candidates before we initiate clinical trials.

Animal Rule. Conducting controlled clinical trials with human patients to determine efficacy may sometimes be unethical or unfeasible. Under the ''Animal Rule,'' under some circumstances, approval of 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 animal studies.

Investigational New Drug Application. Before clinical testing may begin, the results of pre-clinical testing and other available clinical data must be submitted to the FDA as part of an Investigational New Drug (IND) application. The data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial clinical studies.

Clinical Trials. Clinical trials involve administration of a product candidate to healthy human volunteers or patients under the supervision of a qualified physician under an FDA-reviewed protocol. Initial human clinical trials typically are conducted in the following three sequential phases.

- Phase 1 involves introduction of the drug into healthy human subjects to assess metabolism, pharmacokinetics, pharmacological actions, side effects and early evidence of effectiveness.
- Phase 2 involves studies to assess the efficacy of the drug in specific, targeted indications, explore tolerance, optimal dosage, and safety risks.
- Phase 3 trials must demonstrate clinical efficacy and safety in a larger number of patients, and permit the FDA to evaluate the overall benefit-risk relationship of the drug and provide adequate information for drug labeling.

Phase 4 studies may also be conducted following marketing approval to provide additional data related to drug use. The FDA may impose a temporary or permanent clinical hold, or other sanctions, if it believes that a clinical trial is not being conducted in accordance with the FDA requirements or presents an unacceptable risk to the clinical trial subjects.

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 clinical trials.

Marketing Approval – Biologics, Drugs and Vaccines

Biologics License Application/New Drug Application. For large molecule products, such as vaccines, products derived from blood and blood components, and antibodies, 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, in which case the application must be resubmitted. Most applications are subject to a substantial application fee and, if approved, will be assessed an annual fee. Under the U.S. Food, Drug, and Cosmetic Act (FDCA), the FDA has the authority to grant waivers of certain user fees.

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 and/or that the drug is not safe for use under the conditions of use in the proposed labeling. 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).

We currently intend to submit a BLA to the FDA for AV7909 by the end of 2021. The receipt of regulatory approval may take many years, and typically involves the expenditure of substantial financial resources. Accordingly, there can be no assurances we will receive approval for AV7909 from the FDA. The FDA may also impose conditions upon approval or significantly limit the indications approved for a given product and/or require, as a condition of approval,

enhanced labeling, packaging, post-approval clinical trials, expedited reporting of certain adverse events, pre-approval of promotional materials or restrictions on consumer advertising, 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 under an NDA for innovator products, or an abbreviated new drug application 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 (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 demonstrate bioequivalence (i.e. that their product performs in the same manner). 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.

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 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 pre-clinical 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 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.

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.

Although NARCAN Nasal Spray is protected by patents covering its manufacture, formulation, distribution system and method of use, multiple third parties have filed ANDAs seeking FDA approval of generic versions of NARCAN Nasal Spray. Notwithstanding our patents, it is possible that once its application is approved, an ANDA filer could introduce a competing naloxone hydrochloride product before our patents expire if it is determined that it does not infringe our patents, or that our patents are invalid or unenforceable, or if such company or companies decide, before applicable ongoing patent litigation is concluded, to launch a naloxone hydrochloride product at risk of being held liable for damages for patent infringement. As discussed herein, the FDA has approved the first ANDA for a generic version of NARCAN Nasal Spray.

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. The FDA may also require post-approval clinical trials and/or safety labeling changes.

Facilities involved in the manufacture and distribution of approved products are required to be registered with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA for compliance with cGMP and other laws.

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 Protocol. 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.

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.

Medical devices are classified into one of three classes – Class I, Class II or Class III – depending on the degree of risk and the level of control necessary to assure the safety and effectiveness of each medical device. Medical devices deemed to pose lower risks are generally placed in either Class I or II. Pre-market review and clearance by the FDA for Class I and II medical devices is accomplished through a pre-market notification procedure, unless the device is exempt. Devices deemed by the FDA to pose the greatest risk, such as life-supporting or implantable devices, are generally placed in Class III.

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.

A combination product is a product comprising of two or more regulated components (e.g., a drug and device) that are combined into a single product, co-packaged, or sold separately but intended for co-administration, as evidenced by the labeling for the products. Like their constituent products – e.g., drugs and devices – combination products are highly regulated and subject to a broad range of post marketing requirements including cGMPs, adverse event reporting, periodic reports, labeling and advertising and promotion requirements and restrictions, market withdrawal and recall.

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.

Regulation Outside of the U.S.

Currently, we maintain a commercial presence in the United States and Canada as well as certain other countries. In the European Union, medicinal products are authorized following a process that is 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. Each foreign country subjects medical devices to its own regulatory requirements. 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).

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.

Health regulatory authorities in other countries have similar rules and regulations although the specifics vary jurisdiction to jurisdiction.

Fraud, Abuse and Anti-Corruption Laws

The United States 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 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 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 United States. continue to be enacted and considered.

Data Privacy Laws

A number of states in the United States have passed or introduced bills, which, if passed, impose operational requirements on U.S. companies similar to the requirements reflected in the General Data Protection Regulation (GDPR) in the EU. For example, the California Consumer Privacy Act of 2018 (CCPA), which came into effect on January 1, 2020, requires covered companies that process personal information on California residents to make new disclosures to consumers about their data collection, use and sharing practices, allows consumers to opt out of certain data sharing with third parties and provides a new private right of action for data breaches. Additionally, the Federal Trade Commission and many state attorney generals are interpreting federal and state consumer protection laws to impose standards for the online collection, use, dissemination and security of data. The compliance and other burdens imposed by the EU's GDPR, CCPA and similar privacy laws and regulations may be substantial as they are subject to differing interpretations and implementation among jurisdictions. The restrictions imposed by such laws may require us to modify our data handling practices and impose additional compliance costs and burdens.

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 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 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.

HUMAN CAPITAL

We value the diversity of each of our employees and the contributions they make to helping us achieve our mission to protect and enhance life. We are committed to working together toward our long-term aspiration to protect and enhance one billion lives by 2030. One of the five core objectives of our current 2020-2024 strategic plan is to evolve the culture of our organization consistent with our strategic objectives and our values. We strive to create an environment that is professionally and personally rewarding by offering challenging work and projects for individual and team contribution, and opportunities for professional and personal development. Another core objective of our current strategic plan is to build scalable capabilities; this objective includes continuing to invest in growing and developing leadership, innovation and engagement at all levels of our workforce. As of December 31, 2020, we had approximately 2,200 employees.

Health, Wellness and Safety

Employee safety and well-being is of paramount importance to us and was of particular focus in 2020 in light of COVID-19. In response to the pandemic, we adjusted our operations to ensure that only operation-critical development and manufacturing employees worked on-site, and we transitioned all other employees to remote work, providing productivity and collaboration tools and resources for them

Ensuring the health and safety of our on-site employees demanded increased attention. We provided personal protective equipment to them and implemented new safety protocols. These included re-engineered workplace designs that facilitate physical distancing, temperature screening and access to COVID-19 testing. Frequency and methods of communication between management and employees was increased with regular all-hands virtual meetings to discuss what we were doing as a company to combat COVID-19 in conjunction with our USG and private sector partners, and what we were doing to protect our workers.

In addition, we enhanced and promoted programs to support our employees' physical and mental well-being. For example, in 2020 we provided supplemental paid time off to employees who were unable to work due to COVID-19 symptoms or diagnosis, or even to deal with family COVID issues. We arranged and paid for COVID-19 tests for people who work on-site. We also partnered with a leading provider of online mental health support and counseling to maintain and expand our employees' access to offered mental health resources.

Hiring and Talent Management

In 2020, we hired approximately 700 new employees. More than 250 of these new hires were hired to work with numerous company employees in new roles working on our public-private partnership with the USG and other innovators related to COVID-19. We have consistent talent processes and systems across the company including performance management, training and development and succession planning. We use the Gallup Q12 instrument to measure employee engagement progress on an annual basis.

Compensation and Benefits

Our programs support our pay-for-performance philosophy and enhance our total compensation package. Competitive bonuses and equity awards are granted subject to eligibility based on company and individual performance. We focus on results and behavior because we value how we do things as much as getting them done. We practice salary transparency whereby certain information is shared to enhance employees' transparency into the salaries they receive, which helps employees become more knowledgeable and confident their pay is fair and competitive. We recognize the need for ongoing skill enhancement and support continued learning through on-the-job assignments, training programs, tuition assistance, professional memberships and professional conference attendance. This past year, to thank employees for the extra-ordinary effort they gave during unprecedented times, leadership made a non-recurring special equity award with immediate vesting that was provided to all employees below the senior vice president level.

Diversity, Equity, and Inclusion Commitment

Diversity, equity and inclusion are integral parts of our culture. We are committed to attracting, developing, and retaining the best talent reflecting a diversity of ideas, backgrounds, and perspectives. Diversity drives innovation in the products and services we develop, in the way we solve problems, and in the way we serve the needs of an increasingly global and diverse customer and partner base. We recognize the value that diversity contributes to our global organization and the competitive advantage we can maintain by having a broad range of talents, perspectives, and ideas with a commitment to continuously improving our business. We ensure every employee is treated fairly and equitably. We are also a proud supporter of our military veterans. We value the diversity that each employee brings, and while we look for people who share our core values, we thrive on our differences. Employees come from different backgrounds and take on a wide variety of roles, but they are all working toward the same mission – to protect and enhance life.

Social, Environmental, and Community Responsibility

Our mission to protect and enhance life applies not only to the products and services that we deliver, but also to how we are cognizant of our social and environmental responsibilities as well as serve the

communities in which we live and work. Starting in 2012, we established a platform, that we call eGIVE (Give, Invest, Volunteer), that we have continued to expand since its inception. Through this platform, we have encouraged employees to make contributions to select charitable organizations and volunteer their time, which we have supported with paid time off to support socially responsible activities.

As our organization has grown, we have continually explored ways in which we can have impact at broader scale. To that end, in December 2020, we initiated a comprehensive enterprise-wide Environmental, Social and Governance (ESG) project to understand our current and desired ESG profile, engage internal and external stakeholders in the ESG conversation, identify priority ESG action items and issue our maiden sustainability report focused on our ESG initiatives by the end of 2021, consistent with our corporate strategy and our commitment to the communities in which we operate.

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

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The occurrence of any of the following risks or of unknown risks and uncertainties may adversely affect our business, operating results and financial condition.

RISK FACTOR SUMMARY

The COVID-19 coronavirus pandemic could have a material adverse impact on our business, results of operations and financial performance.

In addition, there are a number of government contracting risks that could impact our business, financial condition, operating results and cash flows, including:

- Failure to receive FDA licensure of AV7909 in a timely manner or at all.
- Reduced demand for and/or funding for procurement of AV7909 and/or BioThrax or ACAM2000 and discontinuation of funding of our other USG procurement and development contracts.
- Failure to comply with laws and regulations pertaining to government contracts and resources required for responding to related government inquiries.

There are a number of product development and commercialization risks that could impact our business, financial condition, operating results and cash flows, including:

- The COVID-19 product candidates we are working on may not be safe or effective and we may be unable to manufacture sufficient quantities to meet demand.
- Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain.
- We may fail to capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.

There are a number of regulatory and compliance risks that could impact our business, financial condition, operating results and cash flows, including:

- Conditions associated with approvals and ongoing regulation of products may limit how we manufacture and market them.
- Failure to comply with various health care laws could result in substantial penalties.
- Failure to comply with obligations under U.S. governmental pricing programs may require reimbursement for underpayments and the payment of substantial penalties, sanctions and fines.
- The authority to sell unapproved MCMs to certain government entities can be ambiguous and subject us to regulatory enforcement actions.

There are a number of manufacturing risks that could impact our business, financial condition, operating results and cash flows, including:

- Disruption at, damage to or destruction of our development and/or manufacturing facilities may impede our ability to manufacture our products, as well as deliver our CDMO services.
- Our operations, including our use of hazardous materials, chemicals, bacteria and viruses expose us to significant potential liabilities.

There are a number of risks related to reliance on third parties that could impact our business, financial condition, operating results and cash flows, including:

- The loss of sole-source suppliers or an increase in the price of inventory.
- If third parties do not perform as contractually required or as expected, we may not be able to obtain regulatory approval for or commercialize our product candidates.

There are a number of risks related to our strategic acquisitions and collaborations that could impact our business financial condition, operating results and cash flows, including:

- Our strategy of generating growth through acquisitions may be unsuccessful.
- Our failure to successfully integrate acquired businesses and/or assets into our operations and our ability to realize the benefits of such acquisitions.

There are a number of competitive and political risks that could impact our business, financial condition, operating results and cash flows, including:

- Development and commercialization of pharmaceutical products are subject to evolving private and public sector competition.
- NARCAN® Nasal Spray may be subject to potential branded and generic competition.
- Biologic Products may be affected by the approval and entry of follow-on biologics, or biosimilars in the United States and other jurisdictions.

There are a number of risks related to our intellectual property that could impact our business, financial condition, operating results and cash flows, including:

- Failure to protect our intellectual property rights from patent infringement challenges.
- Failure to comply with obligations under our licenses with third parties.
- Potential loss of proprietary information and know-how, which carries the risk of reducing the value of our technology and products.
- Early competition from generic drugs.

There are a number of financial risks that could impact our business, financial condition, operating results and cash flows, including:

- Our ability to maintain sufficient cash flow from our operations to pay our substantial debt, both now and in the future.
- Our ability to obtain additional funding and be able to raise capital when needed.

There are a number of unique business risks that could impact our business, financial condition, operating results and cash flows, including:

- The potential for cyber security incidents to harm our ability to operate our business effectively in light of our heightened risk profile.
- Inherent product liability exposure due to our unique business.

There are a number of risks associated with our common stock, including, but not limited to:

- Our business or our share price could be negatively affected as a result of the actions of shareholders.
- Due to his substantial ownership percentage, our Executive Chairman has the ability to exert significant influence over us with respect to the election of the members of our Board of Directors and to delay or prevent a change of control of us.
- The price of our common stock has been and remains subject to extreme volatility.

The risk factors below contain more detailed descriptions of the risks identified above, which may materially harm our business, financial condition or results of cash flows.

GLOBAL PANDEMIC RISK

The COVID-19 coronavirus pandemic could have a material adverse impact on our business, results of operations and financial performance.

Our business, operations and financial condition and results have been and may continue to be impacted by the COVID-19 pandemic to varying degrees. The pandemic has presented a number of risks and challenges for our business, including, among others, impacts due to travel limitations and government-mandated work-from-home or shelter-in-place orders; manufacturing disruptions and delays; supply chain interruptions, including challenges related to reliance on third-party suppliers; disruptions to pipeline development and clinical trials and decreased product demand for our travel health vaccines due to the significant reduction in international travel. Additional travel restrictions and other governmental measures may result in further disruptions or continued delays in delivery of supplies by our third-party contractors and suppliers.

We continue to implement a work from home policy, with our administrative employees working outside of our offices, and on-site staff restricted to only those required to execute certain manufacturing, laboratory and related support activities. Working remotely could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. In addition, as a result of state or local restrictions, our on-site staff conducting research and development may not be able to access our laboratories, and these core activities may be significantly limited or curtailed, possibly for extended periods of time.

We also face uncertainties related to our efforts and those of our collaborative partners to develop a potential treatment or vaccine for COVID-19, including uncertainties related to pre-clinical or clinical trials, the risk that such development programs may not be successful, commercially viable, or that EUA or regulatory approval will not be received from regulatory authorities.

In addition, the trading price of our common stock, and that of other biopharmaceutical companies, has been highly volatile due to the COVID-19 pandemic, especially as a result of investor concerns and uncertainty related to the impact of the pandemic on the economies of countries worldwide. These broad market and industry fluctuations, as well as general economic, political and market conditions, may negatively impact the market price of shares of our common stock.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic further negatively impacts our business, supply chain, disrupts key clinical trials, diverts government funding away from our primary procured products and product candidates due to changes in government priorities and potential delays in the delivery of products to our customers will depend on future developments, which are highly uncertain. The ultimate geographic spread of the disease, the duration of the pandemic, further travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease cannot be predicted with certainty.

GOVERNMENT CONTRACTING RISKS

We currently derive a substantial portion of our revenue from USG procurement of AV7909 and ACAM2000 and have historically derived a substantial portion of our revenue from USG procurement of BioThrax. If the USG's demand for and/or funding for procurement of AV7909 and/or 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. 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 such 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 our anthrax vaccines. If priorities for the SNS change generally or with respect to our anthrax vaccines, funding to procure future doses of AV7909 or BioThrax may be delayed, 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 additional 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 or 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 approximately $261 million) in July 2019 to procure 10 million doses of AV7909 and another option in July 2020 to procure additional doses (valued at approximately $258 million) for inclusion into the SNS in support of anthrax preparedness.

We also plan to submit a BLA to the FDA related to AV7909 this year. 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 procured 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 and, more recently, from reservation of CDMO capacity by BARDA via our public- private CDMO partnership. 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 AV7909 to be supplied under our development and procurement contract with BARDA are subject to the availability of funding, mostly from annual appropriations. These appropriations can be subject to political considerations, changes in priorities due to global pandemics, the results of elections 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. 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. 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.

A significant portion 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 GlaxoSmithKline LLC, completed in November 2019. As another example, our development and procurement contract for AV7909 expires this year. We intend to negotiate a follow-on procurement contract for raxibacumab and intend to negotiate follow-on procurement contracts for most of our PHT products upon the expiration of a related procurement contract, 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 or procured product candidates 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;
- the commitment of substantial time and attention of management and key employees to the preparation of bids and proposals;
- 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 through 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. For a detailed description of the most significant regulations that affect our government contracting business, see the prior discussion under ''Regulation—Government Contracting''.

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 DoD are generally fixed price contracts. We expect that additional future procurement contracts we successfully secure with the USG would likely 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;
- unilaterally reduce or modify contracts or subcontracts;
- 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 certain 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 development and procurement contracts 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 may not be able to limit third parties, including our competitors, from accessing certain of these technology or data rights, including intellectual property, in providing products and services to the USG.

PRODUCT DEVELOPMENT AND COMMERCIALIZATION RISKS

The COVID-19 product candidates we are working on may not be safe or effective and, even if they are, we may not be able to manufacture sufficient quantities to meet demand.

We are developing two product candidates for the possible prophylaxis or treatment of COVID-19 and we are also providing CDMO services for the development and/or manufacture of multiple vaccine product candidates for customers. There can be no assurance that any of these product candidates will be safe or effective. There can also be no assurance that any of these product candidates will be authorized for emergency use or approval by the FDA or any other health regulatory authority. Even if these product candidates are safe and/or effective and receive authorization or approval by a health regulatory authority, the manufacturing processes for our CDMO COVID-19 programs are under development and will be complex. As a result, there can be no assurance that we will be able to produce any significant quantity of these products in a timely basis or at all, or negotiate further commitments under our existing CDMO contracts to manufacture vaccines against COVID-19, which could

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

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;
- 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;
- 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 pre-clinical studies and clinical trials to establish proof of concept and demonstrate the safety and efficacy of our product candidates. Pre-clinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of such trials do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing.

Pre-clinical 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 for some of our CBRNE product candidates. 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. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our product candidates in humans.

Prior to FDA approval of the countermeasure product candidates, the Secretary of HHS can contract to purchase MCMs for the SNS under Project BioShield under certain circumstances. Under PAHPRA, the USG may also, at its discretion, purchase critical biodefense products for the SNS prior to FDA approval after the filing of a pre-EUA application with the FDA. If our product candidates are not procured or funded under regulatory authority, they generally will have to be fully 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, pre-clinical 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 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.

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 an NDA or 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.'' Under the Animal Rule, 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 under the Animal Rule, product development can take a considerable amount of time, and the FDA may decide that our data are insufficient to support approval and require additional pre-clinical, 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. 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 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 pre-clinical 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, mostly related to clinical trials.

Failure to successfully develop future product candidates 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 and may refuse to accept any application or may decide that our data are insufficient to support approval and require additional pre-clinical, clinical or other studies.

Unapproved and investigational stage 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 conditions 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 sell any products we develop for indications or uses for which they are not approved.

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.

Certain of our products are subject to post marketing requirements (PMRs), which we are required to conduct, and post marketing 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. Violations of the 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, manufacturing partners or manufacturing processes, or failure to comply with regulatory requirements, may result in various penalties and sanctions. See the prior discussion regarding ''Regulation—Potential Sanctions'' above for a detailed list of the various potential penalties and sanctions to which we may be subject.

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 foreign 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 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 substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. However, some provisions of the ACA have yet to be fully implemented and certain provisions have been subject to legal and political challenges, as well as efforts by the last Presidential administration to repeal or replace certain aspects of the ACA. More recently on January 28, 2021, however, President Biden issued an executive order to strengthen implementation of the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing penalties as of January 1, 2019 for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point- of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. Additionally, on December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Cuts & Jobs Act. That ruling is currently under review by the U.S. Supreme Court and a decision is expected this year. It is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 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. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 under the CARES Act.

Additionally, there has been recent heightened federal governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the last Presidential administration released a ''Blueprint'', or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers.

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.
- 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. 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 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 require certain manufacturers of drugs, biologics, medical devices and medical supplies for which payment is available under Medicare, Medicaid or the CMS to report 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 challenges 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 otherwise, 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 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 fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws, 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 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 of 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 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 on us.

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;
- Significant legal fees and payment of damages or penalties;
- Limitations on our ability to continue certain operations;
- Decreased product demand; 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 would 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, 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 would also 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, under 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. 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 is complex, 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 and purchased by certain federal agencies and 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 under 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. Under the VHCA, knowingly providing 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.

From time to time, we sell unapproved MCMs to government entities under certain circumstances. While this is permissible in some cases, the extent to which we may be able to lawfully offer to sell 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, 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 local enforcement authorities disagree with our conclusion that such activities are permissible, they may 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 or unauthorized products, such as a declaration issued under the PREP Act, may lead plaintiffs to assert that their claims are not barred under the PREP Act.

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 record-keeping 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 currently sell certain of our products outside the United States and intend to expand the countries in which we sell our products and have 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 in desired jurisdictions 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 under a withdrawal agreement. On December 24, 2020, the United Kingdom and European Union entered into a Trade and Cooperation Agreement to govern the United Kingdom's departure from the European Union, known as Brexit. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the effects of the U.K.'s departure from the E.U., 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. 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 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. We believe we are currently in compliance with such laws and regulations. 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 anthrax vaccines, ACAM2000 or our other products, as well as deliver our CDMO 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 and product candidates for delivery to satisfy the 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 slowdowns, particularly due to the impact of COVID-19;
- civil unrest and protests, including by animal rights activists;
- injunctions;
- damage to or destruction of one or more facilities; 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. We do not have any redundant manufacturing facilities for any of our marketed products. Accordingly, any damage to, or disruption or destruction of one or more of our 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 delays in the performance of our contractual obligations or delays in our clinical trials, any of which could be costly to us and materially harm our business, financial condition, operating results and cash flows.

Problems may arise during the production of our marketed products and product candidates, as well as those we produce for our CDMO customers, due to the complexity of the processes involved in their manufacturing and shipment. Significant delays in product manufacturing or development and our ability to ramp up production to meet the needs of our customers could cause delays in recognizing 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 biologics, 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, which has the potential to result in similar consequences. 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.

In addition, we may not be able to ramp up our manufacturing processes to meet the rapidly changing demand or specifications of our customers on the desired timeframe, if at all. For example, we have not previously had to ramp our organization for a commercial launch of any product at the current pace required to address treatments related to COVID-19 and doing so in a pandemic environment with an urgent, critical global need creates unique manufacturing challenges, challenges related to distribution channels, and the need to establish teams of people with the relevant skills. Our inability to ramp up manufacturing to meet the demand or specifications of our customers could also harm our business, financial condition, operating results and cash flows.

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 in this area can require significant costs and we could be subject to substantial fines and penalties in the event of noncompliance. In addition, the risk of contamination or injury from these materials cannot be completely eliminated. In such event, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials. From time to time, we have been involved in remediation activities and may be so involved in the future. Any related cost or liability might not be fully covered by insurance, could exceed our resources and could have a material adverse effect on our business, financial condition, operating results and cash flows. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS, U.S. Department of Agriculture and the DoD, as well as regulatory authorities in Canada.

RISKS RELATED TO RELIANCE ON THIRD PARTIES

The loss of any of our non-exclusive, sole-source or single source suppliers, a shortage of related supplies 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. We depend on certain single-source suppliers for key materials and services necessary to manufacture the majority of our products and certain 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 AV7909 and BioThrax and the specialty plasma in our hyperimmune specialty plasma products and certain ingredients for ACAM2000. We also rely on single- source suppliers for the materials necessary to produce NARCAN® Nasal Spray, such as the naloxone active pharmaceutical ingredient and other excipients, along with the vial, stopper and device.

Where a particular single-source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation of materials prior to use in our products, and the complex nature of manufacturing processes. In addition, we may lose a sole-source supplier due to, among other things, the impact of COVID-19 on such supplier, the acquisition of 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 product candidates, a reduction in quality or an increase in the price of those materials or components could adversely affect us. 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 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. 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;
- managing tax costs or inefficiencies associated with integrating operations; and
- risks associated with intellectual property rights related to an acquisition or collaboration.

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

Development and commercialization of pharmaceutical products, including for PHT preparedness, are routinely subject to evolving private and public sector competition.

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. The market for current products can be subject to development of safer, more effective, more convenient or less costly products. The market for current products can also depend on what resources can be devoted to marketing or selling products, or how companies are positioned to adapt more quickly to new technologies, respond to scientific advances or patient preferences and needs, initiate or withstand substantial price competition and/or procure 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. Factors to consider include competitors' financial, technical and marketing resources as well as potential leverage that their intellectual property estates may offer.

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.

Biological products and product candidates, otherwise referred to as our ''Biologic Products,'' can be affected by the approval and entry of ''biosimilars'' in the United States and other jurisdictions. Biologic Products in our current pipeline include AV7909, BioThrax, and ACAM2000. 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.

NARCAN® Nasal Spray may be subject to potential competition.

NARCAN® Nasal Spray is the first FDA-approved needle-free naloxone nasal spray for the emergency reversal of opioid overdoses. NARCAN® Nasal Spray faces branded competition from other injectable naloxone, auto-injectors and improvised nasal kits including Amphastar Pharmaceuticals, Inc.'s naloxone injection product and Kaléo's EVZIO™ (naloxone HCl injection) Auto-Injector. NARCAN®Nasal Spray may face additional branded competition in the future.

With respect to potential generic competition, ANDAs seeking regulatory approval to market a generic version of NARCAN®Nasal Spray were filed with the FDA by Teva (in 2016), and by Perrigo (in 2018). ANDA litigation involving Teva is pending with us (via our Adapt subsidiaries) having appealed the June 5, 2020 decision of the U.S. District Court for the District of New Jersey to the Court of Appeals for the Federal Circuit. An at-risk launch by Teva remains possible. Settlement with Perrigo regarding their ANDA filing was entered on February 12, 2020 providing for a license effective January 5, 2033, or earlier under certain circumstances, including those related to the outcome of the current Teva litigation or future ANDA filers.

Sales of generic versions of NARCAN® Nasal Spray at prices lower than our branded product have the potential to erode our sales and could impact our product revenue related to NARCAN® Nasal Spray. In addition, 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.

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.

INTELLECTUAL PROPERTY RISKS

Protection of our intellectual property rights is an important tool for sustaining our business and the failure to do so could impact our financial condition, operating results, and cash flows.

We actively seek to protect intellectual property rights related to our Company's assets, including patent rights, trademark rights, trade secrets and proprietary confidential information, through defense and enforcement of existing rights and pursuit of protection on new and arising innovations.

Obtaining, maintaining and defending our intellectual property rights in the United States and other countries remains a critical component of the development and commercialization of our Company's assets.

Some of the risks associated with procurement, maintenance and enforcement of intellectual property rights include changes in patent laws or administrative patent office rules, evolving criteria and eligibility of obtaining patent protection on particular subject matter, the validity and enforceability of our intellectual property rights, the potential scope of coverage of our intellectual property rights, and/or the availability or strength of legal remedies in a particular country to defend and enforce intellectual property rights.

Other risks include associated costs, such as costs of patent prosecution and maintenance, costs associated with post-grant challenges including, for example, *inter partes review* (IPR) proceedings in the United States and oppositions in Europe, as well as costs associated with litigating and enforcing patent and trademark rights.

Additional risks include limitations on our extent or ability to procure, maintain or defend intellectual property rights associated with in-licensed or acquired intellectual property, where, for example, third parties may have the first right to maintain or defend intellectual property rights in which we have an interest, or may pursue strategies that our divergent to the interest of our Company.

Third party challenges for patent infringement could impact our business, financial condition, operating results, and cash flows.

Challenges by third parties for alleged patent infringement could delay or affect the development and commercialization of our products. Such challenges, while ongoing, could be costly, requiring and utilizing company resources. Such challenges, if successful, may impact marketing or launch of products, or require ongoing license and/or royalty fees associated with potential settlement agreements. These may have the potential to materially harm our business, financial condition, operating results, and cash flows.

Intellectual property licenses with third parties carry risks of challenges, which may be costly and time consuming and could impact the commercialization of our products.

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. Such license agreements or collaboration arrangements can be subject to challenges if interests or expectations under such license agreements diverge. Such challenges may be costly, risk time and resources, and could delay or impact development, commercialization or launch of our products.

Potential loss of proprietary information and know- how generally carries the risk of reducing the value of our technology and products.

We also rely upon unpatented proprietary technology, processes, and know-how, particularly as to our proprietary manufacturing processes. 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 always be successful in protecting our trade secrets and confidential information.

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 FDCA, which may render it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process. Other of our products may be susceptible to challenges by entry of biosimilars through the route established under the Biologics Price Competition and Innovation Action of 2009.

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.

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 further 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 can have significant adverse consequences for our business, including:

- requiring us to dedicate a substantial portion of cash flows from operations to payment on our debt, which would reduce available funds for 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 such risk through our hedging instruments;
- subjecting us, as under our Senior Secured Credit Facilities and the indenture governing the 3.875% Senior Unsecured Notes due 2028 (Senior Unsecured Notes), to restrictive covenants that 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, including the maintenance of a specified consolidated net leverage ratio and debt service coverage ratio under our Senior Secured Credit Facilities, 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 restricts and any additional debt financing may restrict the operation of our business and limit the cash available for investment in our business operations.

The Senior Secured Credit Facilities include a $450 million Term Loan Facility and the ability to borrow up to $600 million under our Revolving Credit Facility, of which we had outstanding borrowings of approximately $421.9 million and no outstanding balance, respectively, as of December 31, 2020. On August 7, 2020, we completed an offering of $450 million aggregate principal amount of Senior Unsecured Notes, of which $353 million of the net proceeds were used to pay down our Revolving Credit Facility. We may also seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing can have significant adverse consequences for our business, including:

- the level, timing and cost of product sales and CDMO 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 common stock under any future share repurchase program; and
- the costs of commercialization activities, including product marketing, sales and distribution.

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, such as the current economic recession, 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 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. Debt financing, if available, may involve agreements that include covenants, like those contained in our Senior Secured Credit Facilities and the indenture governing the Senior Unsecured Notes, 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 as well as the indenture governing the Senior Unsecured Notes restrict our ability to incur additional 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 on an annual basis since becoming a public company, 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 receivable 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 materially impact our operating results.

A substantial portion of our indebtedness bears interest at variable interest rates based on LIBOR and certain of our financial contracts are also indexed to LIBOR. Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness and may otherwise adversely affect our financial condition and results of operations.

In July 2017, the Financial Conduct Authority, the authority that regulates the London Inter-bank Offered Rate (LIBOR) announced that it intended to stop compelling banks to submit rates for the calculation of LIBOR after 2021. We have certain financial contracts, including the amended credit agreement related to our Senior Secured Credit Facilities and our interest rate swaps, that are indexed to LIBOR. Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness. Any transition process may

involve, among other things, increased volatility or illiquidity in markets for instruments that rely on LIBOR, reductions in the value of certain instruments or the effectiveness of related transactions such as hedges, increased borrowing costs, uncertainty under applicable documentation, or difficult and costly consent processes. The transition away from LIBOR may result in increased expenses, may impair our ability to refinance our indebtedness or hedge our exposure to floating rate instruments, or may result in difficulties, complications or delays in connection with future financing efforts, any of which could adversely affect our financial condition and results of operations.

UNIQUE BUSINESS RISKS

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. We also have contracted with the USG and pharmaceutical companies, such as Johnson & Johnson and AstraZeneca, for the development and manufacture of a significant quantity of COVID-19 vaccines, and separately we are working on proprietary COVID-19 therapeutics with support from the USG and other private sector entities, which has raised our security profile, and heightened potential risks that malicious actors may seek to disrupt our systems or misappropriate our information. 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. Our systems are also potentially vulnerable to data security breaches through employee error, phishing scams and malfeasance, which may expose sensitive data to unauthorized persons. No system of protection is adequate to protect against all such threats, even if they are deemed to be industry standard, and there can be no assurance that we will be able to repel any such attacks. Data security breaches could lead to the loss of trade secrets or other intellectual property or the public exposure of personal information, including sensitive personal information, of our employees, clinical trial patients, customers and others. Responding to any such threats may also be expensive and time-consuming.

A significant business disruption or a breach in security resulting in misappropriation, theft or sabotage with respect to proprietary and confidential business and employee information could result in significant financial losses, legal, business or reputational harm to us, compromise our business prospects and our commitments to the USG or other customers, any of which could materially and adversely affect our business, financial condition and operating results.

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 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.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

Our business or our share price could be negatively affected as a result of the actions of shareholders.

In recent years, some shareholders have placed increasing pressure on publicly traded companies in our industry and others to effect changes to corporate governance practices, executive compensation practices, social and environmental practices and to undertake certain corporate actions. This may be true even if they only hold a minority of shares. In addition, some institutional investors are increasingly focused on ESG factors. These investors may be seeking enhanced ESG disclosures or implement policies adverse to our business. There can be no assurances that shareholders will not publicly advocate for us to make corporate governance changes or engage in certain corporate actions. Responding to challenges from shareholders, such as proxy contests, media campaigns or other public or private means, could be costly and time consuming and could have an adverse effect on our reputation and divert the attention and resources of management and our board, which could have an adverse effect on our business and operational results. Any such shareholder actions or requests, or the mere public presence of shareholders with a reputation for taking such actions among our shareholder base, could also cause the market price of our common stock to experience periods of significant volatility.

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 December 31, 2020, Mr. El-Hibri was the beneficial owner of approximately 9% of our outstanding common stock. As a result, Mr. El-Hibri could exercise substantial influence over 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 12, 2021, our common stock has traded as high as $137.61 per share and as low as $4.17 per share. Due to fears associated with COVID-19, the stock market has recently experienced extreme volatility and the market for biopharmaceutical companies has generally 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 our anthrax vaccines and our other products and product candidates;
- CDMO contracts related to COVID-19 with collaboration partners;
- 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 and the indenture governing our Senior Unsecured Notes 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 based on current expectations.

Future issuances of our common stock or securities convertible into common stock could result in dilution of our stockholders and could cause our share price to decline.

We expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations or for general corporate purposes. To the extent we raise additional capital by issuing equity securities or securities convertible or exchangeable into common stock, our stockholders may experience substantial dilution. We may sell common stock, and we may sell convertible or exchangeable securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell such common stock, convertible or exchangeable securities or other equity securities in subsequent transactions, existing stockholders may be materially diluted.

GENERAL RISKS

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.

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 (including quality and manufacturing 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We own and lease approximately 1.6 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 25 locations in North America and Europe. Properties that have been leased expire on various dates between 2021 to 2034. Principal locations include:

Location	Use	Approximate square feet	Owned/ leased
Lansing, Michigan	Manufacturing operations, office and laboratory space.	336,000	Owned
Winnipeg, Manitoba, Canada	Manufacturing operations, office and laboratory space.	315,000 (Owned); 6,000 (Leased)	Owned/ Leased
Gaithersburg, Maryland	Laboratory space, office space and rental real estate.	173,000	Owned
Canton, Massachusetts	Manufacturing operations and warehouse space.	122,508 (Owned); 27,000 (Leased)	Owned/ Leased
Baltimore, Maryland (Bayview)	Manufacturing facilities, office and laboratory space.	112,000	Owned
Elkridge, Maryland	Warehouse space.	103,182	Leased
Baltimore, Maryland (Camden)	Manufacturing facilities, office and laboratory space.	86,900 (Owned); 41,000 (Leased)	Owned/ Leased
San Diego, California	Manufacturing facilities and office space.	87,000	Leased
Bern, Switzerland	Manufacturing operations, office and laboratory space.	81,000	Owned
Rockville, Maryland	Manufacturing facilities, office and warehouse space.	59,000	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

See ''Item 8 of Part II, ''Financial Statements and Supplemental Data – Notes to consolidated financial statements – Note 19 – Litigation.''

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 12, 2021, the closing price per share of our common stock on the New York Stock Exchange was $125.19 and we had 19 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Purchases of Equity Securities

Not applicable.

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.

The remaining information required by Item 5 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2021 Annual Meeting of the Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

	Year Ended December 31,				
(in millions, except per share data)	2020	2019	2018	2017	2016
Statements of operations data:					
Revenues:					
Product sales	$ 989.8	$ 903.5	$ 606.5	$ 421.5	$ 296.3
Contract development and manufacturing services	450.5	80.0	98.9	68.9	49.1
Contracts and grants	115.1	122.5	77.0	70.5	143.4
Total revenues	1,555.4	1,106.0	782.4	560.9	488.8
Total operating expenses	1,121.6	991.9	692.6	436.6	383.3
Income from operations	433.8	114.1	89.8	124.3	105.5
Net income from continuing operations	305.1	54.5	62.7	82.6	62.5
Net loss from discontinued operations	—	—	—	—	(10.7)
Net income	$ 305.1	$ 54.5	$ 62.7	$ 82.6	$ 51.8
Net income per share-basic	$ 5.79	$ 1.06	$ 1.25	$ 1.98	$ 1.29
Net income per share-diluted	$ 5.67	$ 1.04	$ 1.22	$ 1.71	$ 1.13
Weighted average number of shares – basic	52.7	51.5	50.1	41.8	40.2
Weighted average number of shares – diluted	53.8	52.4	51.4	50.3	49.3

	As of December 31,				
(in millions)	2020	2019	2018	2017	2016
Balance Sheet Data:					
Cash and cash equivalents	$ 621.3	$ 167.8	$ 112.2	$ 178.3	$271.5
Working capital	811.4	469.9	420.4	385.3	404.4
Total assets	2,883.2	2,327.3	2,229.4	1,070.2	970.1
Total long-term liabilities	1,051.7	1,022.5	1,018.1	57.8	268.1
Total stockholders' equity	1,447.0	1,088.5	1,010.9	912.2	596.2

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 five 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 procured product candidates that are procured under special circumstances by certain government agencies, although they are not approved by the FDA or any other health agency. 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 CDMO services. Our CDMO service offerings cover development services, drug substance manufacturing and drug product manufacturing across pharmaceutical and biotechnology industries as well as the USG and non-governmental organizations. The majority of our revenue comes from the following products and procured product candidates:

Vaccines

- Anthrax vaccines, including our AV7909 (Anthrax Vaccine adsorbed with Adjuvant) procured 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 single-dose oral vaccine approved by the FDA and EMA 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 procured 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

Our CDMO business unit consists of a fully integrated molecule-to-market CDMO services business, with offerings across development services, drug substance and drug product manufacturing and packaging and fill, finish services. Our customers for such services include pharmaceutical and biotechnology organizations as well as governments and non-governmental organizations ranging from small to mid to large pharmaceutical and biotechnology companies whose programs range from clinical stage to commercial stage. 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 2020

- On January 13, 2020, received agreement from the EMA and FDA on the Company's proposed development plan to use Serum Neutralizing Antibodies (SNA) as surrogate endpoint to predict likely clinical benefit of CHIKV VLP, the Company's chikungunya virus virus-like particle (VLP) vaccine candidate, in a Phase 3 safety and immunogenicity study anticipated in the second quarter of 2021.
- On January 31, 2020, received positive opinion and subsequent approval from EMA of Vaxchora® (Cholera Vaccine, Live, Oral), the Company's cholera vaccine, making it the only single-dose oral vaccine indicated for active immunization against disease caused by *Vibrio cholerae* serogroup 01 in adults and children from 6 years of age across all 27 member states of the European Union and the European Economic Area countries.
- On March 10, 2020, signed a development and manufacturing agreement with Novavax, Inc. for an experimental vaccine candidate for COVID-19.
- On March 11, 2020, initiated development of two investigational plasma-derived therapies. COVID-Human Immune Globulin (COVID-HIG) is being developed as a human plasma-derived therapy candidate for potential treatment of COVID-19 in severe hospitalized and high-risk patients, and COVID-Equine Immune Globulin (COVID-EIG) is being developed as an equine plasma-derived therapy candidate for potential treatment of severe disease in humans.
- On March 18, 2020, signed a development and manufacturing agreement with Vaxart, Inc. to produce its experimental oral vaccine candidate for COVID-19.
- On March 31, 2020, signed an agreement with Novavax, Inc. to manufacture NanoFlu™, its seasonal influenza vaccine candidate.
- On April 2, 2020, announced HHS funding valued at $14.5 million to support the development of COVID-HIG for treatment, which will be included in at least one of the studies of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, evaluating potential treatments for COVID-19.
- On April 23, 2020, announced an initial agreement, valued at $135 million, to be the U.S. manufacturing partner of Johnson & Johnson's lead COVID-19 vaccine candidate.
- On May 28, 2020, announced the exercise by the HHS of the first of nine annual contract options, valued at $176 million, to procure doses of ACAM2000® (Smallpox (Vaccine, Live) into the U.S. Strategic National Stockpile (SNS).
- On June 1, 2020, announced an agreement to join the USG's Warp Speed Program in public-private CDMO partnership for COVID-19 vaccine development and manufacturing. The agreement has a contract value of $628 million and includes manufacturing capacity valued at $542.7 million and $85.5 million for expansion of viral and non-viral CDMO drug product fill/finish capacity.
- On June 11, 2020, announced an agreement to be the U.S. manufacturing partner for AstraZeneca's COVID-19 vaccine candidate to provide large-scale manufacturing capacity through 2020. The agreement has a contract value of $87 million.
- On June 18, 2020, announced a $75 million planned expansion of a property adjacent to our Canton, Massachusetts live viral drug substance development and manufacturing facility. The expansion will increase advanced therapy (viral vector and gene therapy) capability, which is expected to be available beginning in 2023.
- On July 2, 2020, further announced signing a large scale drug substance manufacturing agreement for Johnson & Johnson's lead COVID-19 vaccine candidate for up to five years beginning in 2021. The first two years are valued at approximately $480 million, with the remaining three years providing flexible capacity.
- On July 6, 2020, announced the award of approximately $34.6 million by the U.S. Department of Defense Joint Program Executive Office and formed collaboration with Mount Sinai Health System and ImmunoTek Bio Centers to advance COVID-HIG for potential post-exposure prophylaxis in populations at high risk of COVID-19.

- On July 14, 2020, announced the exercise by BARDA of the contract option, valued at $258 million, to procure additional doses of AV7909 (anthrax vaccine adsorbed with adjuvant) for delivery into the SNS over 12 months.
- On July 27, 2020, further announced the signing of a large-scale drug substance manufacturing agreement for AstraZeneca's COVID-19 vaccine candidate, valued at approximately $174 million through 2021.
- On August 7, 2020, announced the completion of an offering of $450 million in aggregate principal amount 3.875% Senior Unsecured Notes due in 2028. The Company utilized the proceeds from the offering to repay $353 million outstanding under its revolving credit facility with the remainder to be utilized for general corporate purposes.
- On October 8, 2020, announced the initiation of a Phase 3 clinical trial to evaluate the safety, tolerability, and efficacy of hyperimmune globulin products, including our COVID-19 Human Immune Globulin, as a potential treatment in adult patients hospitalized with COVID-19.
- On December 29, 2020, announced the initiation of the clinical program to evaluate the Company's COVID-HIG product candidate in the first of two Phase 1 studies to support its use for potential post-exposure prophylaxis in individuals at high risk of exposure to SARS-CoV-2.

Financial Operations Overview

Revenues

We generate product revenues from the sale of our marketed products and procured product candidates which include vaccines, therapeutics and devices which have been described above. 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 our CDMO business unit, which is based on our established development and manufacturing infrastructure, technology platforms and expertise. Our services include a fully integrated molecule-to-market CDMO services business offering across development services, drug substance and drug product for small to mid to large pharmaceutical and biotechnology industry and government agencies/non-governmental organizations.

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 vary quarterly based on the timing of production and deliveries and the nature of our business to provide large scale bundles of products and services as needs arise. During 2020, our revenues have increased due largely to the contribution of CDMO arrangements with industry and government customers to combat the COVID-19 pandemic. This increase in CDMO revenues has been offset by reduced sales of our vaccine products that target travelers which have declined due to the reduction of international travel caused by the COVID-19 pandemic. We expect continued variability in our quarterly financial statements.

Cost of Product Sales and CDMO 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 CDMO service contracts. We operate nine manufacturing facilities, five of which perform manufacturing activities for CDMO services customers. As a result, management reviews expenses associated with manufacturing our own products as well CDMO service contracts on an aggregate basis when analyzing the financial performance of its manufacturing and development facilities. Our manufacturing process for our own products and our CDMO service 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 CDMO 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 and development of 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 CDMO services 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, 2020, income tax expense totaled $102.1 million. For every 1% change in the 2020 effective rate, income tax expense would have changed by approximately $4.1 million.

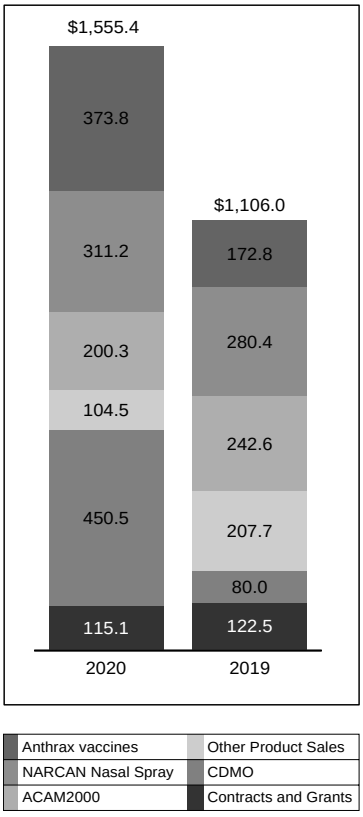
For additional information on our uncertain tax positions and income tax expense, please see note 12, *Income taxes* to our consolidated financial statements included in this report.

Results of Operations

(in millions)	Year ended December 31, 2020	2019	$ Change	% Change
Product sales net:				
Anthrax vaccines	$ 373.8	$ 172.8	$ 201.0	NM
NARCAN Nasal Spray	311.2	280.4	30.8	11%
ACAM2000	200.3	242.6	(42.3)	(17)%
Other	104.5	207.7	(103.2)	(50)%
Total product sales, net	989.8	903.5	86.3	10%
Contract development and manufacturing services	450.5	80.0	370.5	NM
Contracts and grants	115.1	122.5	(7.4)	(6)%
Total revenues	1,555.4	1,106.0	449.4	41%
Operating expenses:				
Cost of product sales and contract development and manufacturing services	524.0	433.5	90.5	21%
Research and development	234.5	226.2	8.3	4%
Selling, general and administrative	303.3	273.5	29.8	11%
Amortization of intangible assets	59.8	58.7	1.1	2%
Total operating expenses	1,121.6	991.9	129.7	13%
Income from operations	433.8	114.1	319.7	NM
Other income (expense):				
Interest expense	(31.3)	(38.4)	7.1	(18)%
Other income (expense), net	4.7	1.7	3.0	NM
Total other expense, net	(26.6)	(36.7)	10.1	(28)%
Income before income taxes	407.2	77.4	329.8	NM
Income taxes	102.1	22.9	79.2	NM
Net income	$ 305.1	$ 54.5	$ 250.6	NM

NM – Not meaningful

Total Revenues



Product Sales, net

Anthrax Vaccines

The increase in anthrax vaccine sales for the year ended December 31, 2020 was primarily due to the transition of SNS deliveries from BioThrax to a more consistent cadence of deliveries of AV7909. There were lower sales of anthrax vaccines during the year ended December 31, 2019 as the USG transitioned from BioThrax to AV7909. Deliveries of AV7909 began in September of 2019.

NARCAN Nasal Spray

The increase in NARCAN Nasal Spray sales for the year ended December 31, 2020 was primarily due to an increase in sales to the public interest markets in the United States and Canada and to a lesser extent an increase in commercial sales.

ACAM2000

The decrease in ACAM2000 sales for the year ended December 31, 2020 was due to timing of deliveries to the SNS partially offset by standard inflationary rate increases. ACAM2000 product sales are made under a long-term procurement contract. The fluctuations in ACAM2000 revenue are dictated by the timing and delivery of orders to the USG.

Other Product Sales

The decrease in the Company's other product sales during the year ended December 31, 2020, was mostly due to a decline in sales of raxibacumab, and Vaxchora and Vivotif due to the reduction of global travel.

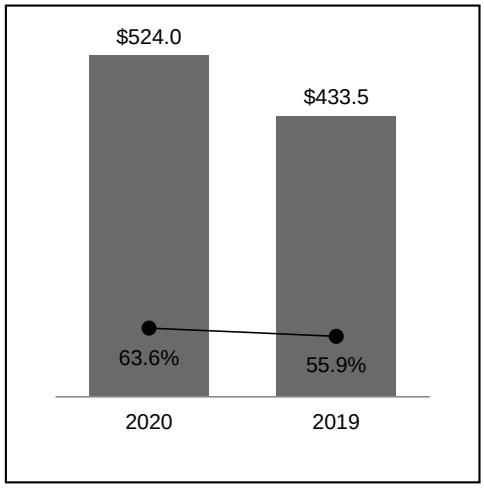
Contract Development and Manufacturing Services

The increase in CDMO services revenue for the year ended December 31, 2020 is due to the Company's public-private partnership with BARDA in support of the USG's efforts to address the COVID-19 pandemic and arrangements with AstraZeneca and Johnson & Johnson.

Contracts and Grants

The decrease in contracts and grants revenue for the year ended December 31, 2020 is due to the completion of developmental activities associated with our AV7909 procured product candidate partially offset by increases in development awards related to the Company's COVID related product candidates and other product candidates.

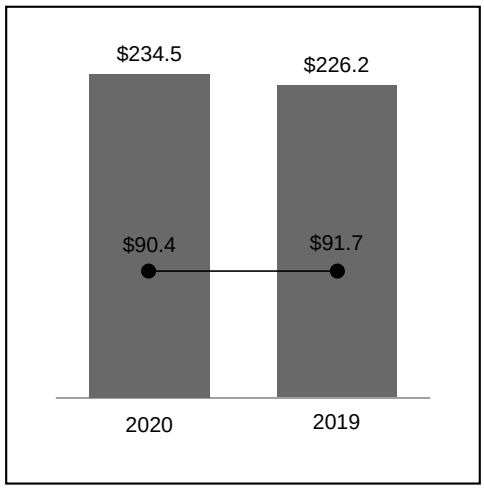
Cost of Product Sales and CDMO Services



Cost of Product Sales and CDMO Services
Gross profit margin for product sales and CDMO services

Cost of product sales and CDMO services increased for the year ended December 31, 2020 due to an increase in product sales and CDMO services. Additionally, the increase in the cost of product sales and CDMO services was impacted due to a write-down of travel health vaccine inventory and contingent consideration charges.

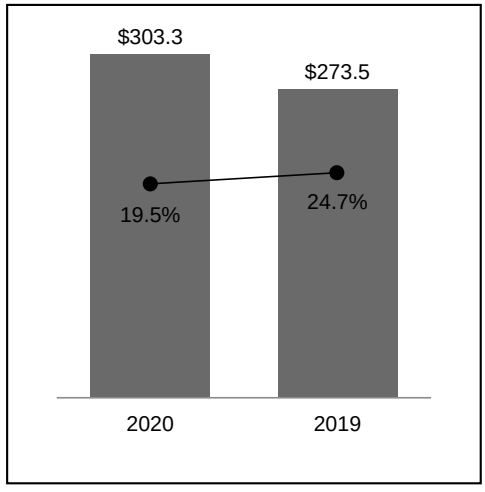
Research and Development Expenses (Gross and Net)



Research and Development expense
Research and Development expense, net of contracts and grants revenue and IPR&D impairment expense

The increase in research and development expenses during the year ended December 31, 2020 is due to the impairment of our IPR&D intangible asset of $29 million. Excluding the impacts of the IPR&D impairment charge research and development expenses decreased for the year ended December 31, 2020. The decrease was due to a decline in spending associated with the Company's AV7909 product candidate offset by increased spending related to the Company's COVID-HIG and other product candidates.

Selling, General and Administrative Expenses

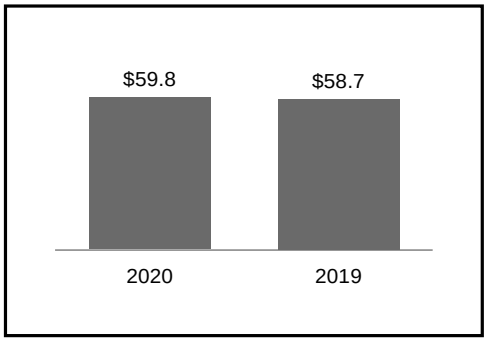


Selling, General and Administrative
SG&A as a percentage of total revenue

Selling, general and administrative expenses increased for the year ended December 31, 2020 primarily due to an increase in staffing costs to support the Company's growth as well as a special

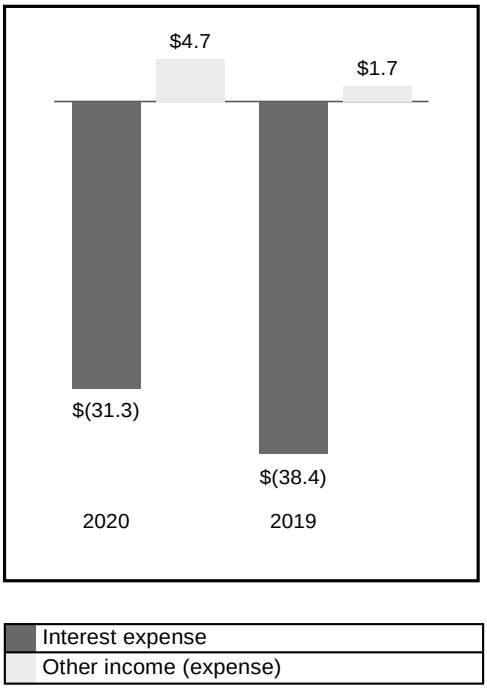
broad-based, immediately vested equity award granted to employees below the senior vice president level offset by a decrease in travel expenses.

Amortization of intangible Assets



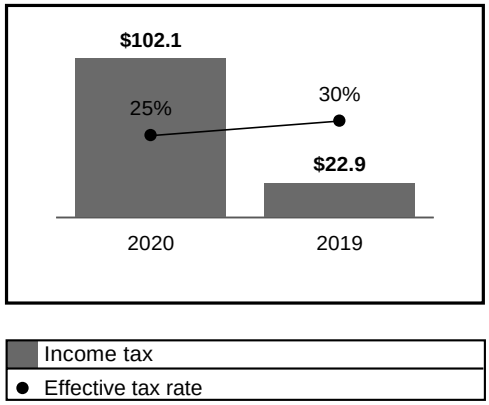
Amortization of intangible assets for the year ended December 31, 2020 was consistent with the year ended December 31, 2019.

Total Other Income (Expense), Net



Total other expense, net decreased primarily due to a decrease in interest expense. The decrease in interest expense was driven by a decline in the average interest rates during the year ended December 31, 2020 as compared to 2019 partially offset by an increase in average outstanding debt during the year ended December 31, 2020 as compared to 2019.

Income Taxes



During the year ended December 31, 2020, income taxes increased largely due to an increase in income before income taxes. The effective tax rate was 25% for the year ended December 31, 2020 as compared to 30% in 2019. The effective tax rate decreased largely due to a decrease in the rate impact of non-deductible expenses as a percent of income before income taxes. Excluding these non- deductible expenses, the effective tax rate was approximately 23% in both 2020 and 2019.

Discussion and analysis of the year ended December 31, 2019 compared to the year ended December 31, 2018 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, 2019, as filed with the SEC on February 25, 2020.

Liquidity and Capital Resources

Sources of Liquidity

The Company has 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 annual periods. As of December 31, 2020, we had cash and cash equivalents of $621.3 million and capacity under our revolving credit facility of $597.2 million. As of December 31, 2020, 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, 2020, 2019 and 2018.

(in millions)	Year ended December 31, 2020	2019	2018
Net cash provided by (used in):			
Operating activities	$536.0	$188.0	$ 41.8
Investing activities	(151.0)	(96.9)	(897.2)
Financing activities	69.5	(35.9)	788.7
Effect of exchange rate changes	$ (1.0)	$ 0.4	$ (0.2)
Net increase (decrease) in cash and cash equivalents	$453.5	$ 55.6	$ (66.9)

Certain significant cash flows were as follows:

Operating Activities:

Net cash provided by operating activities of $536.0 million in 2020 was due to net income excluding non-cash items of $527.2 million and working capital changes of $8.8 million.

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 negative 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.

Investing Activities:

Net cash used in investing activities of $151.0 million in 2020 largely relates to purchases of property, plant and equipment. We also made a milestone payment related to an asset acquisition of $10.0 million from our acquisition of raxibacumab in October 2017. The cash used in investing activities increased during the year ended December 31, 2020 largely due to infrastructure and equipment investments related to our CDMO arrangements and the purchase of a building near our Canton, Massachusetts facility.

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.

Financing Activities:

Net cash provided by financing activities of $69.5 million in 2020 was primarily due to proceeds from the $450.0 million Senior Unsecured Notes and net employee share-based compensation activity of $17.8 million offset by payments of $387.1 million on the term loan and revolving credit facility and $8.4 million of debt issuance costs.

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.

Long-term debt

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 CDMO 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 CDMO 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 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 Unsecured Notes due 2028 and the 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.

Economic conditions, including market volatility and adverse impacts on financial markets as a result of the COVID-19 pandemic, may make it more 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.

Amended and Restated Credit Agreement

See further discussion around the amended and restated credit agreement in Item 8. Financial Statements and Supplementary Data Note 9 Long-term debt.

Unused Credit Capacity

Available room under the revolving credit facility for the years ended December 31, 2020 and 2019 was:

(in millions)			
December 31, 2020			
Total Capacity	Outstanding Letters of Credit	Outstanding Indebtedness	Unused Capacity
$600.0	2.8	—	$597.2
December 31, 2019			
$600.0	2.2	373.0	$224.8

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2020:

	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	$ 885.5	$ 35.9	$397.6	$2.0	$450.0
Lease obligations	39.1	6.7	16.6	7.4	8.4
Purchase commitments	84.7	69.1	15.6	—	—
Total contractual obligations	$1,009.3	$111.7	$429.8	$9.4	$458.4

Critical Accounting Policies and Estimates

Our consolidated financial statements and related disclosures are prepared in accordance with US GAAP, which requires management to make estimates, judgments and assumptions that affect the amounts reported. Note 2, ''Summary of Significant Accounting Policies'' of the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K describes the accounting policies and methods used in the preparation of the Company's consolidated financial statements. 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. Management bases its estimates on historical experience and on various other assumptions it believes 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.

Management believes the Company's critical accounting policies and estimates are those related to revenue recognition, contingent consideration, and income taxes.

Revenue Recognition

The Company recognizes revenue when or as the customer obtains control of the promised product or services, in an amount that reflects the consideration in which the Company expects to receive in exchange for the product or services. The Company's products are typically recognized when the customer obtains control of the product, which occurs at a point-in-time, typically upon delivery to the customer. The Company's services are recognized either over-time as the service is being performed or at a point-in-time generally upon delivery to the customer, depending on the performance obligation which the Company is delivering.

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 based on the best available information.

Revenues are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with customers. The Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Estimates of variable consideration includes allowances for returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, chargebacks and rebates under managed care plans. 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. Provisions for variable consideration revenues from sales of products are recorded at the net sales price. For additional information on our revenues, please read Note 2, Revenue Recognition, of Item 8. Financial Statements and Supplementary Data.

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, as applicable. 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. A one-percent change in the discount rate would result in an approximate $0.5 million change in the fair value of the Company's contingent consideration as of December 31, 2020.

Income Taxes

The Company recognizes deferred tax assets and liabilities 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. Valuation allowances are recorded as appropriate to reduce deferred tax assets to the amount considered likely to be realized.

The Company's income tax expense, deferred tax assets and liabilities and liabilities for unrecognized tax benefits reflect management's best assessment of estimated current and future taxes to be paid. As tax laws are complex and subject to different interpretations, significant management judgement is required 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 from tax benefits ultimately realized.

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 2020 Annual Report.

Market Risks

We have interest rate and foreign currency market risk. 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.

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 rate, 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 2020 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, 2020 would increase our interest expense by approximately $0.7 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 either entering into foreign currency hedging transactions or incurring operating expenses in the local currency in the countries in which we operate, to the extent practicable. We currently do not hedge all of 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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. and subsidiaries (the Company) as of December 31, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 18, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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 determining the stand alone selling price of each performance obligation and the transaction price including variable consideration

Description of the Matter

As described in Note 3 to the consolidated financial statements, the Company recognized revenues of $1,555.4 million for the year ended December 31, 2020. 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, the determination of standalone selling prices underlying each performance obligation, and the determination of the 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. 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 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 estimate the standalone selling price using various estimation approaches that maximizes observable inputs. 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, the determination of standalone selling prices underlying each performance obligation, 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, the evaluation of management's determination of standalone selling prices, and the estimation uncertainty in management's determination of the variable consideration and the related constraint (or lack thereof). For example, the determination of standalone selling price for certain of the Company's arrangements involves significant judgement as the performance obligation may not have directly observable inputs. In addition, 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, determination of standalone selling price underlying each performance obligation, and estimation of variable consideration. For example, we tested controls over management's review of the identification of performance obligations and determination of standalone selling price underlying each performance obligation, 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 the determination of standalone selling price underlying each performance obligation as well as 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 identification of performance obligations and the determination of standalone selling price underlying each performance obligation we reviewed observable data which was available and considered the factors used by management in estimating the standalone selling price. 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 third party industry data where available.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2004.
Baltimore, Maryland
February 18, 2021

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

	December 31,	
	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 621.3	$ 167.8
Restricted cash	0.2	0.2
Accounts receivable, net	230.9	270.7
Inventories	307.0	222.5
Prepaid expenses and other current assets	36.5	25.0
Total current assets	1,195.9	686.2
Property, plant and equipment, net	644.1	542.3
Intangible assets, net	663.1	712.9
In-process research and development	—	29.0
Goodwill	266.7	266.6
Other assets	113.4	90.3
Total assets	$2,883.2	2,327.3
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 136.1	$ 94.8
Accrued expenses	46.9	39.5
Accrued compensation	84.6	62.4
Debt, current portion	33.8	12.9
Other current liabilities	83.1	6.7
Total current liabilities	384.5	216.3
Contingent consideration, net of current portion	34.2	26.0
Debt, net of current portion	841.0	798.4
Deferred tax liability	53.2	63.9
Contract liabilities, net of current portion	55.5	85.6
Other liabilities	67.8	48.6
Total liabilities	1,436.2	1,238.8
Stockholders' equity:		
Preferred stock, $0.001 par value; 15.0 shares authorized, no shares issued and outstanding	—	—
Common stock, $0.001 par value; 200.0 shares authorized, 54.3 and 53.0 shares issued; 53.1 and 51.7 shares outstanding, respectively.	0.1	0.1
Treasury stock, at cost, 1.2 common shares	(39.6)	(39.6)
Additional paid-in capital	784.9	716.1
Accumulated other comprehensive loss, net	(25.3)	(9.9)
Retained earnings	726.9	421.8
Total stockholders' equity	1,447.0	1,088.5
Total liabilities and stockholders' equity	$2,883.2	$2,327.3

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,		
	2020	2019	2018
Revenues:			
Product sales, net	$ 989.8	$ 903.5	$606.5
Contract development and manufacturing services	450.5	80.0	98.9
Contracts and grants	115.1	122.5	77.0
Total revenues	1,555.4	1,106.0	782.4
Operating expenses:			
Cost of product sales and contract development and manufacturing services	524.0	433.5	322.3
Research and development	234.5	226.2	142.8
Selling, general and administrative	303.3	273.5	202.5
Amortization of intangible assets	59.8	58.7	25.0
Total operating expenses	1,121.6	991.9	692.6
Income from operations	433.8	114.1	89.8
Other income (expense):			
Interest expense	(31.3)	(38.4)	(9.9)
Other, net	4.7	1.7	1.6
Total other income (expense), net	(26.6)	(36.7)	(8.3)
Income before income taxes	407.2	77.4	81.5
Income taxes	102.1	22.9	18.8
Net income	$ 305.1	$ 54.5	$ 62.7
Net income per share-basic	$ 5.79	$ 1.06	$ 1.25
Net income per share-diluted (Note 15)	$ 5.67	$ 1.04	$ 1.22
Weighted-average number of shares - basic	52.7	51.5	50.1
Weighted-average number of shares - diluted	53.8	52.4	51.4

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

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

	Year Ended December 31,		
	2020	2019	2018
Net income	$305.1	$54.5	$62.7
Other comprehensive income (loss), net of tax:			
Foreign currency translation	(1.7)	0.4	(1.6)
Unrealized gains (losses) on hedging activities	(9.4)	(1.6)	—
Unrealized losses on pension benefit obligation	(4.3)	(3.2)	(0.2)
Total other comprehensive income (loss), net of tax	(15.4)	(4.4)	(1.8)
Comprehensive income	$289.7	$50.1	$60.9

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,		
	2020	2019	2018
Cash flows from operating activities:			
Net income	$ 305.1	$ 54.5	$ 62.7
Adjustments to reconcile to net cash provided by operating activities:			
Stock-based compensation expense	51.0	26.7	23.2
Depreciation and amortization	114.5	110.7	62.2
Impairment of IPR&D intangible asset	29.0	12.0	—
Change in fair value of contingent consideration, net	31.7	24.8	3.1
Amortization of deferred financing costs	3.5	3.0	0.9
Deferred income taxes	(2.4)	(1.1)	8.6
Other	(5.2)	(0.2)	0.2
Changes in operating assets and liabilities:			
Accounts receivable	49.0	(8.2)	(94.2)
Inventories	(83.2)	(16.7)	(1.9)
Prepaid expenses and other assets	(29.2)	(39.1)	(13.0)
Accounts payable	19.8	16.5	(7.0)
Accrued expenses and other liabilities	19.4	(15.1)	(11.6)
Accrued compensation	21.8	4.2	8.4
Contract liabilities	11.2	16.0	0.2
Net cash provided by operating activities:	536.0	188.0	41.8
Cash flows from investing activities:			
Purchases of property, plant and equipment and other	(141.0)	(86.9)	(72.1)
Milestone payment from asset acquisition	(10.0)	(10.0)	—
Business acquisitions, net of cash acquired	—	—	(827.7)
Proceeds from sale of assets	—	—	2.6
Net cash used in investing activities:	(151.0)	(96.9)	(897.2)
Cash flows from financing activities:			
Proceeds from revolving credit facility	—	130.0	348.0
Principal payments on revolving credit facility	(373.0)	(105.0)	—
Proceeds from term loan facility	—	—	450.0
Principal payments on term loan facility	(14.1)	(11.3)	(2.8)
Proceeds from senior unsecured notes	450.0	—	—
Debt issuance costs	(8.4)	—	(13.4)
Proceeds from share-based compensation activity	31.6	8.2	15.9
Taxes paid for share-based compensation activity	(13.8)	(7.4)	(6.6)
Contingent consideration payments	(2.8)	(50.4)	(3.4)
Receipts and payments of restricted cash	—	—	1.1
Purchase of treasury stock	—	—	(0.1)
Net cash provided by (used in) financing activities	69.5	(35.9)	788.7
Effect of exchange rate changes on cash and cash equivalents	(1.0)	0.4	(0.2)
Net change in cash and cash equivalents and restricted cash	453.5	55.6	(66.9)
Cash and cash equivalents and restricted cash at beginning of year	168.0	112.4	179.3
Cash and cash equivalents and restricted cash at end of year	$ 621.5	$ 168.0	$ 112.4
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ 21.0	$ 34.5	$ 10.2
Cash paid during the year for income taxes	$ 109.3	$ 30.8	$ 14.0
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	$ 22.0	$ 12.3	$ 14.7
Reconciliation of cash and cash equivalents and restricted cash:			
Cash and cash equivalents	$ 621.3	$ 167.8	$ 112.2
Restricted cash	0.2	0.2	0.2
Total	$ 621.5	$ 168.0	$ 112.4

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 Capital	Treasury Stock		Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount		Shares	Amount			
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
Employee equity plans activity	1.3	—	68.8	—	—	—	—	68.8
Net income	—	—	—	—	—	—	305.1	305.1
Other comprehensive income	—	—	—	—	—	(15.4)	—	(15.4)
Balance at December 31, 2020	54.3	$ 0.1	$ 784.9	(1.2)	$ (39.6)	$ (25.3)	$ 726.9	$ 1,447.0

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 civilian and military populations with a portfolio of innovative preparedness and response products and solutions that address accidental, deliberate and naturally occurring public health threats (''PHTs,'' each a ''PHT'').

The Company is focused on the following five 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) services. The Company has a product portfolio of ten products (vaccines, therapeutics, and drug-device combination products) that contribute a substantial portion of our revenue. The Company has two product candidates that are procured under special circumstances by certain government agencies, although they are not approved by the U.S. Food and Drug Administration (FDA) or any health agency. The U.S. government (USG) is the Company's largest customer and provides the Company with substantial funding for the development of a number of its product candidates.

The Company's product and services 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 FDA, for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- Vaxchora® (Cholera Vaccine, Live, Oral), the only single-dose oral vaccine licensed by the FDA and the European Medicines Agency (EMA) for the prevention of cholera; 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 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; and
- 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.

Therapeutics

- raxibacumab (Anthrax Monoclonal), a 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.

Procured Product Candidates

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

CDMO Services

The Company's CDMO service offerings cover development services, drug substance manufacturing and drug product manufacturing across the pharmaceutical and biotechnology industries as well as the USG and non-governmental organizations. The Company's technology platforms include mammalian, microbial, viral, plasma and advanced therapies utilizing the Company's core capabilities for manufacturing to third parties on a clinical and commercial (small and large) scale. Additional services include 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 on multiple platforms.

The Company operates 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 requires management to make estimates, judgments and assumptions that affect reported amounts and disclosures 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. Management continually re-evaluates its estimates, judgments and assumptions. 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.

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. 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 consideration (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 in-process research and development (''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 and convertible senior notes approximate their fair values due to their short maturities. The carrying amounts of the Company's long-term variable interest rate debt arrangements (level 2) approximate their fair values.

Significant customers and accounts receivable

Billed accounts receivable are stated at invoice amounts and consist of amounts due from the USG, commercial CDMO customers, 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. We do not adjust our receivables for the effects of a significant financing component at contract inception if we expect to collect the receivables in one year or less from the time of sale. We provide reserves against accounts receivable for estimated losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are charged or written-off against the reserve. 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 ACAM2000 and Anthrax Vaccines are subject to unilateral termination or modification by the government. The Company may fail to achieve significant sales of ACAM2000 and Anthrax Vaccines to customers in addition to the USG, which would harm its growth opportunities. 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 securing 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 accounts receivables do not represent a significant concentration of credit risk. The USG accounted for approximately 64%, 61% and 76% of total revenues for 2020, 2019 and 2018, respectively. The Company's accounts receivable as of December 31, 2020 and 2019, consist primarily of amounts due from the USG or other large multi-national highly reputable customers for product sales, CDMO services or from government agencies under government grants. Management does not deem 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, 2020, 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. subject to reviews for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. The cost of normal, recurring or periodic repairs and maintenance activities related to property, plant and equipment are expensed as incurred. The cost for planned major maintenance activities, including the related acquisition or construction of assets, is capitalized if the repair will result in future economic benefits.

Interest costs incurred during the construction of major capital projects are capitalized until the underlying asset is ready for its intended use, at which point the interest costs are amortized as depreciation expense over the life of the underlying asset.

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.

We generally depreciate or amortize the cost of our property, plant and equipment using the straight-line method over the estimated useful lives of the respective assets, which are summarized as follows:

Land	Not depreciated
Buildings	31-39 years
Building improvements	10-39 years
Furniture and equipment	3-15 years
Software	3-7 years
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 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 includes federal, state, local and foreign taxes. Income taxes are accounted for using the asset and 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. Valuation allowances are recorded as appropriate to reduce deferred tax assets to the amount considered likely to be realized.

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.

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 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 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 from tax benefits ultimately realized.

Acquisitions

In determining whether an acquisition is a business combination versus an asset acquisition, the Company evaluates 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 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 until the completion or abandonment of the associated research and development effort and are evaluated for impairment at least annually. 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.

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 represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for using the purchase method of accounting. Goodwill is not amortized, but is reviewed for impairment. 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 one-step process. The process is to compare the fair value of a reporting unit with its carrying amount. If the fair value of a reporting unit exceeds its carrying amount, goodwill of the reporting unit is not impaired. If the carrying amount of a reporting unit exceeds its fair value, goodwill of the reporting unit is impaired and an impairment loss is recognized in an amount equal to that excess. The Company utilized a quantitative assessment for our goodwill impairment testing of one reporting unit in 2020. The Company used a qualitative assessment for our goodwill impairment testing for all other reporting units in 2020 and all reporting units in 2019. The assessments completed during the years ended December 31, 2020 and 2019 indicated no impairment losses.

The Company had material indefinite lived intangible assets associated with in-process research and development (IPR&D). 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, the Company compares the estimated fair value of the intangible 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 (see Notes 5. Fair value measurements and 8. Intangible assets and goodwill).

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 or decrease 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 assessment of the 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 CDMO 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 CDMO. 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 CDMO 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.

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 CDMO 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.

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, gives 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 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, 2020.

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, EID, emerging health crisis

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 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.

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 Company's contracts for the sale of the Company's CBRNE products also include certain acceptance criteria before title passes to the customer.

Acute/emergency care (Opioid) and travel health

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. Estimates of variable consideration includes allowances for returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, chargebacks and rebates under managed care plans. 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. Provisions for variable consideration revenues from sales of products are recorded at the net sales price. 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. 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.

CDMO services

The Company performs CDMO 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, technology transfer, manufacturing validations, laboratory analytical development support, aseptic filling, lyophilization, final packaging and accelerated and ongoing stability studies. These contracts vary in duration and number of performance obligations. Performance obligations can include technology transfer activities, stand-ready obligations, suite-reservations and drug substance manufacturing. The Company has determined that the technology transfer, stand-ready and suite-reservation performance obligations are satisfied over time; drug substance manufacturing performance obligations are satisfied when the goods have been released, legal title has passed and the goods are in the customer's possession. The suite-reservation

performance obligations generally are considered an operating lease as the customer obtains substantially all of the economic benefits of the identified asset and has the right to direct its use. The associated revenue is recognized on a straight-line basis over the term of the lease.

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. Revenue for long-term development contracts is generally recognized over-time 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.

Research and development

The Company expenses 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 CDMO 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, 2020, 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. 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.

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 seven 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 estimates and recognizes 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 the Company's 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 day prior to 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 2016-13, 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. The Company adopted the standard as of January 1, 2020 and has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's 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 is 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 adopted the standard as of January 1, 2020 which has resulted in expanded disclosures around the Company's recurring level 3 fair value measurements. The disclosures are included in note 5 of the condensed consolidated financial statements.

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. The Company adopted the standard on a retrospective basis for the reporting period ended December 31, 2020. There was no impact on the Company's 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. The Company adopted the standard as of January 1, 2020 and has evaluated the effects of this standard and determined that the adoption did 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. The Company's measurement period is October 1. The Company adopted the standard as of January 1, 2020 and has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidation financial statements.

Not Yet Adopted

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 will adopt the standard as of January 1, 2021 and has determined that the adoption will not impact the Company's consolidated financial statements.

ASU 2020-04, Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting

In March 2020, the FASB issued Topic 848. Topic 848 provides relief for impacted areas as it relates to impending reference rate reform. ASC 848 contains optional expedients and exceptions to debt arrangements, contracts, hedging relationships, and other areas or transactions that are impacted by reference rate reform. This guidance is effective upon issuance for all entities and elections of certain optional expedients are required to apply the provisions of the guidance. The Company continues to assess all potential impacts of the standard and will disclose the nature and reason for any elections that the Company makes.

3. Revenue recognition

For the years ended December 31, 2020, 2019 and 2018 the Company's revenues disaggregated by the major sources was as follows:

(in millions)	Year Ended December 31,								
	2020			2019			2018		
	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	$626.0	$363.8	$ 989.8	$568.8	$334.7	$ 903.5	$526.1	$ 80.4	$606.5
CDMO services	253.3	197.2	450.5	—	80.0	80.0	—	98.9	98.9
Contracts and grants	109.2	5.9	115.1	105.9	16.6	122.5	71.5	5.5	77.0
Total revenues	$988.5	$566.9	$1,555.4	$674.7	$431.3	$1,106.0	$597.6	$184.8	$782.4

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

	2020	2019	2018
% of product sales:			
Anthrax Vaccines	38%	19%	46%
NARCAN Nasal Spray	31%	31%	7%
ACAM2000	20%	27%	19%
Other	11%	23%	28%

As of December 31, 2020, 2019 and 2018, aside from sales to the USG, there were no sales to an individual customer in excess of 10% of total revenues. For the years ended December 31, 2020, 2019, and 2018, the Company's revenues within the United States comprised 93%, 90% and 91%, respectively, of total revenues.

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.

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, 2018	$ 73.1
Deferral of revenue	46.7
Revenue recognized	(30.9)
Balance at December 31, 2019	88.9
Deferral of revenue	146.2
Revenue recognized	(135.0)
Balance at December 31, 2020	$ 100.1

As of December 31, 2020 and 2019, the current portion of contract liabilities was $44.6 million and $3.3 million, respectively, and was included in other current liabilities on the balance sheet.

Transaction price allocated to remaining performance obligations

As part of the Company's multi-year CDMO services arrangements that were entered into during 2020, the Company identified a suite-reservation performance obligation which is considered an operating lease as the

customer obtains substantially all of the economic benefits of the identified asset and has the right to direct its use. The associated revenue is recognized on a straight-line basis over the term of the lease. The remaining term on the Company's operating lease performance obligations approximates 2.3 years. The Company utilizes a cost-plus model to determine the stand-alone selling price of the lease component to allocate contract consideration between the lease and non-lease components. During the year ended December 31, 2020, the Company's lease revenues were $30.5 million, which is included within CDMO services in the consolidated statement of operations. The Company did not recognize lease revenue during the years ended December 31, 2019 and 2018. The Company has allocated contracted operating lease revenues due under our long-term CDMO service arrangements as follows:

	Year Ended December 31,
2021	74.8
2022	74.8
2023	15.7
	$165.3

As of December 31, 2020, the Company expects future revenues of approximately $1.9 billion associated with all performance obligations described above that have not been satisfied and all other arrangements entered into by the Company. The Company expects to recognize a majority of these revenues within the next 24 months. 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 procured 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.

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 equipment, as contract assets. As of December 31, 2020 and 2019, the Company had contract assets associated with deferred costs of $41.1 million and $34.0 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)	2020	2019
Billed, net	$172.7	$227.3
Unbilled	58.2	43.4
Total, net	$230.9	$270.7

As of December 31, 2020 and 2019, the allowance for doubtful accounts was $3.1 million and de minimis, respectively.

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. The Company has recorded impairment charges of $29.0 million and $12.0 million during the years ended December 31, 2020 and December 31, 2019, respectively. The fair value of the IPR&D intangible asset is de minimus at December 31, 2020 (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 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 CDMO 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, 2019, which were recorded in selling, general and administrative expenses.

5. Fair value measurements

The Company's recurring fair value measurement items recorded on a recurring basis primarily consist of contingent consideration, 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 CDMO services. 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, 2020 and 2019.

(in millions)	
Balance at December 31, 2018	$ 60.0
Expense included in earnings	24.8
Measurement period adjustment	1.5
Settlements	(57.1)
Balance at December 31, 2019	$ 29.2
Expense included in earnings	31.7
Settlements	(2.8)
Balance at December 31, 2020	$ 58.1

As of December 31, 2020 and 2019, the current portion of the contingent consideration liability was $23.9 million and $3.2 million, respectively, and was included in other current liabilities on the balance sheet.

The recurring Level 3 fair value measurements for the Company's contingent consideration liability include the following significant unobservable inputs:

Contingent Consideration Liability	Fair Value as of December 31, 2020	Valuation Technique	Unobservable Input	Range	Weighted Average
Revenue milestone and royalty based	$58.1 million	Discounted cash flow	Discount rate	3.0% - 7.1%	3.6%
			Probability of payment	25.0% - 100.0%	90.0%
			Projected year of payment	2020 - 2028	2022

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, 2020 and 2019, the Company held cash in money market accounts of $352.2 million and $52.2 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, 2020 there were no assets or liabilities measured at fair value on a non-recurring basis. As of December 31, 2019, the Company’s IPR&D assets were measured at fair value. See 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)	2020	2019
Raw materials and supplies	$160.6	$ 70.5
Work-in-process	102.5	89.7
Finished goods	43.9	62.3
Total inventories	$307.0	$222.5

Inventories, net is stated at the lower of cost or net realizable value. During the year ended December 31, 2020, the Company recorded a charge of $17.3 million for inventories associated with the travel health business that are not expected to be realized before product expiration following a reduction in travel due to COVID-19. The charge was reflected as a component of cost of product sales and CDMO services.

7. Property, plant and equipment

Property, plant and equipment consist of the following:

	December 31,	
(in millions)	2020	2019
Land and improvements	$ 52.7	$ 46.5
Buildings, building improvements and leasehold improvements	246.3	234.8
Furniture and equipment	362.1	334.2
Software	58.7	55.7
Construction-in-progress	183.4	81.5
	903.2	752.7
Less: Accumulated depreciation and amortization	(259.1)	(210.4)
Total property, plant and equipment, net	$ 644.1	$ 542.3

For the years ended December 31, 2020 and 2019, construction-in-progress primarily includes costs incurred related to construction to advance the Company’s CDMO capabilities.

Depreciation and amortization expense associated with property, plant and equipment was $50.1 million, $49.5 million and $36.3 million for the years ended December 31, 2020, 2019, and 2018, 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, 2020		
(in millions)	Estimated Life	Cost	Accumulated Amortization	Net
Products	9-22 years	$798.0	$137.8	$660.2
Customer relationships	8 years	28.6	26.5	2.1
CDMO	8 years	5.5	4.7	0.8
Total intangible assets		$832.1	$169.0	$663.1

		December 31, 2019		
(in millions)	Estimated Life	Cost	Accumulated Amortization	Net
Products	9-22 years	$788.0	$ 82.2	$705.8
Customer relationships	8 years	28.6	23.0	5.6
CDMO	8 years	5.5	4.0	1.5
Total intangible assets		$822.1	$109.2	$712.9

The Company achieved sales milestones that resulted in a $10.0 million obligation during each of the years ended December 31, 2020 and 2019 related to the Company's asset acquisition of raxibacumab in October 2017 which increased products related intangible assets. As of December 31, 2020, there are no remaining contractual obligations for sales milestones related to the raxibacumab acquisition.

For the years ended December 31, 2020, 2019, and 2018, the Company recorded amortization expense for intangible assets of $59.8 million, $58.7 million and $25.0 million, respectively, which is included in the amortization of intangible assets in the consolidated statements of operations. As of December 31, 2020, the weighted average amortization period remaining for intangible assets is 12.7 years.

Future amortization expense as of December 31, 2020 is as follows:

(in millions)	
2021	$ 58.6
2022	55.9
2023	55.8
2024	55.8
2025 and beyond	437.0
Total remaining amortization	$663.1

The Company monitored the recoverability of its IPR&D intangible asset, AP004 (Naloxone prefilled syringe), at each reporting period. Due to changes in fair value, the Company has recorded impairment charges of $29.0 million and $12.0 million during the years ended December 31, 2020 and December 31, 2019, respectively. As of December 31, 2020, the Company does not expect to generate future cash flows from AP004 and as such there is no remaining balance at December 31, 2020. The impairment charges are reflected as a component of research and development expense in the consolidated statement of operations.

The following table is a summary of changes in goodwill:

	Year ended December	
(in millions)	2020	2019
Balance at beginning of the year	$266.6	$259.7
Measurement period adjustments	—	6.9
Foreign currency translation	0.1	—
Balance at end of the year	$266.7	$266.6

9. Long-term debt

The components of debt are as follows:

(in millions)	December 31, 2020	2019
Senior secured credit agreement - Term loan due 2023	$421.9	$435.9
Senior secured credit agreement - Revolver loan due 2023	—	373.0
3.875% Senior Unsecured Notes due 2028	450.0	—
2.875% Convertible Senior Notes due 2021	10.6	10.6
Other	3.0	3.0
Total debt	$885.5	$822.5
Current portion of debt, net of debt issuance costs	(33.8)	(12.9)
Unamortized debt issuance costs	(10.7)	(11.2)
Debt, net of current portion	$841.0	$798.4

As of December 31, 2020, the Company had approximately $2.0 million and $3.5 million of debt issuance costs associated with the revolver loan that were classified as other current assets and other assets, respectively, on the Company's consolidated balance sheets because there was no outstanding revolver balance at December 31, 2020. As of December 31, 2019, the Company had approximately $1.8 million and $5.0 million of debt issuance costs associated with the revolver loan that were classified as debt, current portion and debt, net of current portion, respectively, on the Company's consolidated balance sheets because there was an outstanding revolver balance at December 31, 2019.

3.875% Senior Unsecured Notes due 2028

On August 7, 2020, the Company completed its offering of $450 million aggregate principal amount of 3.875% Senior Unsecured Notes due 2028 (the ''2028 Notes'') of which the majority of the net proceeds were used to pay down the Revolving Credit Facility (as defined below). Interest on the 2028 Notes is payable on February 15th and August 15th of each year until maturity, beginning on February 15, 2021. The 2028 Notes will mature on August 15, 2028. As of December 31, 2020, the fair value of the 2028 Notes based on level 2 inputs is 466.0 million.

On or after August 15, 2023, the Company may redeem the 2028 Notes, in whole or in part, at the redemption prices set forth in the related Indenture, plus accrued and unpaid interest. Prior to August 15, 2023 the Company may redeem all or a portion of the 2028 Notes at a redemption price equal to 100% of the principal amount of the 2028 Notes plus a ''make-whole'' premium and accrued and unpaid interest. Prior to August 15, 2023, the Company may redeem up to 40% of the aggregate principal amount of the 2028 Notes using the net cash proceeds of certain equity offerings at the redemption price set forth in the related Indenture. Upon the occurrence of a change of control, the Company must offer to repurchase the 2028 Notes at a purchase price of 101% of the principal amount of such 2028 Notes plus accrued and unpaid interest.

Negative covenants in the Indenture governing the 2028 Notes, among other things, limit the ability of the Company to incur indebtedness and liens, dispose of assets, make investments, enter into certain merger or consolidation transactions and make restricted payments.

Senior secured credit agreement

Also on August 7, 2020, the Company entered into a Second Amendment (the ''Credit Agreement Amendment'') to its senior secured credit agreement, dated October 15, 2018, with multiple lending institutions relating to the Company's senior secured credit facilities (the ''Credit Agreement,'' and as amended, the ''Amended Credit Agreement''), consisting of a senior revolving credit facility (the ''Revolving Credit Facility'') and senior term loan facility (the ''Term Loan Facility,'' and together with the Revolving Credit Facility, the ''Senior Secured Credit Facilities''). The Credit Agreement Amendment amended, among other things, the definition of incremental facilities limit, the consolidated net leverage ratio financial covenant by increasing the maximum level, increased the permissible applicable margins based on the Company's consolidated net leverage ratio and increased the commitment fee that the Company is required to pay in respect of the average daily unused commitments under the Revolving Credit Facility, depending on the Company's consolidated net leverage ratio.

The Amended Credit Agreement includes (i) a Revolving Credit Facility of $600 million with a maturity date of October 13, 2023, and (ii) a Term Loan Facility with a principal amount of $450 million. The Company may request incremental term loan facilities or increases in the Revolving Credit Facility (each an ''Incremental Loan'') as long as certain requirements involving our net leverage ratio will be maintained on a pro forma basis. Borrowings under

the Revolving Credit Facility and the Term Loan Facility bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.25% to 2.25% 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 1.25%, depending on the Company's consolidated net leverage ratio. The Company is required to make quarterly payments on the last business day of each calendar quarter 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 0.35% per annum, depending on the Company's consolidated net leverage ratio, for 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 on the last business day of each calendar quarter 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 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 (b) receive cash proceeds in excess of $100 million during the term of the Credit Agreement from certain dispositions of property or from casualty events involving their property, subject to certain reinvestment rights. The financial covenants under the Amended Credit Agreement currently require the quarterly presentation of a minimum consolidated 12-month rolling debt service coverage ratio of 2.50 to 1.00, and a maximum consolidated net leverage ratio of 4.50 to 1.00 (subject to an increase to 5.00 to 1.00 for an applicable four quarter period, at the election of the Company, in connection with a permitted acquisition having an aggregate consideration in excess of $75.0 million). 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, enter into certain merger or consolidation transactions and make restricted payments. As of the date of these financial statements, the Company is in compliance with all affirmative and negative covenants.

2.875% Convertible senior notes due 2021

On January 29, 2014, the Company issued 2.875% convertible senior notes due 2021 (the ''Notes''). The Notes bear interest at a rate of 2.875% per year, payable semi-annually in arrears on January 15 and July 15 of each year. The Notes matured and were paid on January 15, 2021.

Debt Maturity

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

(in millions)	December 31, 2020
2021	$ 35.9
2022	33.8
2023	363.6
2024	0.2
2025 and thereafter	452.0
Total debt	$885.5

10. Derivative Instruments and hedging activities

Risk management objective of using derivatives

The Company is exposed to certain risks 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.

As of December 31, 2020, 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
Interest Rate Swaps	7	350.0

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.

	Asset Derivatives				Liability Derivatives			
	December 31, 2020		December 31, 2019		December 31, 2020		December 31, 2019	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Interest Rate Swaps	Other Current Assets	$ —	Other Current Assets	$ —	Other Current Liabilities	$5.7	Other Current Liabilities	$ —
	Other Assets	$ —	Other Assets	$ —	Other Liabilities	$9.3	Other Liabilities	$2.0

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.

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

	Cumulative 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	
Hedging derivatives	December 31, 2020	December 31, 2019		December 31, 2020	December 31, 2019
Interest Rate Swaps	$(15.0)	$(2.0)	Interest expense	$(3.9)	$0.6

If current fair values of designated interest rate swaps remained static over the next twelve months, the Company would reclassify $5.7 million of net deferred losses from accumulated other comprehensive loss to the statement of operations over the next twelve month period. All outstanding cash flow hedges mature in October 2023.

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 stock options and performance and restricted stock units.

As of December 31, 2020, an aggregate of 21.9 million shares of common stock were authorized for issuance under the Emergent Plan, of which a total of approximately 4.2 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. Options granted under the Emergent Plan have a contractual life of 7 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,		
	2020	2019	2018
Expected dividend yield	0%	0%	0%
Expected volatility	39-48%	37-39%	38-39%
Risk-free interest rate	0.27-1.42%	1.57-2.48%	2.54-3.03%
Expected average life of options	4.5 years	4.5 years	4.5 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 per share data)	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2019	1.9	$36.74	$34.5
Granted	0.4	63.07	
Exercised	(0.9)	29.77	
Forfeited	(0.1)	54.02	
Outstanding at December 31, 2020	1.3	$49.07	$53.4
Exercisable at December 31, 2020	0.6	$37.48	$33.8

The weighted average remaining contractual term of options outstanding as of December 31, 2020 and 2019 was 4.3 years and 3.3 years, respectively. The weighted average remaining contractual term of options exercisable as of December 31, 2020 and 2019 was 2.9 years and 2.3 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2020, 2019, and 2018 was $21.69, $21.13 and $18.48 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2020, 2019, and 2018 was $38.2 million, $5.3 million and $24.4 million, respectively.

The following is a summary of performance stock and restricted stock unit award activity under the Emergent Plan.

(in millions, except per share data)	Number of Shares	Weighted-Average Grant Price	Aggregate Intrinsic Value
Outstanding at December 31, 2019	0.9	$52.77	$51.5
Granted	0.9	68.63	
Vested	(0.6)	55.25	
Forfeited	(0.1)	60.49	
Outstanding at December 31, 2020	1.1	$63.30	$96.3

The total fair value of restricted stock unit awards vested during 2020, 2019 and 2018 was $35.3 million, $16.9 million and $16.9 million, respectively. As of the year ended December 31, 2020, the total compensation cost and weighted average period over which total compensation is expected to be recognized related to unvested equity awards was $54.4 million and 1.6 years, respectively.

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

(in millions)	Year Ended December 31, 2020	2019	2018
Cost of product sales and CDMO services	$12.4	$ 3.1	$ 1.7
Research and development	8.4	4.0	3.1
Selling, general and administrative	30.2	19.6	18.4
Total stock-based compensation expense	$51.0	$26.7	$23.2

During the year ended December 31, 2020, the Company incurred $14.7 million of stock-based compensation expense due to a one-time special broad-based, immediately vested equity award to employees.

Accumulated Other Comprehensive (Loss) Income

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

(in millions)	Defined Benefit Pension Plan	Derivative Instruments	Foreign Currency Translation Losses	Total
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
Balance, December 31, 2019	$(3.4)	$ (1.6)	$(4.9)	(9.9)
Other comprehensive (loss) income before reclassifications	(4.3)	(13.3)	(1.7)	(19.3)
Amounts reclassified from accumulated other comprehensive income	—	3.9	—	3.9
Balance, December 31, 2020	$(7.7)	$(11.0)	$(6.6)	$(25.3)

During 2020, there were tax benefits related to unrealized losses on pension benefit obligations and derivative instruments of $0.7 million and $3.6 million; the tax effects of foreign currency translation were de minimus. 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, the tax effect of the amounts presented was de minimus.

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.

The Coronavirus Aid, Relief and Economic Security Act (the ''CARES Act'') was enacted on March 27, 2020. The CARES Act established new provisions, including but not limited to, expanded deduction of certain qualified capital expenditures, delayed payment of certain employment taxes, expanded use of net operating losses, reduced limitations on deductions of interest expense and extension of funding for defined benefit plans. The provisions in the CARES Act are not expected to have a significant impact on our financial position, results of operations or cash flows.

The Tax Reform Act of 2017 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, 2020. BEAT provisions do not have material impact on the consolidated financial statements.

For the years ended December 31, 2020 and 2019, the Company has not recognized deferred tax liabilities for temporary differences related to investments in foreign subsidiaries that were deemed permanent reinvested. Determination of the amount of unrecognized deferred income tax liabilities on these earnings is not practicable because such liability, if any, depends on certain circumstances existing if and when remittance occurs. A deferred tax liability will be recognized if and when the Company no longer plans to permanently reinvest these undistributed earnings.

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

(in millions)	December 31, 2020	2019	2018
Current			
Federal	$ 62.8	$ 1.4	$ 1.8
State	27.7	11.6	2.4
International	14.0	11.0	6.0
Total current	104.5	24.0	10.2
Deferred			
Federal	1.1	1.9	7.5
State	—	1.1	3.0
International	(3.5)	(4.1)	(1.9)
Total deferred	(2.4)	(1.1)	8.6
Total income taxes	$102.1	$22.9	$18.8

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

(in millions)	December 31, 2020	2019
Federal losses carryforward	$ 8.1	$ 8.5
State losses carryforward	3.1	17.4
Research and development carryforward	7.5	9.0
State research and development carryforward	5.0	5.0
Scientific research and experimental development credit carryforward	8.4	11.0
Stock compensation	8.6	7.6
Foreign NOLs	36.9	36.9
Deferred revenue	26.2	18.1
Inventory reserves	1.7	1.8
Lease liability	8.2	6.0
Other	10.8	7.5
Deferred tax asset	124.5	128.8
Fixed assets	(54.6)	(51.2)
Intangible assets	(50.4)	(54.5)
Right-of-use asset	(7.7)	(5.9)
Other	(4.5)	(3.2)
Deferred tax liability	(117.2)	(114.8)
Valuation allowance	(51.1)	(64.5)
Net deferred tax asset (liability)	$ (43.8)	$ (50.5)

As of December 31, 2020, the Company has a net U.S. deferred tax liability in the amount of $3.9 million and a foreign net deferred tax liability in the amount of $39.9 million. The Company had 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 as of December 31, 2019.

As of December 31, 2020, the Company has approximately $38.3 million ($8.0 million tax effected) in U.S. federal net operating loss carryforwards along with $12.5 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. States have their own statutes concerning whether a NOL should be carried forward pre or post apportionment.

As of December 31, 2020, the Company had pre-apportionment state NOLs totaling approximately $697.0 million (de minimis when tax effected) primarily in Maryland which will begin to expire in 2025 and post-apportionment NOLs totaling approximately $55.6 million ($3.1 million tax effected) primarily in California that will begin to expire in 2025. The U.S. state tax loss carryforwards are recorded with a valuation allowance of $54.2 million ($2.8 million tax effected).

The Company has approximately $198.8 million ($36.9 million tax effected) in net operating losses from foreign jurisdictions as of December 31, 2020, 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 $34.5 million.

As of December 31, 2020, the Company currently has approximately $8.4 million in Manitoba scientific research and experimental development credit carryforwards that will begin to expire in 2029. 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.

Income taxes differ from the amount of taxes determined by applying the U.S. federal statutory rate to income before taxes as a result of the following:

(in millions)	December 31, 2020	2019	2018
US	$362.0	$63.9	$71.0
International	45.2	13.5	10.5
Earnings before taxes on income	407.2	77.4	81.5
Federal tax at statutory rates	$ 85.5	$16.3	$17.1
State taxes, net of federal benefit	23.2	10.3	4.3
Impact of foreign operations	(7.8)	(6.9)	2.8
Change in valuation allowance	1.5	(1.0)	(0.1)
Tax credits	(7.6)	(3.6)	(1.8)
Transition tax	—	—	(0.2)
Change in U.S. tax rate	—	—	(4.5)
Stock compensation	(7.9)	(2.4)	(5.8)
Other differences	—	—	(1.3)
Return to provision true-ups	(0.7)	(2.3)	1.1
Transaction costs	6.0	4.7	5.4
Compensation limitation	2.2	1.3	1.1
FIN 48	(0.3)	1.1	0.3
GILTI, net	5.4	3.6	0.4
Permanent differences	2.6	1.8	—
Income taxes	$102.1	$22.9	$18.8

The effective annual tax rate for the years ended December 31, 2020, 2019, and 2018 was 25%, 30% and 23%, respectively.

The effective annual tax rate of 25% in 2020 is higher than the statutory rate primarily due to the impact of state taxes, GILTI, contingent consideration, other non-deductible items and other jurisdictional mix of earnings. This is partially offset by stock option deduction benefits, tax credits, and favorable rates in foreign jurisdictions.

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 Company recognizes interest in interest expense and recognizes potential penalties related to unrecognized tax benefits in selling, general and administrative expense. The total unrecognized tax benefits recorded at December 31, 2020 and 2019 of $9.2 million and $10.4 million, respectively, is classified as a non-current liability on the balance sheet.

The table below presents the gross unrecognized tax benefits activity for 2020, 2019 and 2018:

(in millions)	
Gross unrecognized tax benefits at December 31, 2017	$ 2.0
Unrecognized tax benefits acquired in business combinations	6.5
Increases for tax positions for current year	0.3
Gross unrecognized tax benefits at December 31, 2018	$ 8.8
Increases for tax positions for prior years	0.5
Increases for tax positions for current year	1.5
Settlements	(0.4)
Gross unrecognized tax benefits at December 31, 2019	$10.4
Increases for tax positions for current year	0.6
Settlements	(1.8)
Gross unrecognized tax benefits at December 31, 2020	$ 9.2

The total gross unrecognized tax benefit of $9.2 million, includes $7.4 million that relates to the acquisition of PaxVax, which is entirely offset by a $7.4 million 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 2017 to 2019 remain open to examination. The Company's tax returns in the United Kingdom remain open to examination for the tax years 2013 to 2019, 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 2015 to 2019.

As of December 31, 2020, the Company's Canadian 2018 Scientific Research and Experimental Development Claim is under audit and the Company's 2017 Canadian income tax return for the Adapt entities is under audit. In addition, the Company's 2016 through 2018 Wisconsin state income tax returns for the Paxvax entity 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's 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 recognized pension expense related to the Swiss Plan of $2.4 million, $1.5 million and $0.3 million reflected as a component of selling, general and administrative for the years ended December 31, 2020, 2019 and 2018, respectively.

The funded status of the Swiss Plan is as follows:

(in millions)	December 31, 2020	December 31, 2019
Fair value of plan assets, beginning of year	$ 20.6	$ 18.2
Employer contributions	1.4	1.0
Employee contributions	0.8	0.7
Net benefits received (paid)	6.8	1.7
Actual return on plan assets	0.3	1.7
Settlements	(4.5)	(3.0)
Currency impact	2.2	0.3
Fair value of plan assets, end of year	$ 27.6	$ 20.6
Projected benefit obligation, beginning of year	$ 35.2	$ 28.6
Service cost	1.9	1.3
Interest Cost	0.1	0.2
Employee contributions	0.8	0.7
Actuarial loss	5.0	7.0
Net benefits received (paid)	6.8	1.7
Plan amendment	—	(1.7)
Settlements	(4.5)	(3.0)
Currency impact	3.9	0.4
Projected benefit obligation, end of year	$ 49.2	$ 35.2
Funded status, end of year	$(21.6)	$(14.6)
Accumulated benefit obligation, end of year	$ 43.0	$ 31.0

Since assets exceed the present value of expected benefit payments for the next twelve months, the liability is classified as non-current. During the years ended December 31, 2020 and 2019, actuarial losses affecting the projected benefit obligation of $5.0 million and $7.0 million, were recognized, respectively, largely as a result of changes in the discount rate.

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

(in millions)	December 31, 2020	December 31, 2019	December 31, 2018
Service cost	$ 1.9	$ 1.3	$ 0.3
Interest cost	0.1	0.2	0.1
Expected return on plan assets	(0.6)	(0.5)	(0.1)
Settlements	1.0	0.5	—
Net periodic benefit cost	$ 2.4	$ 1.5	$ 0.3

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

	December 31, 2020	December 31, 2019
Discount rate	0.02%	0.2%
Expected rate of return	3.0%	3.0%
Rate of future compensation increases	1.4%	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, 2021 is $1.5 million.

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

(in millions)	Year Ended December 31, 2020	Year Ended December 31, 2019
Net actuarial loss	$ 9.9	$5.4
Prior service cost	(1.5)	(1.7)
Total recognized in accumulated other comprehensive income (loss)	$ 8.4	$3.7

Future benefits expected to be paid as of December 31, 2020 are as follows:

(In millions)	31,
2021	$ 1.3
2022	1.9
2023	1.3
2024	1.3
2025	1.5
Thereafter	41.9
Total	$49.2

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, 2020, 2019 and 2018, the Company made matching contributions of approximately $6.6 million, $5.1 million and $3.1 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 with future minimum lease payments in excess of 12 months and total lease payments greater than $0.1 million are included in right-of-use (''ROU'') assets and liabilities. The Company has elected to record expense on a cash basis for leases with minimum lease payments of 12 months or less and/or total lease payments less $0.1 million.

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 13 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:

	Year Ended December 31,	
(In millions)	2020	2019
Operating lease cost:		
Amortization of right-of-use assets	$4.5	$2.7
Interest on lease liabilities	1.1	0.6
Total operating lease cost	$5.6	$3.3

For the year ended December 31, 2018 total lease expense was $3.3 million.

Supplemental balance sheet information related to leases was as follows:

(In millions, except lease term and discount rate)	Balance Sheet Location	Year Ended December 31, 2020	2019
Operating lease right-of-use assets	Other assets	$31.0	$24.7
Operating lease liabilities, current portion	Other current liabilities	5.4	3.6
Operating lease liabilities	Other liabilities	27.8	22.1
Total operating lease liabilities		33.2	25.7
Operating leases:			
Weighted average remaining lease term (years)		7.7	8.0
Weighted average discount rate		4.1%	4.2%

15. Earnings per share

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

(in millions, except per share data)	Year Ended December 31, 2020	2019	2018
Numerator:			
Net income	$305.1	$54.5	$62.7
Denominator:			
Weighted-average number of shares-basic	52.7	51.5	50.1
Dilutive effect of employee incentive plans	1.1	0.9	1.3
Weighted-average number of shares-diluted	53.8	52.4	51.4
Net income per share-basic	$ 5.79	$1.06	$1.25
Net income per share-diluted	$ 5.67	$1.04	$1.22

Basic net income per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted income per share is computed using the treasury method by dividing net income by the weighted average number of shares of common stock outstanding during the period, adjusted for the potential dilutive effect of other securities if such securities were converted or exercised and are not anti-dilutive.

The following table presents the share-based awards that are not considered in the diluted net income per share calculation generally because the exercise price of the awards was greater than the average per share closing price during the year ending December 31, 2020, 2019 and 2018. In certain instances awards may be anti-dilutive even if the average market price exceeds the exercise price when the sum of the assumed proceeds exceeds the difference between the market price and the exercise price.

	Year Ended December 31, 2020	2019	2018
Anti-dilutive stock awards	—	0.9	—

16. Purchase commitments

As of December 31, 2020 the Company has approximately $84.7 million of purchase commitments associated with raw materials and CDMO services that will be purchased in the next 3 years. For the years ended December 31, 2020, 2019, and 2018, the Company purchased $108.0 million, $51.3 million and $12.1 million, respectively, of materials under these commitments.

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 years ended December 31, 2020 and 2019, the Company had long-lived assets outside of the United States of approximately $98.6 million and $90.6 million, respectively, which are primarily located within Canada and Switzerland.

18. Quarterly financial data (unaudited)

Quarterly financial information for the years ended December 31, 2020 and 2019 is presented in the following tables:

	Quarter Ended			
(in millions, except per share data)	March 31,	June 30,	September 30,	December 31,
2020:				
Revenue	$192.5	$394.7	$385.2	$583.0
Income (loss) from operations	(11.6)	126.0	61.3	258.1
Net income (loss)	(12.5)	92.7	39.5	185.4
Net income (loss) per share-basic	$ (0.23)	$ 1.76	$ 0.75	$ 3.51
Net income (loss) per share-diluted	$ (0.23)	$ 1.74	$ 0.72	$ 3.44
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

19. Litigation

Emergent BioSolutions' Adapt Pharma subsidiaries (''Emergent'') are as follows: Emergent Devices Inc. (''EBPA''), formerly known as Adapt Pharma Inc.; Emergent Operations Ireland Limited (''EIRE''), formerly known as Adapt Pharma Operations Limited; and Emergent BioSolutions Ireland Limited (''EIR2''), formerly known as Adapt Pharma Limited.

ANDA Litigation – Teva 4mg

On or about September 13, 2016, Emergent BioSolutions' Adapt Pharma subsidiaries EBPA and EIRE, and Opiant received a notice letter from Teva Pharmaceuticals Industries Limited and Teva Pharmaceuticals USA (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 4 mg/spray before the expiration of U.S. Patent No. 9,211,253, (the '''253 Patent''). Emergent and Opiant received additional notice letters from Teva relating to U.S. Patent Nos. 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'') and 10,085,937 (the '''937 Patent''). Teva's notice letters asserted that the commercial manufacture, use or sale of its generic drug product described in its ANDA would 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 were invalid or unenforceable. Emergent and Opiant filed a complaint for patent infringement against Teva in the U.S. District Court for the District of New Jersey with respect to the '253 Patent. Emergent and Opiant also filed complaints for patent infringement against Teva in the U.S. District Court for the District of New Jersey with respect to the '747, the '177, the '965, and the '838 Patents. All five proceedings were consolidated.

On June 5, 2020, the U.S. District Court for the District of New Jersey ruled in favor of Teva. Emergent filed its Notice of Appeal on July 23, 2020 with the Court of Appeals for the Federal Circuit and filed its Opening Brief on November 2, 2020.

Emergent has also filed suit in the Federal Court in Canada against Teva Pharmaceuticals (on July 23, 2020). The litigation in Canada is related to Teva Pharmaceuticals' recent filing of an abbreviated new drug submission (''ANDS'') in Canada seeking to manufacture and sell a generic form of NARCAN® Nasal Spray ahead of the expiry of the Canadian patent covering our product.

ANDA Litigation – Teva 2mg

On or about February 27, 2018, Emergent BioSolutions' Adapt Pharma subsidiaries EBPA and EIRE, and Opiant received a notice letter 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 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 asserted that the commercial manufacture, use or sale of its generic drug product described in its

ANDA would not infringe the '644 Patent or the '226 Patent, or that the '644 Patent and '226 Patent were invalid or unenforceable. Emergent and Opiant filed a complaint for patent infringement against Teva in the U.S. District Court for the District of New Jersey. This case is currently stayed pending the outcome of the appeal of the NARCAN® Nasal Spray 4 mg/ spray case.

ANDA Litigation – Perrigo 4mg

ANDA litigation between Emergent BioSolutions' Adapt Pharma subsidiaries and Perrigo UK FINCO Limited Partnership (''Perrigo'') has been resolved through settlement. On September 14, 2018, Emergent BioSolutions' Adapt Pharma subsidiaries EBPA, EIRE and EIR2, and Emergent's partner Opiant received a notice letter from Perrigo that Perrigo had filed an ANDA with the FDA, seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of the '253, '747, '177, '965, and '838 Patents, and on or about October 25, 2018, Perrigo sent a subsequent notice letter relating to the '937 Patent (collectively, the ''Patents''). The notice letters asserted that the Patents were invalid, unenforceable, or would not be infringed by the commercial manufacture, use or sale its generic product. On October 25, 2018, Emergent and Opiant filed a complaint against Perrigo in the U.S. District Court for the District of New Jersey for infringement of the '253, '747, '177, '965, and '838 Patents Emergent and Opiant filed a second complaint against Perrigo on December 7, 2018, for infringement of the '937 Patent. On February 12, 2020, ANDA litigation with Perrigo was resolved after Emergent and Perrigo entered into a settlement agreement. Under the terms of the settlement, Perrigo has received a nonexclusive license to make, have made, and market its generic naloxone hydrochloride nasal spray. Perrigo's license will be effective as of January 5, 2033 or potentially earlier under certain circumstances related to the outcome of Emergent's current NARCAN® (naloxone hydrochloride) Nasal Spray ANDA litigation against Teva, or litigation against subsequent ANDA filers.

Inter Partes Review (''IPR'') Proceedings

On or about February 19, 2019, Emergent BioSolutions' Adapt Pharma subsidiaries EBPA and EIRE, and Opiant received notice from Nalox-1 Pharmaceuticals LLC that it had filed fifteen petitions for inter partes review (''IPR'') of the '253 Patent, the '747 Patent, the '177 Patent, the '965 Patent, and the '838 Patent with the Patent Trial and Appeal Board (the ''PTAB'') of the United States Patent and Trademark Office. Nalox-1's petitions asserted that each of the foregoing patents are unpatentable as obvious in view of prior art. Three of these petitions, IPR Nos.

2019-00685, 2019-00688, and 2019-00694, were instituted on August 27, 2019, September 9, 2019, and September 11, 2019, respectively. An oral hearing for the three instituted IPR proceedings was held before the PTAB on May 19, 2020. On August 21, 2020, the PTAB issued its final written decisions for the above-listed IPRs confirming that claims of the relevant U.S. patents in the NARCAN® Nasal Spray patent portfolio are not unpatentable as obvious in view of prior art.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. 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, 2020, 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, 2020. 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, 2020, 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, 2020, a copy of which is included in this annual report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act that occurred during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited Emergent BioSolutions Inc. and subsidiaries' internal control over financial reporting as of December 31, 2020, 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, 2020 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, 2020 and 2019, 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, 2020, and the related notes and financial statement schedule listed in the Index at Item 15 and our report dated February 18, 2021 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 18, 2021

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 2021 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 2021 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 2021 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 2021 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 2021 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 II, Item 8.

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2020 and 2019

Consolidated Statements of Operations for the years ended December 31, 2020, 2019 and 2018

Consolidated Statements of Comprehensive Income for the years ended December 31, 2020, 2019 and 2018

Consolidated Statements of Cash Flows for the years ended December 31, 2020, 2019 and 2018

Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2020, 2019 and 2018

Notes to Consolidated Financial Statements

Financial Statement Schedules

Schedule II – Valuation and Qualifying Accounts for the years ended December 31, 2020, 2019 and 2018 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, 2020					
Inventory allowance	$ 17.9	$ –	$ 48.0	$ (28.3)	$ 37.6
Prepaid expenses and other current assets allowance	4.0	–	0.5	(0.6)	3.9
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

ITEM 16. FORM 10-K SUMMARY

Not applicable.

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	#† †	Asset Purchase Agreement, dated July 19, 2017, among GlaxoSmithKline LLC, Human Genome Sciences, Inc., and Emergent BioSolutions Inc.
2.2	†	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).
2.3	†	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		Indenture, dated as of August 7, 2020, by and among the Company, certain subsidiaries of the Company and U.S. Bank National Association, as trustee. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed on August 7, 2020.) (incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
4.5		Form of 3.875% Senior Unsecured Note due 2028 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed on August 7, 2020.) (incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
4.6	#	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	#	First Amendment to Amended and Restated Credit Agreement, dated June 27, 2019.
10.3	*	Second Amendment to Amended and Restated Credit Agreement, dated August 7, 2020 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on August 7, 2020).

10.4	† †	Purchase Agreement, dated as of August 4, 2020, by and among the Company, the subsidiaries of the Company named therein as guarantors, and Wells Fargo Securities, LLC, as representative of the several initial purchasers identified therein. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on August 7, 2020.
10.5	*	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).
10.6	*	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).
10.7	*	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).
10.8	*	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).
10.9	*	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).
10.1	*	Emergent BioSolutions Inc. Stock Incentive Plan (incorporated by reference to Exhibit 99 to Registration Statement on Form S-8, filed on May 30, 2018).
10.11	*	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).
10.12	*	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).
10.13	#*	Global Form of Restricted Stock Unit Award Agreement.
10.14	*	Global Form of Non-Qualified 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).
10.15	*	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).
10.16	*	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).
10.17	*	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).
10.18	*	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).
10.19	*	Form of 2021-2023 Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 99 to the Company's Current Report on Form 8-K filed on February 16, 2021).
10.2	*	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).
10.21	*	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).
10.22	*	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).
10.23	*	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).

10.24	†	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).
10.25	†	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).
10.26	†	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).
10.27		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).
10.28	†	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).
10.29	†	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).
10.3	†	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).
10.31	†	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).
10.32		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).
10.33	†	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).
10.34	†	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).
10.35	†	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).
10.36	†	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).
10.37	†	Modification No. 13, effective September 21, 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).
10.38	†	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).
10.39	†	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).
10.4		Modification No. 16, effective January 14, 2019, 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).
10.41	† †	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).

10.42	† †	Modification No. 18, effective September 11, 2019, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.39 the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.43	† †	Modification No. 19, effective January 6, 2020, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.40 the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.44	† †	Modification No. 20, effective January 7, 2020, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.41 the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.45	#† †	Modification No. 21, effective January 7, 2020, to the CDC BioThrax Procurement Contract.
10.46	#† †	Modification No. 22 to the CDC BioThrax Procurement Contract.
10.47	#† †	Modification No. 23, effective September 30, 2020, to the CDC BioThrax Procurement Contract.
10.48	†	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).
10.49	†	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).
10.5	†	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).
10.51	† †	Modification No. 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).
10.52	† †	Modification No. 4, effective March 3, 2020, to the BARDA AV7909 contract (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 1, 2020).
10.53	† †	Modification No. 5, effective April 10, 2020, to the BARDA AV7909 contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 1, 2020).
10.54	† †	Modification No. 6, effective July 13, 2020, to the BARDA AV7909 contract (incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.55	†	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).
10.56	†	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).
10.57		Amendment No. 2 to License Agreement, dated December 15, 2014, by and between Opiant Pharmaceuticals, Inc. and Adapt Pharma Operations Limited, effective March 18, 2019 (incorporated by reference to Exhibit 10.1 the Company's Quarterly Report on Form 10-Q filed on May 8, 2019).
10.58	† †	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. (incorporated by reference to Exhibit 10.48 the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.59	† †	Modification No. 1, effective, May 28, 2020 to the ACAM 2000 Contract (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).

10.6	#† †	Modification No. 2, effective, October 28, 2020 to the ACAM 2000 Contract.
10.61	†	Award/Contract, effective June 15, 2012 (BARDA ADM Contract), from the BioMedical Advance Research and Development Authority to Emergent Manufacturing Operations Baltimore LLC. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).
10.62	† †	Order for Supplies and Services Between Emergent Manufacturing Operations Baltimore LLC and the BioMedical Advance Research and Development Authority, dated May 24, 2020, under the BARDA ADM Contract (Task Order 75A50120F33007) (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).
10.63	† †	Modification No. 1, effective August 24, 2020, to Task Order 75A50120F33007 (incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.64	#† †	Modification No. 2, effective September 18, 2020, to Task Order 75A50120F33007.
10.65	#† †	Modification No. 3, effective October 7, 2020, to Task Order 75A50120F33007.
10.66	† †	Order for Supplies and Services Between Emergent Manufacturing Operations Baltimore LLC and the BioMedical Advance Research and Development Authority, dated August 6, 2020, under the BARDA ADM Contract (Task Order 75A50120F33008). (incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.67	† †	Modification No. 1, effective August 24, 2020, to Task Order 75A50120F33008 (incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.68	#† †	Modification No. 2, effective November 17, 2020, to Task Order 75A50120F33008.
10.69	† †	Modification No. 19, effective, May 25, 2020, to the BARDA ADM Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).
10.7	† †	Modification No. 20, effective, May 26, 2020, to the BARDA ADM Contract (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).
10.71	† †	Order for Supplies and Services Between Emergent Manufacturing Operations Baltimore LLC and the BioMedical Advance Research and Development Authority, dated May 24, 2020, under the BARDA ADM Contract (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).
10.72	† †	Modification No. 21, effective June 12, 2020 to the BARDA ADM Contract (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.73	† †	Modification No. 22, effective June 12, 2020 to the BARDA ADM Contract (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.74	† †	Modification No. 23, effective July 22, 2020 to the BARDA ADM Contract (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.75	† †	Modification No. 24, effective August 28, 2020 to the BARDA ADM Contract (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.76	† †	Modification No. 25, effective September 25, 2020 to the BARDA ADM Contract (incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.77	† †#	Modification No. 26, effective November 2, 2020 to the BARDA ADM Contract.
10.78	† †	Manufacturing Services Agreement, dated July 24, 2020, by and between Emergent Manufacturing Operations Baltimore, LLC and AstraZeneca Pharmaceuticals LP. (AZ MSA) (incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).

10.79	† †	Manufacturing Product Schedule, dated July 26, 2020 to AZ MSA (incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.80	† †	Work Order to Manufacturing Services Agreement, dated June 10, 2020, between Emergent Manufacturing Operations Baltimore, LLC and AstraZeneca Pharmaceuticals LP (included as part of AZ MSA) (incorporated by reference to Exhibit 10.14 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.81	† †	Amendment No. 1, effective September 30, 2020, to AZ MSA (incorporated by reference to Exhibit 10.15 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.82	† †	Manufacturing Services Agreement, dated July 2, 2020, by and between Emergent Manufacturing Operations Baltimore, LLC and Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson (incorporated by reference to Exhibit 10.16 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
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, 2020, 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.

† † 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, 2020 and 2019, (ii) Consolidated Statements of Operations for the Years Ended December 31, 2020, 2019 and 2018, (iii) Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2020, 2019 and 2018 (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2020, 2019 and 2018, (v) Consolidated Statements of Changes in Stockholders' Equity for the Years ended December 31, 2020, 2019 and 2018, 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

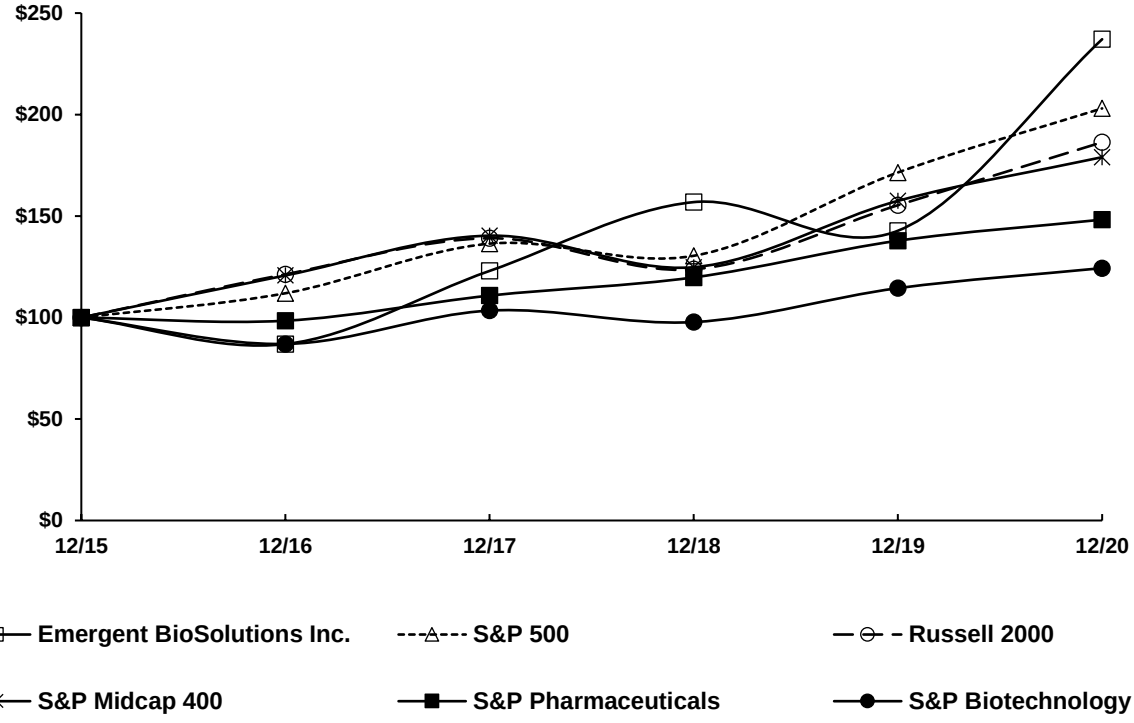
Date: February 18, 2021

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 18, 2021
/s/ Richard S. Lindahl Richard S. Lindahl	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 18, 2021
/s/ Fuad El-Hibri Fuad El-Hibri	Executive Chairman of the Board of Directors	February 18, 2021
/s/ Zsolt Harsanyi, Ph.D. Zsolt Harsanyi, Ph.D.	Director	February 18, 2021
/s/ Kathryn Zoon, Ph.D. Kathryn Zoon, Ph.D.	Director	February 18, 2021
/s/ Ronald B. Richard Ronald B. Richard	Director	February 18, 2021
/s/ Louis W. Sullivan, M.D. Louis W. Sullivan, M.D.	Director	February 18, 2021
/s/ Dr. Sue Bailey Dr. Sue Bailey	Director	February 18, 2021
/s/ George Joulwan George Joulwan	Director	February 18, 2021
/s/ Jerome Hauer, Ph.D. Jerome Hauer, Ph.D.	Director	February 18, 2021
/s/ Marvin White Marvin White	Director	February 18, 2021

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 Midcap 400 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 12/31/2015 to 12/31/2020.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Emergent BioSolutions Inc., the S&P 500 Index, the Russell 2000 Index, the S&P Midcap 400 Index, the S&P Pharmaceuticals Index and the S&P Biotechnology Index



* $100 invested on 12/31/15 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

	12/15	12/16	12/17	12/18	12/19	12/20
Emergent BioSolutions Inc.	**100.00**	**86.91**	**122.98**	**156.88**	**142.77**	**237.12**
S&P 500	**100.00**	**111.96**	**136.40**	**130.42**	**171.49**	**203.04**
Russell 2000	**100.00**	**121.31**	**139.08**	**123.76**	**155.35**	**186.36**
S&P Midcap 400	**100.00**	**120.74**	**140.35**	**124.80**	**157.49**	**179.00**
S&P Pharmaceuticals	**100.00**	**98.44**	**110.81**	**119.78**	**137.85**	**148.23**

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.

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

Marvin L. White[4,5]
President and Chief Executive Officer,
Aptevo Therapeutics Inc.

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 M. 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

Karen L. Smith, M.D., Ph.D.*
Executive Vice President,
Chief Medical Officer

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

Howard Anderson
Senior Vice President,
Chief Information Officer

Chris Cabell, M.D., M.S.Hc.
Senior Vice President,
Clinical Development

Nina DeLorenzo
Senior Vice President,
Global Communications and Public Affairs

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

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

Brian Millard
Senior Vice President,
Finance and Corporate Controller

Dino Muzzin
Senior Vice President,
Manufacturing Operations

Mary Oates, Ph.D.
Senior Vice President,
Global Quality

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

Manish Vyas
Senior Vice President,
Regulatory Affairs

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, 2020, 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: investorrelations@ebsi.com Tel: 240-413-1917 Fax: 240-631-3203

MARKET INFORMATION

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

ANNUAL MEETING

The annual meeting of Emergent BioSolutions Inc. will be held in virtual format via live audio webcast on May 20, 2021, at 9:00 a.m. Eastern Time. Stockholders can attend the meeting online at www.virtualshareholdermeeting.com/EBS2021.

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®

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Gaithersburg, Maryland 20879 USA

emergentbiosolutions.com