
EMERGENT
2022 Annual Report
WE PERCEIVE.
WE PREPARE.
WE PROTECT.

Dear Fellow Shareholder,

Following two long years in a pandemic, the world began to pivot to a new post-Covid reality. Employees returned to the office, stadiums filled with fans, and travelers returned to the skies. Despite the return to normalcy, events like Russia's aggression against Ukraine and the outbreak of mpox remind us that we cannot rest in our preparation for threats – accidental or intentional.

Like the rest of the world, Emergent transitioned into the post-pandemic environment in 2022, taking bold and decisive actions to invest in our core Products and Services businesses. In December, we announced that the U.S. Food and Drug Administration (FDA) had accepted for Priority Review our supplemental New Drug Application to switch NARCAN® (naloxone HCl) Nasal Spray 4 mg, our opioid overdose treatment, to over-the-counter (OTC). On March 29th, the FDA approved our application, making NARCAN® Nasal Spray the first 4 mg naloxone nasal spray to receive OTC status in the U.S.

We also acted to further strengthen our medical countermeasures franchises, specifically smallpox and anthrax vaccines and treatments. In September, we closed the deal to acquire TEMBEXA® (brincidofovir), an FDA-approved oral antiviral for the treatment of smallpox, and completed two deliveries to the Strategic National Stockpile by the end of the year. And, in June, we announced the FDA's acceptance of our Biologics License Application for AV7909 (Anthrax Vaccine Adsorbed, Adjuvanted), our new anthrax vaccine candidate. In 2019, the AV7909 vaccine was granted pre-Emergency Use Authorization (pre-EUA) status by the FDA, and since then, the U.S. government has been procuring this product for the Strategic National Stockpile. We will work on transitioning this product, if approved, to post-approval procurement in 2023.

Additionally, we invested in our operational, quality and compliance systems and enhanced our technical capabilities and expertise across all our manufacturing sites. These investments will take time to yield dividends, but will strengthen the company's global manufacturing operations so that Emergent can reliably, efficiently, and compliantly provide high-quality products to patients.

While we are pleased with these accomplishments, 2022 handed us a fair share of challenges that we are addressing with strength and resolve to further position the company for success and growth at rates more in line with pre-Covid trends. We are focusing our efforts to improve overall profitability, to supply our ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) vaccine, a first line of defense in a smallpox event, to restructure and extend our debt obligations, and to complete the sale of our Travel Health business that we announced recently. We look forward to delivering on these as well as the aforementioned priorities to enable positive outcomes for all stakeholders – patients, customers, employees, equity investors, and debt capital providers.

I am proud of the Emergent team's dedication to protecting and enhancing life. Threats to public health are real and Emergent is one of a few companies wholly committed to helping governments prepare for and respond to those threats.

As we gear up to celebrate our 25th anniversary in September, I remain confident in the long-term success of this company and the noble mission it serves.

Sincerely,

Robert G. Kramer

Robert G. Kramer
President and Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

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

EMERGENT BIOSOLUTIONS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware		**14-1902018**
(State or Other Jurisdiction of Incorporation or Organization)		**(I.R.S. Employer Identification No.)**

400 Professional Drive, Suite 400
(Address of Principal Executive Offices)

Gaithersburg,	**MD**	**20879**
(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.

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 ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2022 was approximately $1.5 billion based on the price at which the registrant's common stock was last sold on that date as reported on the New York Stock Exchange.

As of February 22, 2023, the registrant had 50,140,158 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2023 annual meeting of stockholders 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, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K. With the exception of the portions of the registrant's definitive proxy statement for its 2023 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, 2022

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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 performance of Emergent BioSolutions Inc. or any of our businesses, our business strategy, future operations, future financial position, future revenues and earnings, projected costs, prospects, plans and objectives of management and the ongoing impact of the Coronavirus Disease 2019 ("COVID-19") pandemic, are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," should," "will," "would," and similar expressions or variations thereof, the negative thereof, but these terms are not the exclusive means of identifying such statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. You should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. You are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date on which such statement is made and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

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

- the availability of U.S. Government ("USG") funding for contracts related to procurement of our medical countermeasures, including AV7909 (Anthrax Vaccine Adsorbed (AVA), Adjuvanted), BioThrax® (Anthrax Vaccine Adsorbed) and ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) among others, as well as contracts related to development of medical countermeasures;
- our ability to meet our commitments to quality and compliance in all of our manufacturing operations;
- our ability to negotiate additional USG procurement or follow-on contracts for our medical countermeasures ("MCM") products that have expired or will be expiring;
- failure to obtain, or delays in obtaining, approval by the U.S. Food and Drug Administration ("FDA") of NARCAN® (naloxone HCl) Nasal Spray for over-the-counter use;
- the impact of a generic marketplace on NARCAN® (naloxone HCl) Nasal Spray and future NARCAN sales;
- 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 and/or product candidates of our customers at required levels and on required timelines;
- the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices and other regulatory obligations;
- our ability to negotiate new CDMO contracts and the negotiation of further commitments related to the collaboration and deployment of capacity toward future commercial manufacturing under our existing CDMO contracts;
- our ability to collect reimbursement for raw materials and payment of service fees from our CDMO customers;
- the results of pending shareholder litigation and government investigations and their potential impact on our business;

- our ability to comply with the operating and financial covenants required by our senior secured credit facilities ("Senior Secured Credit Facilities") and the amended and restated credit agreement related to such facilities (as amended, the "Credit Agreement") and our 3.875% Senior Unsecured Notes due 2028 ("Senior Unsecured Notes");
- our ability to refinance our Senior Secured Credit Facilities prior to their maturity in October 2023;
- the procurement of our product candidates by USG entities under regulatory authorities that permit government procurement of certain medical products prior to FDA marketing authorization, and corresponding procurement by government entities outside of the U.S.;
- the full impact of the COVID-19 pandemic on our markets, operations and employees as well as those of our customers and suppliers;
- the impact on our revenues from and duration of declines in sales of our vaccine products that target travelers due to the reduction of international travel caused by the COVID-19 pandemic;
- the ability of the Company and Bavarian Nordic to consummate the transactions contemplated under the Purchase and Sale Agreement (the "Sale Agreement") pursuant to which we agreed to sell our travel health business, to meet expectations regarding the conditions, timing and completion of the transactions, and to realize the potential benefits of the transactions;
- the impact of the organizational changes we announced in January 2023;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- 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. When evaluating our forward-looking statements, you should consider this cautionary statement along with the risk factors identified in the sections entitled "Risk Factor Summary," "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K and the risk factors identified in our other periodic reports filed with the SEC when evaluating our forward-looking statements. 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.

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

Emergent®, BioThrax®, BaciThrax®, RSDL®, BAT®, Trobigard®, Anthrasil®, CNJ-016®, ACAM2000®, Vivotif®, Vaxchora®, NARCAN®, TEMBEXA® and any and all Emergent BioSolutions Inc. brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent BioSolutions Inc. or its subsidiaries in the United States or other countries. All other brands, products, services and feature names or trademarks are the property of their respective owners.

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 portfolio, and a contract development and manufacturing ("CDMO") services portfolio. 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, which we have agreed to sell to Bavarian Nordic, as described below;
- public health crises (such as the opioid crisis and the Coronavirus Disease 2019 ("COVID-19") pandemic); and
- acute, emergency, and community care.

Our revenues are derived from a combination of the sale and procurement of our product/product candidate portfolio (described below), the provision of our CDMO services to external customers, and non-dilutive contract and grant funding for research and development ("R&D") projects from various third-party sources.

OUR OPERATING SEGMENTS

Beginning in 2022, we report financial results for our business under the following two operating segments:

- our **Products Segment** consisting of Government—MCM and Commercial products; and
- our **Services Segment** consisting of our CDMO services portfolio.

Additionally, we have a centralized R&D organization and an enterprise-wide governance approach to managing our portfolio of R&D projects.

Products Segment

Government—MCM Products

Our Government—MCM business focuses primarily on procurement of MCM products and procured product candidates by domestic and international government customers, with an emphasis on the United States ("U.S.") Government ("USG"), which is our largest customer. We also sell MCM products and procured product candidates to domestic and international non-government organizations and to governments outside of the U.S.

Commercial Products

In the U.S. and international markets, our Commercial business primarily focuses on sales of NARCAN® (naloxone HCl) Nasal Spray and our travelers' vaccines. NARCAN® Nasal Spray is sold commercially through physician-directed or standing order prescriptions at retail pharmacies and to state and local governments and first responders including police, firefighters and emergency medical teams. Our travelers' vaccines include Vaxchora® (Cholera Vaccine, Live, Oral) and Vivotif® (Typhoid Vaccine Live Oral Ty21a), which are approved for use in the U.S. and other territories, and are sold primarily to travel clinics, retail pharmacies, vaccination centers, health departments, and integrated hospital networks.

On February 15, 2023, we entered into the Sale Agreement with Bavarian Nordic, under which we agreed to sell our travel health business, including rights to Vaxchora and Vivotif, as well as our development-stage chikungunya vaccine candidate CHIKV VLP, our manufacturing site in Bern, Switzerland and certain of our development facilities in San Diego, California for a cash purchase price of $270.0 million, subject to certain customary adjustments. In addition, we may receive milestone payments of up to $80.0 million related to the development of CHIKV VLP and receipt of marketing approval and authorization in the U.S. and Europe, and sales-based milestones payments of up to $30.0 million based on aggregate net sales of Vaxchora and Vivotif in calendar year 2026. Approximately 280 employees are expected to join Bavarian Nordic as part of the transaction.

The transaction is expected to close in the second quarter of 2023, subject to certain customary closing conditions, including (1) the expiration or earlier termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (2) receipt of required clearances and approvals under Spain's competition laws, (3) receipt of certain Swiss real property approvals, (4) no material adverse effect having occurred with respect to the business, and (5) certain other customary conditions.

Services Segment

CDMO Services

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). These services, which we collectively refer to as a "molecule-to-market" offering, employ diverse technology platforms across a network of development and manufacturing sites operated by us. These CDMO services support all phases of the drug development life cycle, from pre-clinical development programs through commercial manufacturing of approved pharmaceutical products. The customer base for CDMO services is primarily innovators in the biotechnology and pharmaceutical segments.

THE OUR STRATEGY

In second half of 2022, we conducted an evaluation of our corporate performance relative to our 2020-2024 Strategic Plan and of changes to the external environment in which the Company operates. We decided to replace the 2020-2024 Strategic Plan with a new three-year strategy (2023-2025). Our management believes this three-year plan is necessary to strengthen the Company's financial position and adapt to new strategic priorities. We expect that this strategy will refocus the business and increase the Company's ability to make more aggressive investments for future growth.

For 2023-2025, our priorities will align with a sharpened focus on:

MCMs and Commercial Products — We will focus on products including NARCAN Nasal Spray and on public health preparedness and response, which will leverage our longstanding relationship as a reliable partner to the U.S. and allied governments helping protect against chemical, biological and man-made threats.

Contract Development and Manufacturing Services — We will focus our investments in our existing network of manufacturing sites to strengthen operational, quality, and compliance systems across the enterprise to provide reliable delivery of products and services for both our own products and those of our CDMO customers.

Align R&D Portfolio to focus on areas of leadership — We will continue to focus on advancing our pipeline of vaccines and therapeutic product candidates, with the aim of developing differentiated products that address unmet needs in the PHT space. We fund our pipeline development by investing our own funds and through securing government contracts, grants, or other non-dilutive funding.

PRIMARY PRODUCTS AND PRODUCT CANDIDATES

Government—MCM Products

The current portfolio of our Government—MCM business consists of the following products:

	GOVERNMENT - MCM PRODUCTS	
Product	**Indication(s)**	**Regulatory Approvals, Licensures or Clearances**
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
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
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. BioThrax is approved for: 1. Pre-exposure prophylaxis of disease in persons at high risk of exposure. 2. Post-exposure prophylaxis of disease following suspected or confirmed *Bacillus anthracis* exposure, when administered in conjunction with recommended antibacterial drugs.	United States, Canada, France (where it is known as BaciThrax®), Germany, Italy, the Netherlands, Poland, Singapore and UK
Ebanga™ (Ansuvimab-zykl), a monoclonal antibody	Treatment of infection caused by *Zaire ebolavirus* in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for *Zaire ebolavirus* infection.	United States
Raxibacumab injection, a fully human monoclonal antibody	Treatment of adult and pediatric patients with inhalational anthrax due to *Bacillus anthracis* in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate.	United States
RSDL® (Reactive Skin Decontamination Lotion Kit)	Intended to remove or neutralize chemical warfare agents and T-2 Toxin from the skin.	United States (510k), Australia, Canada, European Union and Israel
TEMBEXA® (brincidofovir), oral antiviral	Treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates.	United States
Trobigard® Auto-injector atropine sulfate, obidoxime chloride auto-injector	Indicated for the emergency treatment of known or suspected exposure to nerve agents or toxic organophosphates in adults > 18 years of age.	Belgium*

GOVERNMENT - MCM PRODUCTS		
Product	**Indication(s)**	**Regulatory Approvals, Licensures or Clearances**
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). VIGIV is not indicated for postvaccinial encephalitis.	United States, Canada

**TROBIGARD® is not approved by the* U.S. Food and Drug Administration ("FDA"). *It is only approved by the Belgian Health Authority but has been procured by various government entities for emergency preparedness purposes*.

Description of MCM Products

ACAM2000®. ACAM2000 vaccine is a smallpox vaccine licensed by the FDA and comprises the largest percentage of the current USG stockpile in the Strategic National Stockpile ("SNS") designated for use in a bioterrorism emergency. ACAM2000 vaccine is currently stockpiled both in the U.S. and internationally. Smallpox is a highly contagious disease caused by the Variola virus. According to the Centers for Disease Control and Prevention ("CDC"), smallpox is a devastating disease, 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 vaccine into the 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 $170.0 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 $176.0 million, to procure doses of ACAM2000 vaccine. The number of doses under the first contract option were delivered by year end 2020. On July 13, 2021, we announced the exercise by HHS of the second contract option, valued at $182.2 million, to procure doses of ACAM2000 vaccine. We completed the delivery of all ACAM2000 doses in 2022. The USG chose to not exercise its option year in 2022. Therefore, we are currently in discussions with HHS regarding future procurement of ACAM2000 vaccine and what is necessary for the USG to maintain ACAM2000 in the SNS. The actual number of ACAM2000 doses to be procured in the future are subject to the outcome of our discussions.

Anthrasil®. Anthrasil [Anthrax Immune Globulin Intravenous (Human)] ("Anthrasil Anthrax IGIV") is the only polyclonal antibody therapeutic licensed by the FDA for the treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs. We currently have two contracts with HHS for Anthrasil Anthrax IGIV: a development and procurement contract that expires in September 2023, 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 USG sales, Anthrasil Anthrax IGIV has been sold to several foreign governments, including the Canadian government.

BAT®. BAT antitoxin is the only equine plasma antitoxin licensed by the FDA and Health Canada for the treatment of all seven botulinum neurotoxin serotypes. BAT antitoxin 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 Extraordinary Use New Drugs regulations. BAT antitoxin is the only heptavalent botulism antitoxin available in the U.S. 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 $550.0 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 $90.0 million, is to supply annual doses of BAT antitoxin 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 $94.0 million over 10 years. The second deliverable, valued at up to approximately $366.0 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 antitoxin continues to be sold internationally, with deliveries to over 17 foreign governments in 2022.

BioThrax®. BioThrax vaccine is the only vaccine licensed by the FDA for pre-exposure prophylaxis of anthrax disease in persons at high risk of exposure. BioThrax vaccine is also approved by the FDA for post-exposure prophylaxis administration in combination with antimicrobial therapy in the event of suspected or confirmed exposure to *Bacillus anthracis*. 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 U.S., BioThrax vaccine 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 six and 12 months after completion of the primary series and at 12- month intervals thereafter. BioThrax vaccine is administered in a post-exposure prophylaxis setting as three subcutaneous injections two weeks apart 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 vaccine 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 vaccine for delivery into the SNS, over a five-year period ending in September 2021. On September 29, 2021, we were granted a no-cost contract extension, which extended the date through which the USG procured BioThrax vaccine to March 31, 2022. On June 16, 2022, the contract's period of performance was extended to June 30, 2022. All deliveries under this contract were completed in August 2022.

Ebanga™ (Ansuvimab-zykl), a monoclonal antibody. Ebanga™ (Ansuvimab-zykl) is a monoclonal antibody with antiviral activity provided through a single IV infusion (over 60 minutes) for the treatment of Zaire ebolavirus in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for Zaire ebolavirus. On July 1, 2022, we entered into an agreement with Ridgeback Biotherapeutics ("Ridgeback") in which the parties agreed to negotiate a Collaboration Agreement to expand the availability of Ebanga™ (Ansuvimab-zykl). We will be responsible for manufacturing, selling and distributing Ebanga™ (Ansuvimab-zykl) in the U.S. and Canada and Ridgeback will serve as the global access partner.

Raxibacumab injection, a fully human monoclonal antibody. 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.

RSDL®. RSDL kit is 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 kit 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 Therapeutic Goods Administration. To date, the principal customers for RSDL kits have been agencies of the USG, including the Department of Defense ("DoD") and the National Guard. In addition to the DoD and other USG agencies, beginning in 2017, we made RSDL kit available for the first time for purchase by civilians in the U.S. Our current contract with the DoD awarded in December 2022 is a five-year contract including a base year period and four single year option periods, valued at up to $379.6 million to supply RSDL kits for use by all branches of the U.S. military. We also sold RSDL kits to nine foreign countries outside the U.S. in 2022. In November 2022, a specific batch of our RSDL kits was recalled due to leakage, which could cause the product not to perform as effectively as intended. There have been no reports of injuries or death related to this recall of which we are aware.

TEMBEXA® (brincidofovir). TEMBEXA is the first oral antiviral approved by the FDA for the treatment of smallpox disease caused by variola virus in adult and pediatric patients, including neonates. On September 26, 2022, we acquired exclusive worldwide rights to brincidofovir from Chimerix Inc. for the treatment of any human smallpox disease or any other disease caused by any orthopox virus. Following the acquisition, the 10-year contract with the Biomedical Advanced Research and Development Authority ("BARDA"), valued at up to $680.0 million, to supply up to 1.7 million tablet and suspension formulations of TEMBEXA was novated to the Company.

Trobigard® atropine sulfate, obidoxime chloride auto-injector. TROBIGARD auto-injector was approved by the Federal Agency for Medicines and Health Products of the Belgium Health Authority on February 18, 2021. TROBIGARD auto-injector is not currently approved or cleared by the FDA. TROBIGARD auto-injector is only distributed to authorized government buyers for use outside the U.S. In Belgium, the TROBIGARD auto-injector is indicated for the emergency treatment of known or suspected exposure to nerve agents or toxic organophosphates in adults (> 18 years of age). In February 2019, Emergent was awarded a 10-year contract, valued at up to approximately $100.0 million, by the U.S. Department of State, to procure our TROBIGARD product, training auto-injectors and RSDL kits for emergency use outside of the U.S. The contract consists of a five-year base period of performance with five one-year option periods.

VIGIV CNJ-016®. VIGIV is the only polyclonal antibody therapeutic licensed by the FDA and Health Canada to address certain complications from replicating virus smallpox vaccination. The principal customer for VIGIV is the USG, specifically HHS. In June 2019, we announced a contract award by HHS valued at approximately $535.0 million over 10 years for the continued supply of VIGIV into the SNS for smallpox preparedness. VIGIV has also been procured by a limited number of foreign governments.

Commercial Products

Our current Commercial portfolio consists of the following products:

	COMMERCIAL PRODUCTS	
Product	**Indication(s)**	**Regulatory Approvals**
NARCAN® (naloxone HCl) Nasal Spray	Emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression.	United States, Canada
Vaxchora® (Cholera Vaccine Live Oral)	U.S.: Vaxchora (Cholera Vaccine Live Oral) is a vaccine indicated for active immunization against disease caused by *V. cholerae* serogroup 01. Vaxchora is approved for use in persons two- 64 years of age traveling to cholera-affected areas. EUROPEAN UNION: Vaxchora is indicated for active immunization against disease cause by *V. cholerae*	United States, European Union

COMMERCIAL PRODUCTS		
Product	**Indication(s)**	**Regulatory Approvals**
	serogroup 01 in adults and children aged two years and older. In February 2023 we agreed to sell Vaxchora as part of the sale of our travel health business to Bavarian Nordic.	
Vivotif® (Typhoid Vaccine Live Oral Ty21a)	For immunization of adults and children greater than 6 years of age against disease caused by *Salmonella typhi.* In February 2023 we agreed to sell Vivotif as part of the sale of our travel health business to Bavarian Nordic.	United States, Austria, Australia, Belgium, Canada, Czech Republic, Denmark, France, Finland, Germany, Israel, Italy, Luxembourg, Malaysia, the Netherlands, New Zealand, Norway, Poland, Portugal, Slovakia, South Korea, Spain, Sweden, Switzerland and United Kingdom

Description of Commercial Products

NARCAN®. NARCAN 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. We completed two important product life cycle improvements in 2020. First, we launched the Generation II NARCAN 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 Nasal Spray from 24 months to 36 months.

In the fourth quarter of 2022, we filed our supplemental New Drug Application ("sNDA") for NARCAN® (naloxone HCl) Nasal Spray, as an over-the-counter ("OTC") emergency treatment for known or suspected opioid overdose. The FDA accepted the application and also granted Priority Review. If approved, it would be the first 4 mg naloxone nasal spray available OTC in the U.S. The Prescription Drug User Fee Act ("PDUFA") goal date is March 29, 2023. On February, 15, 2023, the U.S. Food and Drug Administration (FDA) Nonprescription Drugs Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee unanimously voted in favor (a total of 19 votes) that the benefit-risk profile of NARCAN® (naloxone HCl) Nasal Spray was supportive of its use as a nonprescription opioid overdose reversal agent. The FDA is not bound by the committees' guidance but will take its advice into consideration.

Vaxchora®. Vaxchora vaccine 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 U.S. and Europe, but a high incidence in Africa, Southeast Asia, and other locations around the world. These areas have historically drawn travelers from the U.S. and Europe, so cholera can occur in patients who return to the U.S. or Europe from visits to these regions. Vaxchora vaccine is approved in the U.S. for active immunization against disease caused by *V. cholerae* serogroup 01 in persons two to 64 years of age traveling to cholera-affected areas. Vaxchora vaccine is indicated in the European Union ("EU") for active immunization against disease caused by *V. cholerae* serogroup 01 in adults and children aged two years and older.

We have marketed Vaxchora vaccine to travelers primarily from the U.S. to cholera at-risk destinations. Our sales of Vaxchora vaccine were diminished in 2020 and 2021 due to the broad disruption to travel caused by the COVID-19 pandemic. Vaxchora vaccine was launched in the EU in August 2022. In February 2023, we agreed to sell Vaxchora as part of the sale of our travel health business to Bavarian Nordic.

Vivotif®. Vivotif vaccine 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. In February 2023 we agreed to sell Vivotif as part of the sale of our travel health business to Bavarian Nordic.

We have marketed Vivotif vaccine to travelers primarily from the U.S. and the EU traveling to at-risk destinations. Our sales of Vivotif vaccine were diminished in 2020 and 2021 due to the broad disruption to travel caused by the COVID-19 pandemic. Sales of Vivotif vaccine resumed in 2022 and we expect that global travel will return to pre-pandemic levels by the end of 2023.

Product Candidates

The table below highlights our current portfolio of product candidates:

PRODUCT CANDIDATES

Product Candidate	Target Indication
AV7909 (Anthrax Vaccine Adsorbed, Adjuvanted)	Post-exposure prophylaxis of disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when administrated in conjunction with recommended antibacterial drugs (currently procured by the USG under pre-Emergency Use Authorization ("EUA") prior to approval by the FDA and included in revenue for Anthrax Vaccines).
CGRD-001 (Pralidoxime chloride/atropine auto-injector)	Treatment of poisoning by organophosphorus nerve agents or organophosphorus compounds.
CHIKV VLP Chikungunya virus VLP vaccine	Active immunization to prevent disease caused by Chikungunya virus. In February 2023 we agreed to sell CHIKV VLP as part of the sale of our travel health business to Bavarian Nordic.
EBS-LASV (rVSV-vectored vaccine for Lassa fever)	Active immunization to prevent Lassa fever.
EGRD-001 (Diazepam auto-injector)	Adjunct treatment in status epilepticus and severe recurrent convulsive seizures caused by nerve agent poisoning.
SIAN (stabilized isoamyl nitrite)	Antidote for initial treatment of certain or suspected acute cyanide poisoning. Standard of care supportive measures should be applied as appropriate. SIAN is not a substitute for ongoing emergency medical care.
UniFlu (Universal influenza vaccine)	Intended to induce broad and supra-seasonal immunity against influenza A and B viruses.

Description of Product Candidates

AV7909. We are developing AV7909, an anthrax vaccine product candidate based on anthrax vaccine adsorbed combined with an adjuvant for post-exposure prophylaxis of disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs. In 2021, AV7909 was granted orphan drug designation by the FDA. Studies

have shown that AV7909 elicits a stronger immune response using fewer doses than BioThrax vaccine, which is expected to allow patients to reach a protective level of immunity more rapidly. AV7909 is designed to provide protection with a two-dose regimen (versus the BioThrax three-dose regimen) for post-exposure prophylaxis of anthrax disease, when administered in combination with the recommended antibacterial drugs. 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 50.0 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-EUA submission package related to AV7909. Following this submission, BARDA began procuring AV7909, exercising its first contract option in July 2019 (valued at approximately $261.0 million) to procure doses to be delivered to the SNS through June of 2020, its second contract option in June 2020 (valued at $258.0 million) to procure additional doses of AV7909 for delivery into the SNS over 12 months and, most recently, in September 2021 funding another contract option (valued at approximately $399.0 million) to deliver doses of AV7909 to the SNS over 18 months. In April 2022, we completed our submission of a Biologics License Application ("BLA") for AV7909 to 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).

CGRD-001. The CGRD-001 auto-injector is being developed for treatment of poisoning by organophosphorus nerve agents, as well as organophosphorus compounds for use by military personnel. CGRD-001 is being developed as an auto-injector for delivery of 600 mg of pralidoxime and 2 mg of atropine for intramuscular injection following nerve agent exposure. The product is being designed for injection by non-medical personnel, including self-injection or buddy aid by service members. Currently we are manufacturing registration batches and undergoing design verification.

CHIKV VLP. We are developing a chikungunya virus (CHIKV) virus-like particle (VLP) vaccine candidate, CHIKV VLP, to be administered as a single dose for active immunization against chikungunya disease. There is currently no licensed vaccine, VLP or otherwise, to prevent chikungunya virus disease. The structure of the CHIKV VLP vaccine is nearly identical to the wild-type virus but does not pose a risk of replication. Studies conducted by the National Institute of Allergy and Infectious Diseases ("NIAID") Vaccine Research Center and Emergent have shown that the CHIKV VLP vaccine is well-tolerated and elicits high titer neutralizing antibodies, which are needed to protect against chikungunya virus. CHIKV VLP is currently being investigated in two pivotal phase 3 trials. Our CHIKV VLP vaccine candidate received Breakthrough Therapy designation and Fast Track designation from the FDA in October 2020 and May 2018, respectively, and PRIME designation from the European Medicines Agency (EMA) in September 2019. In February 2023, we agreed to sell CHIKV VLP as part of the sale of our travel health business to Bavarian Nordic.

EBS-LASV. This vaccine candidate is a recombinant, vesicular stomatitis virus vectored, monovalent vaccine encoding the surface glycoprotein precursor gene of Lassa virus. The development program is partnered with the Coalition for Epidemic Preparedness Innovations ("CEPI") and is currently in Phase 1 with the trial ongoing in Ghana. CEPI will decide on Phase 2 funding in the second quarter of 2023. A correlate of protection is not yet identified.

EGRD-001. The EGRD-001 auto-injector is being developed for treatment of status epilepticus and severe recurrent convulsive seizures caused by nerve agent poisoning, for use by military personnel and first responders. EGRD-001 is being developed as an auto-injector for the intramuscular delivery of 10 mg of diazepam in individuals who are actively seizing.

SIAN. We are developing SIAN (stabilized isoamyl nitrate) as an antidote for initial treatment of acute poisoning of cyanide that is judged to be serious or life threatening. The USG consistently identifies cyanide

("CN") as a high-priority threat, most recently in the Public Health Emergency Medical Countermeasure Enterprise 2022 Strategy and Implementation Plan. Historically, CN has been used as a chemical warfare agent and could be an agent for a terrorist attack. CN also represents a threat from accidental poisoning, such as industrial accidents or exposure during building fires. The SIAN program is funded by BARDA and is focused on the development of a single-use intranasal spray device that can be rapidly deployed and easily dispensed so that it will deliver SIAN following a cyanide incident or in a mass exposure setting. In 2022, we initiated a Phase 1 study designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of our SIAN product candidate.

UniFlu. We are developing a universal influenza vaccine candidate based on a nanoparticle technology involving a cross-reactive hemagglutinin (HA) antigen for active immunization against influenza virus A and B. The nanoparticle technology was developed by and licensed from the NIAID Vaccine Research Center. Using this technology, we are seeking to develop a universal influenza vaccine designed to confer protection against numerous strains and subtypes of influenza virus. In 2021, we initiated a Phase 1 study designed to assess safety, tolerability, and immunogenicity of the influenza virus A components of the vaccine candidate with future studies planned to investigate additional components, including for full coverage against all influenza virus A and B strains.

Description of Services

CDMO Services. Our CDMO Services are based on our established development and manufacturing infrastructure, technology platforms and expertise, as well as continuing capital expenditure projects to expand our capabilities and increase capacity.

Our CDMO Services consist of development services, bulk drug substance manufacturing, fill, finish, and packaging of final drug product. Collectively, this portfolio of services provides "molecule-to-market" solutions to clients engaged in all stages of drug development and commercialization. These services are provided to innovator biopharmaceutical companies and non-governmental organizations ("NGOs").

We currently have 10 development and manufacturing sites located in the U.S., Canada and Switzerland. These sites allow us to meet our internal manufacturing needs as well as performing services for our external customers. Eight of these sites currently provide CDMO services to customers.

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

We currently have over 50 active CDMO customers.

Marketing and Sales

We have dedicated sales channels for each of our products and service offerings.

Government—MCM Products.

We partner with stakeholders in the USG and domestic NGOs to support procurement of our MCM products and procured product candidates.

We also partner with foreign governments and international NGOs to support procurement of MCM products and procured product candidates internationally.

Our specialized team has expertise and experience in the public and private sector, dealing with counter terrorism, CBRNE preparedness and public health.

Commercial Products.

In the U.S. market, NARCAN (naloxone HCl) Nasal Spray is sold directly to state and local governments and used by first responders, including: police, firefighters and emergency medical teams. In addition, NARCAN Nasal Spray is dispensed to patients at risk of an opioid overdose through retail pharmacies as prescribed by a physician. In 2022, we submitted a supplemental New Drug Application (sNDA) requesting that FDA switch Narcan (4mg) from a prescription drug to an over-the-counter medicine. The PDUFA goal date for that application is March 29, 2023. On February, 15, 2023, the U.S. Food and Drug Administration (FDA) Nonprescription Drugs Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee unanimously voted in favor (a total of 19 votes) that the benefit-risk profile of NARCAN® (naloxone HCl) Nasal Spray was supportive of its use as a nonprescription opioid overdose reversal agent. The FDA is not bound by the committees' guidance but will take its advice into consideration.

Vivotif® and Vaxchora® vaccines are 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. The primary commercial customers of Vivotif and Vaxchora vaccines are travel clinics, retail pharmacies, vaccination centers, health departments and integrated hospital networks. Sales of these products were significantly reduced in 2020 and 2021 due to the broader disruption to travel caused by the COVID-19 pandemic. Sales of Vivotif vaccine fully resumed in 2022. Vaxchora vaccine was launched in the EU and sales of Vaxchora vaccine are expected in the first quarter of 2023 in the U.S. We expect sales to be influenced by the continued impact of the COVID-19 pandemic on global travel.

CDMO Services.

We market our CDMO services to the global pharmaceutical and biotechnology industry, governments and NGOs. We also provided CDMO services to the USG, which ended in 2021. Our CDMO services are supported by a dedicated group of professionals qualified to represent the full breadth of our service offerings.

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. The competition for our products and product candidates includes the following:

- ***ACAM2000***®. ACAM2000 vaccine 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. ACAM2000 vaccine faces competition from JYNNEOS™ vaccine, which is licensed by the FDA for the prevention of smallpox and mpox disease in adults 18 years of age and older determined to be at high risk for smallpox or mpox infection. JYNNEOS vaccine is also approved in Canada and in the EU under the trade names IMVAMUNE® and IMVANEX®, respectively.
- ***AV7909 and BioThrax***. AV7909 and BioThrax vaccines are currently procured, primarily by the USG, for prevention of anthrax disease. BioThrax vaccine is currently the only anthrax vaccine approved by the FDA for prevention of anthrax disease, and AV7909 and BioThrax are the only anthrax vaccines procured by the USG for the SNS to date. We face potential future competition for the supply of anthrax vaccines if the USG chooses to procure alternative products or product candidates. 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 these product candidates, Altimmune and Blue Willow Biologics have completed Phase 1 trials.
- ***BAT***®. Our botulinum antitoxin immune globulin product is the only heptavalent antitoxin licensed by the FDA and Health Canada for the treatment of symptomatic botulism for all seven botulinum neurotoxin serotypes. Direct competition is currently limited.

- ***CNJ-016***®. 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 EU approval for TPOXX® (tecovirimat), an oral therapy, for the treatment of complications following vaccination against smallpox. TPOXX is currently procured by the USG for the SNS.
- ***Ebanga***™ (Ansuvimab-zykl). A monoclonal antibody therapeutic approved by the FDA in December 2020 for the treatment of infection caused by Zaire Ebolavirus in adult and pediatric patients, including neonates born to RT-PCR+ mother for Zaire Ebolavirus infection. Ebanga faces competition from another monoclonal antibody, Inmazeb (atoltivimab, maftivimab and odesivimab-ebgn), which was approved by the FDA in October 2020 with the same indication. Inmazeb is currently procured by the USG for the SNS.
- ***NARCAN***®. 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 generic versions of an intranasal naloxone spray based on NARCAN approved by the FDA and Health Canada. Teva launched its generic naloxone nasal spray in the U.S. In 2021 Padagis Pharmaceuticals also has a generic version of an intranasal naloxone spray based on NARCAN approved by the FDA. Padagis launched its generic naloxone nasal spray. NARCAN Nasal Spray also faces branded competition: Kloxxado™ (naloxone HCl) nasal spray 8 mg, a branded product developed by Hikma Pharmaceuticals, Inc., Amphastar Pharmaceuticals, Inc.'s naloxone injection product, Teleflex Medical Inc's Intranasal Mucosal Atomization Device and Zimhi™ (naloxone), a branded injectable product developed by Adamis. In addition, Harm Reduction Therapeutics has announced filing of an OTC NDA application for a 3mg naloxone nasal spray formulation intended for use in opioid overdose reversal. NARCAN may face additional generic and branded competition in the future.
- ***Raxibacumab and Anthrasil® [Anthrax Immune Globulin Intravenous (human)]***. Our raxibacumab product is the first FDA-licensed fully human anthrax monoclonal antibody therapeutic and Anthrasil [Anthrax Immune Globulin Intravenous (human)] 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. 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.
- ***RSDL***®. In the U.S., the RSDL Kit is one of only two medical devices 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.
- ***TEMBEXA® (brincidofovir)***. TEMBEXA is the first oral antiviral approved by the FDA, in June 2021, for all age groups for the treatment of smallpox. TEMBEXA faces competition from TPOXX® (tecovirimat), an oral therapy for the treatment of smallpox disease that was approved by the FDA in July 2018 and is currently procured by the USG for the SNS. TPOXX is also approved in Canada and the EU. In the EU, TPOXX is indicated for the treatment of smallpox, mpox and cowpox, as well as the treatment of complications following vaccination against smallpox.
- ***Trobigard® atropine sulfate, obidoxime chloride auto-injector***. In the U.S., Meridian Medical Technologies has been the primary supplier of nerve-agent antidote auto-injectors. The USG has funded the development of a number of nerve agent antidote auto-injectors including development programs at Aktiv Pharma Group, Kaleo and others. Outside of the U.S. there are a number of suppliers of these devices though few with approvals from national or regional regulatory authorities.
- ***Vaxchora***®. In the U.S., Vaxchora vaccine is the only FDA-licensed vaccine available indicated to prevent cholera. Vaxchora vaccine is the only single-dose cholera vaccine in the EU and is subject to

competition by Valneva's Dukoral® two-dose cholera vaccine in the EU. In February 2023, we agreed to sell Vaxchora as part of the sale of our travel health business to Bavarian Nordic.

- ***Vivotif***®. Vivotif vaccine is the only FDA-approved oral typhoid vaccine. In the markets where Vivotif vaccine is licensed, it competes primarily with Sanofi Pasteur's Typhim VI® vaccine, an injectable polysaccharide typhoid vaccine. In February 2023, we agreed to sell Vivotif as part of the sale of our travel health business to Bavarian Nordic.

CDMO Services

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

Companies with which we compete to provide CDMO services include, among others: Lonza Group Ltd., Catalent, Inc., Thermo Fisher Scientific, Curia Global, Inc., Charles River Laboratories, Avid Bioservices, KBI Biopharma, Vetter Pharma, and FUJIFILM Diosynth Biotechnologies. We also compete with in-house research, development and support service departments of other biopharmaceutical companies.

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 vaccines, from a single-source supplier for which we currently 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.

INTELLECTUAL PROPERTY

We actively seek to protect intellectual property related to our 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, materials 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.

REGULATION

Regulations in the U.S. 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 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 the Export Administration Regulations and 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. Our role and status as a large government supplier to HHS, particularly BARDA increases the likelihood of Congressional review and oversight. The legal framework we are subject to as a government contractor imposes 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 laws, 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 CBRNE agents.

The Pandemic and All Hazards Preparedness Act of 2006 and Reauthorization Acts. The Pandemic and All Hazards Preparedness Act of 2006 established the role of Assistant Secretary for Preparedness and Response ("ASPR") within HHS and provided statutory authorities for a number of programs, including the creation of BARDA to support the development and procurement of MCMs to respond to CBRNE. 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 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 CBRNE agents. It has also procured and stockpiled many of our related products for potential use in the event of a PHT emergency, including BioThrax, ACAM2000, Anthrasil, BAT, VIGIV and raxibacumab products.

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

Emergency Use Authorization

Section 564 of the Federal Food, Drug, and Cosmetics Act ("FDCA") authorizes FDA to issue EUAs to permit the introduction into interstate commerce of unapproved MCMs, or approved MCMs for unapproved uses, in the context of certain potential or actual public health emergencies. Several actions are required to trigger FDA's authority to issue EUAs. First, there must be a determination by certain federal officials that a particular threat or emergency exists. This can be (1) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves CBRN agents; (2) a determination by the Secretary of Homeland Security ("DHS") that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a CBRN agent; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces from a CBRN agent; or (4) the identification of a material threat pursuant to section 319F–2 of the Public Health Service Act ("PHSA") sufficient to affect national security or the health and security of United States citizens living abroad. Based on one of these determinations, the Secretary of HHS may make a declaration that circumstances exist justifying EUAs for MCMs to respond to the threat or emergency at issue. Once the relevant determination and declaration are issued, FDA has the authority to issue EUAs for the use of specific medical 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 related to the threat or emergency and that there are no adequate, approved, and available alternatives to the issuance of an EUA. EUAs are subject to additional conditions and restrictions, are product-specific, and terminate when the EUA is revoked or the emergency determination or declaration underlying the EUA terminates.

Under PAHPRA, the USG may purchase certain MCMs for the SNS prior to FDA approval, licensure or authorization, under certain circumstances. BARDA is currently procuring AV7909, a product candidate that has not been approved or authorized by FDA under these authorities.

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 related to a specific disease, condition or public health threat. A PREP Act declaration is intended to provide liability immunity from claims under federal or state law for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered MCM. The only statutory exception to this immunity is for actions or failures to act that constitute willful misconduct. The Secretary of HHS has issued PREP Act declarations covering MCMs for smallpox, mpox, and other orthopox; anthrax; and botulinum toxin. These declarations could apply to BioThrax, ACAM2000, raxibacumab, Anthrasil, BAT and VIGIV products, as covered MCMs. The declarations for anthrax and botulism expire on December 31, 2027. The declaration for smallpox, mpox, and other orthopox expires on December 31, 2032.

Support Anti-Terrorism by Fostering Effective Technology Act of 2002. The Support Anti-terrorism by Fostering Effective Technologies Act of 2002 ("SAFETY Act") was enacted to create certain liability limitations for Qualified Anti-Terrorism Technologies ("QATTs") for claims arising out of, related to, or resulting from an act of terrorism. DHS administers the SAFETY Act program, which provides two potential categories of liability protections – designation and certification. If DHS deems an MCM a "Designated Technology," then the company's liability is limited to the amount of liability insurance that DHS determines the company must maintain. To receive "certification," a QATT must first be "designated" and also be shown to perform as intended, conform to the manufacturer's specifications, and be safe for use as intended. Certification allows the company to assert the Government Contractor defense for claims arising from acts of terrorism.

DHS granted SAFETY Act designation and certification for BioThrax and RSDL in 2006 and has continued to renew those determinations. Any future renewals of the SAFETY Act designation and certification for BioThrax and RSDL products 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 human clinical trials to determine efficacy of MCMs against dangerous pathogens may sometimes be unethical or unfeasible. In such circumstances, products may be approved under the FDA's "Animal Rule." According to the FDA, this regulatory pathway can only be pursued if conducting human efficacy studies would be unethical and field trials to study the product's effectiveness, after an accidental or deliberate exposure, are not feasible. 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 and efficacy data from animal studies. These approvals generally are associated with a requirement for post-approval trials that would be conducted in the event of an act of bioterrorism, a pandemic, or other natural exposure to the pathogen at issue.

Investigational New Drug Application. Before clinical testing may begin, the results of pre-clinical testing and other available clinical data and manufacturing information 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. The FDA may impose a full or partial clinical hold on the effectiveness of an IND pending receipt of additional information.

Clinical Trials. Clinical trials involve administration of a product candidate to healthy human volunteers or patients under the supervision of a qualified physician under a regulatory agency approved protocol for the country in which the human trial is to be conducted. 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 safety, 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.
- Phase 3 trials must assess clinical efficacy and safety in a larger number of healthy subjects or patients, are intended to permit the FDA to evaluate the overall benefit-risk relationship of the product and provide adequate information for drug labeling.

In addition, in certain circumstances Phase 4 studies may be conducted following marketing approval in order 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 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 NDA filing. The submission of an application, either a BLA or an NDA, is not a guarantee that the FDA will find the application complete and accept it for filing. The FDA may issue a refuse to file, or RTF, letter to the applicant 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 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 decline to approve the application if, if among other potential deficiencies, the FDA determines that the application does not provide substantial evidence of effectiveness, the drug is not safe for use under the conditions of use in the proposed labeling, or there are deficiencies in manufacturing quality. If the FDA decides not to approve an application, it will issue a complete response letter, or CRL. During the application, the FDA will also typically inspect one or more clinical sites to ensure compliance with GCPs as well as the facility or facilities at which the candidate is manufactured to ensure compliance with current good manufacturing practices ("cGMPs").

The receipt of regulatory approval may take many years, and typically involves the expenditure of substantial financial resources. 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 a full NDA for innovator products, or an abbreviated new drug application ("ANDA") for generic products. 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 (reference listed drugs, or 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 required to demonstrate that its product contains the same active ingredient as, and is bioequivalent to, the innovator product, among other requirements. For a systemically absorbed drug, bioequivalence generally is established when there is an absence of a significant difference in the rate and extent of absorption of the generic product and the listed drug.

A third alternative for approval of a drug product 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 might 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 submit other information 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 submit to the FDA information about 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 for which the applicant has submitted information in connection with the NDA is then published in the Orange Book. Any subsequent applicant who files an ANDA or a 505(b)(2) NDA must make one of the following certifications to the FDA concerning each patent for which the RLD sponsor was required to submit information in connection with the RLD: (1) the patent information has not been submitted to the FDA; (2) has expired; (3) the date on which the patent will expire; or (4) the patent is invalid, unenforceable, or will not be infringed 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. Alternatively, the ANDA or 505(b)(2) NDA applicant may submit a statement that there are no relevant patents or that a method-of-use patent does not claim a proposed indication or other condition of use for which the applicant is seeking approval.

If the RLD's NDA holder or patent owner initiates patent litigation to enforce an Orange Book-listed patent within 45 days after receiving notice of a paragraph IV certification, the FDA generally is prohibited from approving the application until the earlier of 30 months from the date of receipt of the paragraph IV notice, although this stay may terminate earlier depending upon the resolution of the litigation, if the court issues an order terminating the stay, or if the patent owner or exclusive patent licensee consents to approval of the application before the expiration of the stay. 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 RLD has expired.

Biosimilar Products. When a biological product is licensed for marketing by FDA through the approval of a BLA under section 351(a) of the PHSA, the product may be entitled to exclusivity barring FDA from accepting or approving an application under section 351(k) of the PHSA for a competing products for certain periods of time. The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") added Section 351(k) of the PHSA, which provides an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA may approve a biosimilar product if it finds that the product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the proposed biosimilar product and the reference product in terms of safety, purity, and potency. For the FDA to approve an interchangeable biosimilar product, it must conclude that the product is biosimilar to the reference product, can be expected to produce the same clinical result as the reference product in any given patient, and—for a product that is administered more than once to an individual—alternating or switching between the proposed interchangeable product and the reference product would not create an increased risk in terms of safety or diminished efficacy compared to using the reference product only.

FDA will not accept a biosimilar application until four years after the date of first licensure of a biological product licensed under section 351(a) of the PHSA, and FDA will not approve a biosimilar application until 12 years after such date of first licensure. This type of exclusivity is known as reference product exclusivity. The approval of a supplemental BLA or certain subsequent BLAs does not give rise to a new date of first licensure, and, consequently, does not yield an additional period of reference product exclusivity. from the date of first licensure of a biological product approved under section 351(a), Moreover, reference product exclusivity does not affect the timing of FDA's acceptance or approval of a competing sponsor's section 351(a) BLA containing the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of its product. There have been recent legislative proposals to reduce the duration of the 12-year reference product exclusivity period, but none has been enacted to date. Moreover, many states have enacted laws that address pharmacy practices involving biosimilar products.

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 events, providing FDA with updated safety and efficacy information, product sampling and distribution requirements, restrictions on advertising and promotion, and FDA inspections. 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.

Orphan Drugs. Under the Orphan Drug Act, an applicant can request the FDA to designate a product as an "orphan drug" in the U.S. if the drug is intended to treat a rare disease or condition. A disease or condition is considered rare if it affects fewer than 200,000 people in the U.S. or there is no reasonable expectation that the cost of developing the drug and making it available in the United States will be recovered from sales in the United States. A manufacturer must request orphan drug designation prior to submitting a BLA or NDA. Products designated as orphan drugs may be eligible for special grant funding for R&D, FDA assistance with the review of clinical trial protocols, potential tax credits for research, an exemption from the application fee for marketing applications and a seven-year period of orphan drug exclusivity after marketing approval. A grant of an orphan designation is not a guarantee that a product will be approved.

Orphan drug exclusivity (afforded to the first applicant to receive approval for an orphan designated drug for a particular rare disease or condition) generally prevents FDA approval of another sponsor's application for the same drug or for the same rare disease or condition. Orphan drug exclusivity will not bar approval of the same product marketed by a different manufacturer under certain circumstances, including if the company with orphan drug exclusivity is not able to meet market demand or the subsequent product is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care.

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. FDA may request samples of any lot and, when deemed necessary for the safety, purity, and potency of the product, FDA may prohibit us from distributing a lot until FDA releases the lot. Several of our vaccines are subject to lot release protocols by the FDA and other regulatory agencies.

Marketing Approval – Devices

Devices may be marketed as stand-alone devices or as constituent parts of a Combination Product, such as a device for delivery of a drug product. Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, approval of a premarket approval application ("PMA") or issuance of a de novo classification order.

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. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a pre-market notification. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining life-supporting or many implantable devices, or devices that have been found not substantially equivalent to a legally marketed Class I or Class II predicate device, are placed in Class III, requiring approval of a PMA.

All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption ("IDE") regulations that govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of study review and approval, informed consent, recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. All clinical device studies, including non-significant risk studies, must be approved by, and conducted under the oversight of, an Institutional Review Board ("IRB"). The IRB is responsible for the initial and continuing review of the study and may pose additional requirements for the conduct of the study.

Both before and after a medical device is commercially distributed, manufacturers and marketers of the device have ongoing responsibilities under FDA regulations, including, for example, establishment registration and device listing; compliance with the requirements of the Quality System Regulation ("QSR"); compliance with requirements regarding the labeling and marketing of devices; medical device reporting regulations; correction and removal reporting regulations; compliance with requirements for Unique Device Identification ("UDI"); and post-market surveillance activities and requirements.

Device manufacturers are subject to periodic and unannounced inspection by the FDA. The FDA reviews design and manufacturing practices, record keeping, reports of adverse events, labeling and other information to ensure compliance with the QSR and other applicable requirements, and to identify potential problems with manufacturing processes and marketed medical devices.

A combination product is a product comprised 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 (cross-labeling). Like their constituent parts—e.g., drugs and devices—combination products are highly regulated and subject to a broad range of pre- and post-market requirements including premarket review, cGMPs, or QSRs, adverse event reporting, periodic reports, labeling and advertising and promotion requirements and restrictions, market withdrawal and recall. Combination products are typically reviewed through a marketing submission that corresponds to the constituent part which provides the primary mode of action ("PMOA") for the combination product. For example, if the PMOA of a device-biologic combination product is attributable to the biologic, the agency center that reviews biologics would have the primary jurisdiction for the review.

The FDA also regulates the export of medical devices from the U.S., and medical devices that have not received FDA approval, or clearance or are exempt from premarket review requirements, are subject to FDA export requirements.

Manufacturing Requirements

The FDA's regulations require that drugs be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization and personnel, buildings and facilities, equipment, control of components and product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned and salvaged products. The manufacturing processes for devices must likewise be performed in compliance with the applicable portions of the QSR, which covers the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. Manufacturers and other entities involved in the manufacture and distribution of cleared, approved, or otherwise authorized products are required to register their establishments with the FDA, and in some instances state agencies, and they are subject to periodic unannounced inspections by the FDA for compliance with cGMPs and other requirements.

Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being

deemed to be adulterated. Changes to the manufacturing process, specifications or container closure system for an approved drug product are strictly regulated and often require prior FDA approval before being implemented. Likewise, FDA's regulations require clearance of a new 510(k) premarket notification for modifications to 510(k) cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in the intended use of the device, and approval of a PMA supplement for certain modifications to PMA-approved devices that affect the safety or effectiveness of the device. The FDA's regulations also require, among other things, the investigation and correction of any deviations from cGMP or failures to follow the QSR and the maintenance of applicable documentation by the sponsor and any third-party manufacturers involved in producing the approved, cleared, or otherwise authorized product.

Regulation Outside of the U.S.

Currently, we maintain a commercial presence in the U.S. and Canada as well as certain other countries. In the EU, medicinal products are authorized following a process that is similarly demanding as the process required in the U.S. Drug products may be authorized in one of two ways, either through the mutual recognition/ decentralized procedure, which provides for the mutual recognition procedure of national approval decisions by the competent authorities of the EU Member States or through the centralized procedure, which provides for the grant of a single marketing authorization that is valid for all EU member states. Each foreign country has its own regulatory requirements to medical devices. Before a medical device can be placed on the market in the EU compliance with the requirements of the Medical Devices Regulation (EU) 2017/745 must be demonstrated in order to affix the CE Mark to the product. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a notified body. We are also subject to many of the same continuing post-approval requirements in the EU as we are in the U.S. (e.g., good manufacturing practices).

As of January 1, 2021, the UK is no longer part of the EU following "Brexit". All existing EU law in force on December 31, 2020 has been retained in UK law, subject to certain revisions that have become necessary as a result of Brexit. Thus, at least initially, the UK and the EU laws were aligned. Northern Ireland continues to be subject to EU rules governing medicines and medical devices under the Northern Ireland Protocol. However, EU laws that took effect after January 1, 2021, including the EU Medical Devices Regulation, are not effective in Great Britain, comprising England, Scotland and Wales, and the national laws applicable in Great Britain may further diverge from EU law in the future.

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 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 from jurisdiction to jurisdiction.

Fraud, Abuse and Anti-Corruption Laws

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

- The federal Anti-Kickback Statute;
- The 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.

Our operations are also subject to compliance with the Foreign Corrupt Practices Act ("FCPA") which prohibits corporations and individuals from corruptly paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party or party official, or political candidate, directly or indirectly, in an attempt to influence a person working in an official capacity or otherwise obtain an improper advantage. We also may be impacted under the FCPA by the activities of our distributors, collaborators, contract research organizations, vendors, consultants, agents, or other business partners. 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.

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

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

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

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

Additionally, drug pricing is an active area for regulatory reform at the federal and state levels, and significant changes to current drug pricing and reimbursement structures in the U.S. continue to be considered and enacted. For example, the Inflation Reduction Act of 2022 (the "IRA"), was signed into law on August 16, 2022. As written, the IRA will, among other provisions, give HHS the ability and authority to directly negotiate with manufacturers the price that Medicare will pay for certain single-source drugs that account for the highest total Medicare spending. The IRA will also require manufacturers of certain Part B and Part D drugs to issue to HHS rebates based on certain calculations and triggers (i.e., when drug prices increase and outpace the rate of inflation). The Centers for Medicare & Medicaid Services is in the process of implementing a Medicare Drug Price Negotiation Program, and this program may affect future Medicare reimbursement for certain of our products.

Data Privacy Laws

A number of states in the U.S. 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 activities.

HUMAN CAPITAL

We value our employees and the contributions each of them makes to achieving 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. 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. Ongoing investments in employee engagement and leadership development remain essential to building the capabilities needed to realize our business strategy. As of December 31, 2022, we had approximately 2,500 employees.

In January 2023, we announced an organizational restructuring as part of our sharpened strategic focus, which resulted in the elimination of 132 roles. In February 2023, we announced that we entered into an agreement to sell our travel health business to Bavarian Nordic and approximately 280 employees are expected to join Bavarian Nordic as part of the transaction.

Health and Wellness

Employee health and well-being remain a priority of acute importance to our company. As 2022 progressed and regional health risks and safety requirements changed, we continued to adjust our approach to ensure that operation-critical development and manufacturing employees working on-site had access to appropriate personal protective equipment, enhanced facility procedures, and other resources. Additionally, we transitioned many employees who had been working remotely back into our facilities in a full-time or part-time manner to support business priorities. Other employees maintain a full-time remote work status and we continue to equip them with productivity and collaboration tools and resources.

Hiring and Talent Management

We focus on building leaders at every level with the requisite scientific, technical and professional skills to develop and deliver products and services that protect life. We have consistent talent processes and systems across the company including performance management, training and development and succession planning. 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. We use the Gallup Q12 instrument to measure employee engagement and inclusion and administer "pulse surveys" throughout the year to gather feedback on matters of interest and importance to our employees and our business.

Compensation and Benefits

Our total rewards plan consists of competitive salaries, bonuses, and for employees in eligible roles, equity awards based on company, group and individual performance. We focus on results and behavior because we value how we do things as much as getting them done. This approach is core to our pay-for-performance philosophy. We continue to provide employees access to country-specific salary range information so that they may have greater visibility to their current compensation levels and more context as they explore developing their careers through new roles within our company. In our industry ongoing skill enhancement is essential and we continue to support continuous learning through on-the-job assignments, training programs, tuition assistance, professional memberships and professional conference attendance.

Diversity, Equity and Inclusion Commitment

Diversity, equity and inclusion ("DEI") is integral to how we operate and our success. We are committed to attracting, developing, and retaining the best talent reflecting a diversity of ideas, backgrounds, and perspectives. DEI fuels our business growth, drives innovation in the products and services we develop, in the way we solve problems, and how we serve the needs of a global and diverse patient, customer and partner base. We recognize the value that diversity contributes to our global organization and the competitive advantage we can maintain by cultivating a culture of inclusion to benefit from our broad range of talents, perspectives, and ideas. We demonstrate respect for the individual by providing fair and equal treatment to all our employees and continuously identifying ways to recognize their various needs and interests. One example of our commitment is demonstrated by our first three inaugural Emergent Resource Groups ("ERGs") for black, women and veteran employees. While aligned by constituency, our ERGs are open to all employees and are another way we will look to catalyze a sense of belonging and connection to the organization. These groups open pathways of communication, help to expand learning opportunities, and offer avenues to advance our business strategy.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE

Our mission to protect and enhance life has motivated us to explore our impact at a broader scale — environmental, social and governance ("ESG") stewardship, corporate responsibility, and ethics. Our approach to these issues is the foundation of good governance and strengthens accountability in all aspects of our business

activities and relationships. Our ESG efforts are led by a cross-functional working group, overseen by the Nominating and Corporate Governance Committee, guided by our Internal Executive Steering Committee, and under the responsibility of the Vice President, Assistant Treasurer reporting into the Chief Financial Officer.

Each year, we assess our ESG priority areas and develop action items to advance progress in these areas. These areas include access to medicine, community engagement, compliance, corporate governance, diversity, equity and inclusion, employee engagement, environmental, health and employee safety, governmental relationship, innovation, manufacturing and product quality, patient and drug safety, scientific integrity, and supply chain management. Our strategy is influenced by the Task Force on Climate-Related Disclosures framework as well as the Sustainability Accounting Standards Board's standards focused on the healthcare, biotechnology, and pharmaceutical industries. The annual ESG Report can be found at: www.emergentbiosolutions.com/wp-content/uploads/2022/11/2021-Emergent-ESG-Report.pdf. The information contained in the ESG report is not a part of, or incorporated by reference into, this Annual Report on Form 10-K.

Our ESG strategy is influenced by the Task Force on Climate-Related Financial Disclosures ("TCFD") framework as well as the Sustainability Accounting Standards Board's ("SASB") standards focused on the healthcare, biotechnology, and pharmaceutical industries. The SASB standards provide guidelines on key sustainability issues that directly impact the operational performance and financial condition of our company.

Strengthening our culture and the quality of products and services we offer is an ongoing endeavor. Open and transparent communication with employees, customers, government officials, and community partners is vital to our success.

ESG Priority Issues

Each year, we will conduct an assessment of these priorities and develop action items to advance progress in these areas. Our board will provide oversight and governance over the implementation and disclosures relating to our ESG strategy:

- Access to Medicine
- Community Engagement
- Compliance
- Corporate Governance
- Diversity, Equity and Inclusion
- Employee Engagement
- Environmental, Health and Employee Safety
- Governmental Relationships
- Innovation
- Manufacturing and Product Quality
- Patient and Drug Safety
- Scientific Integrity
- Supply Chain Management

Sustainability and Environmental Management

We recognize that our operations have an impact on our local and global communities from the waste we generate, the energy we source, and the water we discharge. Environmental sustainability is a central consideration when improving and innovating our operational infrastructure across our enterprise and we must do out part to reverse the impacts of climate change which threaten environmental and human health.

We evaluate ESG risks and opportunities related to climate change through the framework that the Task Force on Climate-Related Financial Disclosures ("TCFD") recommends: (i) governance, (ii) strategy, and (iii) risk management. As we further develop our environmental sustainability strategies, we intend to collect data on our Scope 1 and Scope 2 greenhouse gas (GHG) emissions associated with our material operations. Doing so will enable Emergent to establish an energy baseline and prioritize future footprint reductions.

This will also allow us to make informed decisions on setting targets and creating an accompanying strategy and road map for meeting our goals. In congruence, Emergent will determine the relevance of disclosure related to the quantifiable financial impact to our company under various global warming scenarios in line with TCFD recommendations.

Board Committee Oversight

The primary oversight of ESG issues is delegated to the Audit Committee, with active involvement and participation in the oversight activities from both the Compensation and the Nominating and Corporate Governance committees. Our management provides regular updates on ESG initiatives and progress at both the committee and full board meetings. Each director serves on at lease one committee. The composition of the committees, biographies of our directors, and other relevant corporate governance information are available on the investor section of our website under "Governance." In addition, we also provide detailed corporate governance information, disclosures, and data in our annual proxy statement.

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 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

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

- Reduced demand for and/or funding for procurement of AV7909 and/or BioThrax vaccines or ACAM2000 and discontinuation of funding of our other USG procurement and development contracts.
- Inability to secure follow-on product procurement contracts with the USG upon the expiration of any of our existing procurement contracts.
- Inability to receive FDA licensure of AV7909 and realize the full value of our contract for development and procurement of AV7909.

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

- Our inability to maintain quality and manufacturing compliance at our manufacturing facilities for our products and for product candidates for our CDMO customers.
- 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 product development and commercialization risks that could impact our business, financial condition, operating results and cash flows, including:

- 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:

- Failure to comply with complex laws and regulations pertaining to government contracts and resources required for responding to related government inquiries.
- Conditions associated with approvals and ongoing regulation of products may limit how and the extent to which we manufacture and market them.
- Failure to comply with various health care laws could result in substantial penalties.
- Failure to comply with obligations under USG pricing programs may require reimbursement for underpayments and the payment of substantial penalties, sanctions and fines.
- 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 and such activities may subject us to regulatory enforcement actions.

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 is currently subject to branded and generic competition in the

U.S. and may be subject to branded and generic competition in Canada. Narcan Nasal Spray has a pending application with FDA for the switch of Narcan from prescription status to over-the- counter status, and there is no guarantee that FDA will approve that application.

- 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:

- Challenges in obtaining or maintaining intellectual property rights and defense or enforcement of such rights, including against current or potential infringers.
- Potential discrepancies or challenges with respect to licenses, including our failure to comply with obligations under such licenses.
- Potential loss of proprietary information and know-how, which carries the risk of reducing the value of our technology and products.
- Entry of competing generic drugs upon patent and/or regulatory expires or with patents no longer in force.

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 other 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 legal and reputational risks that could impact our business, financial condition, operating results and cash flows, including:

- Unfavorable results of legal proceedings and government investigations could adversely impact our business, financial condition and results of operations.
- Our work on PHTs has exposed us to criticism and may expose us to further criticism, from the media, government personnel and others, which could further harm our reputation, negatively affect our share price, operations and our ability to attract and retain talent.
- The potential for cyber security incidents to harm our ability to operate our business effectively in light of our heightened risk profile.
- We could face product liability exposure associated with the use of our medical products. There can be no assurance that the SAFETY Act, PREP Act, or other liability protections will be sufficient to limit or avoid product liability, and defending such cases requires significant resources.

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, including in order to be able to continue as a going concern.
- Our ability to comply with the covenants under our 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”) and other debt agreements, and to refinance our Senior Secured Credit Facilities prior to their maturity in October 2023.

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

- Our failure to successfully integrate acquired businesses and/or assets into our operations and our ability to realize the benefits of such acquisitions.
- Our failure to consummate the sale of our travel health business to Bavarian Nordic and to realize the anticipated benefits of the transaction.

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.
- 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, as well as additional risks that may materially harm our business, financial condition or results of cash flows.

GOVERNMENT CONTRACTING RISKS

We currently derive a substantial portion of our revenue from USG procurement of the AV7909 vaccine and the TEMBEXA® (brincidofovir), oral antiviral and have historically derived a substantial portion of our revenue from USG procurement of the ACAM2000 vaccine and of BioThrax. If the USG's demand for and/or funding for procurement of AV7909, BioThrax and/or ACAM2000 vaccines and/or TEMBEXA® (brincidofovir), oral antiviral are 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 candidate, there is a higher level of risk that we may encounter challenges causing delays or an inability to deliver AV7909 than with BioThrax, an approved product, 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 procurement by 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 Strategic National Stockpile ("SNS") change generally, or as a result of the conclusion of the USG's audit of the SNS, or with respect to the level of procurement of our anthrax vaccines, funding to procure future doses of AV7909 or BioThrax vaccines 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, in the past we have derived a substantial portion of our revenues from sales of ACAM2000 vaccine to the USG. If priorities for the SNS change with respect to ACAM2000 vaccine 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.

We may not receive FDA approval of AV7909 in a timely manner or at all. Delays in our ability to achieve a favorable outcome from the FDA, or lack of approval 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. Following this submission, BARDA began procuring AV7909, exercising its first contract option in July 2019 to procure 10 million doses of AV7909, its second contract option in July 2020 and, most recently, funding another procurement commitment in October 2021 for inclusion of additional doses into the SNS in support of anthrax preparedness.

In April 2022, we completed the rolling submission of a Biologics License Application ("BLA") filing with the FDA related to AV7909 and

the application has been accepted for review. There can be no guarantee on the outcomes of the FDA review. The FDA may decide that our data are insufficient and may require additional pre-clinical, clinical or other studies. If we are unsuccessful in obtaining FDA licensure, in a timely manner or at all, we may not be able to realize the full potential value of the USG contract for AV7909, 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. Any reduction or discontinuation of funding of any 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 Medical Countermeasures ("MCMs") and the primary source of funds for the development of most of our product candidates in our development pipeline, including our AV7909 procured product candidate. We anticipate that the USG will also be a principal customer for any MCMs that we successfully develop from within our existing product development pipeline, as well as those we acquire in the future. Additionally, a significant portion of our revenue comes from USG development contracts and grants. Over its lifetime, a USG procurement or development program, such as for AV7909 under our development and procurement contract with BARDA, 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. These appropriations can be subject to a number of uncertainties, including 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 and includes options for the delivery of additional doses of AV7909 to the SNS and options for an additional clinical study and post-marketing commitments. This contract was extended in September 2021 through 2025 and provides for additional procurement of AV7909 for the SNS over 18 months. 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 product procurement contracts with the USG upon the expiration of any of our existing procurement contracts.

A significant portion of our revenue is substantially dependent upon product procurement contracts with the USG and foreign governments for our MCMs. Upon the expiration of a procurement contract, we may not be able to negotiate a follow-on procurement contract for the particular product on similar terms. We intend to negotiate follow-on procurement contracts for most of our MCMs 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 approved products or 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 MCM products 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.

The amounts we are paid under our fixed price government procurement contracts are 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 the U.S. Department of Health ("HHS") and the U.S. Department of Defense ("DoD") are generally fixed price contracts. We expect that any 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, and when factoring in higher levels of inflation. 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 their 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.

MANUFACTURING RISKS

An inability to maintain manufacturing compliance at our manufacturing facilities, which could adversely affect our business, financial condition, operating results and cash flows.

The FDA conducts periodic inspections of our manufacturing facilities for compliance with cGMP and QSR requirements relating to quality control. The Company's failure to regain or maintain compliance with cGMP standards at our manufacturing facilities has hindered and could continue to hinder our ability to continue manufacturing for our own products and for CDMO customers, which could adversely affect our business, financial condition, operating results and cash flows. For example in April 2021, we temporarily stopped manufacturing bulk drug substance material for Johnson & Johnson's COVID-19 vaccine at our Baltimore Bayview facility after issues were identified in a viral vaccine drug substance batch. Additionally, in February 2022, FDA inspected Emergent's Camden facility and issued a Form FDA 483. In August 2022, FDA issued a warning letter to Emergent, related to the February 2022 inspection. The warning letter included issues pertaining to equipment cleaning and maintenance; aseptic sterilization technique and procedures; and quality systems. Emergent has responded to the warning letter and continues to make significant progress implementing the corrective and preventive action commitments in the company's warning letter responses.

Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture anthrax vaccines, our ACAM2000 vaccine or our other products or product candidates, as well as impact the delivery of CDMO services, which would harm our business, financial condition, operating results and cash flows.

Any interruptions in our manufacturing operations could result in our inability to produce 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 our manufacturing equipment, or of one or more of our facilities;
- findings and recommendations of health authorities or qualified persons in connection with facility inspections;
- ongoing supply chain interruptions from the COVID-19 pandemic, including lower available plasma levels caused by the pandemic (which has the potential to impact our plasma based products); and
- product contamination or tampering.

The factors listed above could cause disruptions at any of our manufacturing facilities. We do not have any redundant manufacturing facilities for any of our products. Accordingly, any damage to, or disruption or destruction of one or more of our facilities could impede our ability to manufacture our products, and our product candidates and our ability to provide manufacturing and development services 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.

Providers of MCMs 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.

Problems may arise during the production of our products and product candidates, as well as those we produce for our CDMO customers, due to the complexity of the processes involved in their development, manufacturing and shipment or other factors. 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.

The majority of our products and product candidates 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. 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 other restrictions on the marketing or manufacturing of a product, any of which could be costly to us, damage our reputation and negatively impact our business. Regulatory action, including the issuance of Forms FDA 483 and warning letters can also have an impact.

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. Our inability to ramp up manufacturing to meet the demand or specifications of our customers or the inability to timely obtain regulatory authorization to produce the products or product candidates 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.

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 and Switzerland.

PRODUCT DEVELOPMENT AND COMMERCIALIZATION RISKS

The product candidates that we work on for our CDMO customers may not be safe or effective and even if they are, we may be unable to manufacture sufficient quantities to meet demand.

We may provide CDMO services for the development and/or manufacture of various product candidates. There can be no assurance that these product candidates will be safe or effective or that they will be authorized for emergency use or approved by the FDA or any other health regulatory authority. Even if product candidates are found to be safe and/or effective and receive authorization or approval by a health regulatory authority or we receive authorization to produce drug substance or drug product at our facilities, the manufacturing processes for our CDMO programs are under development and are complex. There can be no assurance that we will be able to produce sufficient clinical or commercial quantities of any product candidate in a timely basis or at all. Difficulties manufacturing COVID-19 product candidates for certain CDMO customers and the November 2021 termination of the termination of the Center for Innovation in Advanced Development and Manufacturing ("CIADM") agreement with BARDA for COVID-19 vaccine development and manufacturing (the "BARDA COVID-19 Development Public Private Partnership") caused us to suffer considerable reputational and financial damage and resulted in the instigation of shareholder litigation and government investigations described elsewhere in this Annual Report. Any future failure to satisfy manufacturing commitments could adversely affect our reputation, subject us to potential legal liability and harm 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 efforts 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 can depend on many factors, including accomplishing the following in an economical manner:

- successful development, formulation and cGMP or QSR scale-up of manufacturing that meets FDA and/or foreign regulatory requirements;
- successful program partnering;
- successful completion of clinical or non-clinical development;
- receipt of marketing approvals, clearances, or other authorizations 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;
- competitive pricing and market access; 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 or other authorization 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.

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.

Pre-clinical and clinical testing for certain of our MCM product candidates may face additional difficulties and uncertainties because they cannot ethically or feasibly be tested in human subjects. In the U.S. we expect to rely on the Animal Rule to obtain regulatory approval for some of our MCM product candidates. The Animal Rule permits, for certain limited diseases and 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 clinical studies, such as field studies in the event of an outbreak or act of bioterrorism, to assess the drug's safety and effectiveness. It is possible that results from the animal efficacy studies used to support approval under the Animal Rule may not be predictive of the actual efficacy of our product candidates in humans.

Under the PHSA and the FDCA, the Secretary of HHS can contract to purchase MCMs for the SNS prior to FDA approval, clearance, or other authorization of certain MCM product candidates. If the USG does not provide funding for and procure our MCM product candidates, they generally will have to be approved by the FDA through traditional regulatory mechanisms prior to sale and distribution in the United States.

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 and other factors. 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 R&D, 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 could also cause us to miss valuable opportunities.

REGULATORY AND COMPLIANCE RISKS

There are a number of complex 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 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 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.

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. This includes, but is not limited to, laws and regulations governing product development, product labeling, product testing, manufacturing, storage, product distribution, record keeping, and advertising and promotion. In limited circumstances, governments may have the authority to procure products that have not obtained regulatory approval to stockpile for emergency preparedness and to respond to public health emergencies. In 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 authorization from FDA to market and sell any of our future drug, biologic, or vaccine products, we will be required to submit an NDA or BLA to the FDA. Under the FDCA, the PHSA, and FDA's implementation of those statutes, a company must support an NDA or BLA with substantial evidence that the product candidate is effective and evidence that the product is safe. Ordinarily, FDA requires data from adequate and well-controlled clinical trials, including Phase 3 trials conducted in patients with the disease or condition being targeted, to demonstrate that a drug meets the statutory standards for approval. Once an NDA or BLA is submitted, the FDA has substantial discretion and may refuse to accept our application or may decide that our data are insufficient to support approval and require additional pre-clinical, clinical or other studies. 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 conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Likewise, the data in our device submissions may be insufficient to support approval, de novo classification or clearance where required, and we may not be able to demonstrate to the satisfaction of the FDA that our devices are safe or effective for their intended uses or, for a 510(k) device, that they are substantially equivalent to the predicate. Even if we are granted 510(k) clearances, de novo authorizations, or PMA approvals, they may include significant limitations on the indications for use for the device.

Before we can market a new medical device, or an existing medical device for a new use, or make significant modifications to an existing product, we

must first receive either clearance under Section 510(k) of the FDCA, de novo authorization, or approval of a PMA from the FDA, unless an exemption applies. These marketing submissions must also be supported by appropriate data, including in many cases clinical data. Likewise, changes to our combination products, including changes to the device constituent part, may also require a new submission to, and approval from, FDA.

However, our MCM product candidates may be eligible for approval under the FDA's "Animal Rule," under which findings from adequate and well controlled animal efficacy studies may serve as the basis of an approval when it is not feasible or ethical to conduct efficacy trials in humans. We cannot guarantee that the FDA will permit us to proceed with approval or licensure of any of our MCM product 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 other marketing authorization, or rejection of an application. There is a high rate of failure inherent in the medical product development 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.

Failure to successfully develop future product candidates may materially adversely affect our business, financial condition, operating results and cash flows.

Unapproved and investigational stage products are also subject to the 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. If the FDA or any foreign regulatory authority determines that any of our communications constitute pre-approval promotion or promotion of an off-label use, FDA could request that we modify our promotional materials, issue an untitled letter or warning letter, or subject us to regulatory or enforcement actions, including injunction, seizure, civil fine or criminal penalties.

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, market and sell our products, which could materially impair our ability to generate revenue.

Once marketing authorization has been granted, we and our business partners will remain subject to ongoing regulatory oversight of our medical products, including with respect to labeling; safety surveillance and reporting; registration and listing requirements; cGMP and QSR requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents; advertising and promotional activities; requirements regarding the distribution of samples to physicians and related recordkeeping; medical device design, development and manufacturing.

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 marketing and promotion of medical products to ensure that they are marketed in a manner consistent with the FDA-approved label. For drugs products, we must promote the product in a manner consistent with the full prescribing information or, for 510(k) cleared devices, consistent with the cleared indication. The FDA, DOJ, and OIG impose stringent restrictions on manufacturers' communications regarding unapproved/uncleared products and unapproved/uncleared uses of approved/ cleared products. If we market unapproved/uncleared products or market our approved/cleared products for unapproved/uncleared 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.

Certain of our products are subject to post marketing requirements ("PMRs"), which we are required to conduct, and post marketing commitments, 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.

In addition, 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. 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 other 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;
- refusal to approve pending applications or supplements to approved applications that are submitted;
- delay in or refusal to approve/clear/ authorize pending PMA applications, 510(k) premarket submissions, or de novo authorization requests;
- 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.

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 and sell 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 condit

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.

Likewise, 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 may affect the prices we, or our collaborators, 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 and 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. On January 28, 2021, however, the President issued an executive order to strengthen implementation of the ACA. Concurrently, Congress 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. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, the current Presidential administration issued an executive order initiating a special enrollment period during 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. It is unclear how healthcare reform measures enacted by Congress or implemented by the current Presidential administration or other challenges to the ACA, if any, will impact the ACA or our business.

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 has been 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.

Further, the Inflation Reduction Act of 2022 (the "IRA"), was signed into law on August 16, 2022. While the IRA is still subject to rulemaking (with more information to come via guidance documents from the responsible federal agencies), the IRA, as written, will, among other changes, give the U.S. Department of Health and Human Services (the "HHS") the ability and authority to directly negotiate with manufacturers the price that Medicare will pay for certain high-priced drugs. The IRA will also require manufacturers of certain Part B and Part D drugs to issue to HHS rebates based on certain calculations and triggers (i.e., when drug prices increase and outpace the rate of inflation). At this time, we cannot predict the implications the IRA provisions will have on our business. These types of laws may have a significant impact on our ability to set a product price we believe is fair and may adversely affect our ability to generate revenue and achieve or maintain profitability.

Additionally, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program ("SIP"), to import certain prescription drugs from Canada into the United States. The final rule is currently the subject of ongoing litigation. At least

six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada, and at least three states (Colorado, Florida, and New Mexico) have submitted SIPs to FDA for review and approval.

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. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, and wholesale distributors, to disclose information about pricing of pharmaceuticals. 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 Centers for Medicare & Medicaid Services (CMS) to report certain payments and transfers of value made to U.S. physicians, other healthcare providers and teaching hospitals, and ownership or investment interests held by physicians, other healthcare providers and their immediate family members; 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.

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, the issuance of final regulations implementing those and other 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 could also 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 ensure 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 PHS (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 and narrow 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 certain MCMs, including AV7909 and TROBIGARD in the United States. In the United States, the Secretary of HHS has the authority to contract to purchase MCMs for the SNS prior to FDA approval of the relevant MCM in specified circumstances. FDA also has the authority to permit the emergency use of medical products that have not yet been approved by the FDA under an EUA. An EUA terminates when the EUA is revoked or the emergency declaration underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, clearance, or other marketing authorization for a product. An EUA has not been granted for TROBIGARD or AV7909. Absent an applicable exception, our MCM product candidates generally will have to be approved, licensed, or cleared 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 can be ambiguous, and the permissibility of exporting unapproved products from the United States and importing them to foreign countries may be unclear in some instances. Nevertheless, government bodies, such as U.S. federal entities other than HHS, state and local governments within the United States, and foreign governments have sought and may further seek to procure our MCM product candidates that are not yet approved. In this situation, 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 adequate indemnification or insurance coverage. For example, despite liability protections applicable to claims arising under U.S. law and resulting from the use of certain unlicensed or unauthorized MCMs, such as a declaration issued under the PREP Act, plaintiffs still may bring lawsuits, among other things, that their claims are not barred under the PREP Act.

In the event that a user of one or more of our products experiences 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/uncleared products, such as in the procurement context, could be considered promotion of an unapproved/uncleared product or unapproved/uncleared 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.

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 the continual requirements of and review by the FDA and other regulatory bodies. Our approved products are subject to these requirements and ongoing review. For drugs and vaccines, these requirements include submissions of safety and other post-marketing information and reports, plasma donor testing, registration requirements, cGMP, requirements relating to potency and stability, quality control, quality assurance, restrictions on advertising and promotion, import and export restrictions and recordkeeping requirements. Requirements for medical devices are similar and include QSR compliance, establishment registration and device listing; record keeping; restrictions on advertising and promotion; post-market surveillance, and restrictions on import and export. 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. Some states have similar requirements for devices. 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, QSR, 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 products offered and sold in Canada 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, untitled 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 other marketing submissions, 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. In November 2022, a specific batch of our RSDL kits was recalled due to leakage, which could cause the product not to perform as effectively as intended.

Even if regulatory approval, clearance, or other marketing authorization of a product is granted, the approval, clearance, or marketing authorization may be subject to limitations on the indicated uses for which the product may be marketed or sold or to the conditions of approval. Regulatory approval or other authorization 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/or that differ from the uses approved or cleared by the applicable regulatory agencies). A company that is found to have improperly promoted an unapproved/uncleared product or an unapproved/uncleared use of an approved/cleared 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/uncleared product or the unapproved/uncleared use of an approved/cleared 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 or sell 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.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency (the "MHRA"), became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to European Union rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended) (the "HMR"), as the basis for regulating medicines. The HMR has incorporated into the domestic law of the body of European Union law instruments governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

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

As we continue to expand our commercialization activities outside of the United States, we are subject to an increased risk of

violating, 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 anti-bribery laws that prohibit corporations and individuals from corruptly paying, offering to pay, or authorizing the payment of anything of value, directly or indirectly, to any foreign government official, government staff member, political party or party official, or political candidate in an attempt to influence a person working in an official capacity or otherwise obtain an improper advantage. 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. Some anti-bribery laws also apply to private sector bribery. Compliance with the FCPA and other anti-bribery laws 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 and other parts of the health system are operated by the government, and doctors, hospital employees, and other health care providers are considered foreign officials. Certain payments to hospital employees and other health care professionals 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 U.S., also have various lobbying laws and regulations governing the conduct of individuals and companies who interact with government officials. These laws and regulations typically include certain restrictions and disclosure obligations. If we, our employees, or third parties acting on our behalf do not comply with these laws and regulations, we may be subject to civil and criminal penalties.

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

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

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties, suspension or debarment from government contracting, and other sanctions, and can cause reputational harm. The SEC also may bring enforcement actions against issuers for violations of the FCPA's accounting provisions.

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 will continue to 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 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, marketing and selling 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, which we refer to as "Biologic Products," can be affected by the approval and entry of "biosimilars" in the United States and other jurisdictions. Biosimilar products are licensed through an abbreviated pathway based on a showing that they are "highly similar" to a previously licensed product (known as the reference product) notwithstanding minor differences in clinically inactive components, and there are no clinically meaningful differences from the reference product in terms of safety, purity, and potency. 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® (naloxone HCl) is currently subject to generic competition and may be subject to additional branded and generic competition in the future.

NARCAN currently faces generic competition. In 2016, Teva Pharmaceuticals Industries Limited and Teva Pharmaceuticals USA (collectively, Teva) filed an Abbreviated New Drug Application (ANDA) seeking regulatory approval to market a generic version of NARCAN. In patent litigation related to Teva's ANDA filing, a trial Court decided in favor of Teva, and this decision was subsequently affirmed by the Court of Appeals for the Federal Circuit.

The FDA approved Teva's ANDA on April 19, 2019. On December 22, 2021, Teva commenced the launch of its generic naloxone nasal spray. As part of recent state settlements, including in Florida, Texas, Rhode Island, and West Virginia, Teva has agreed to supply Medication- Assisted Treatment (MAT) and generic opioid overdose reversal agents, like naloxone, to states at no cost in lieu of additional monetary compensation. The terms of these product donation agreements stretch 10 to 15 years.

NARCAN also faces generic competition from Perrigo UK FINCO Limited Partnership (Perrigo, now Padagis), which filed its own ANDA in 2018. Emergent settled with Perrigo on February 12, 2020 providing for a license effective upon the Teva litigation decision. In June 2022, the FDA approved the Padagis ANDA and Padagis launched its generic naloxone nasal spray.

Sales of generic versions of NARCAN at prices lower than our branded product or provided at no cost by Teva have the potential to erode our sales and could impact our product revenue related to NARCAN. For example, certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician, mandate the dispensing of generic products rather than branded products where a generic version is available. 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. In November 2022, the FDA announced its preliminary assessment that naloxone nasal spray products up to 4mg and naloxone auto-injector products for intramuscular or subcutaneous use up to 2mg have the potential to be approvable as safe and effective for nonprescription use.

NARCAN Nasal Spray also faces branded competition Kloxxado™, (naloxone HCl) nasal spray 8mg, a branded product developed by Hikma

Pharmaceuticals, Inc., Amphastar Pharmaceuticals, Inc.'s naloxone injection product, Teleflex Medical Inc.'s Intranasal Mucosal Atomization Device and Zimhi™ (naloxone), a branded injectable product developed by Adamis.

In addition, Harm Reduction Therapeutics has announced filing of an NDA application for a 3mg naloxone nasal spray formulation intended for OTC use in opioid overdose reversal. NARCAN may face additional generic and branded competition in the future.

Political or social factors may delay or impair our ability to market and sell 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 and the level of emphasis placed on such risks by the USG 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 (including as a result of negative publicity we have received based on our longstanding ties to the USG), 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 MCMs and thereby limit the demand for our products, which would adversely affect our business, financial condition, operating results and cash flows.

We may not be able to obtain orphan drug exclusivity for product candidates we may develop, and even if we do, that exclusivity may not prevent the FDA or foreign regulatory authorities from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same rare disease or condition for that time period. The applicable period is seven years in the United States.

In order for the FDA to grant orphan drug designation to one of our products, the agency must find, among other requirements, that the product is being or will be investigated for a condition or disease with a patient population of fewer than 200,000 individuals in the United States, or, for a vaccine, diagnostic drug, or preventive drug, it will be administered to fewer than 200,000 persons per year in the United States. Alternatively, FDA may determine that there is no reasonable expectation that the costs of research and development of the drug can be recovered from sales of the drug in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug designation does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In addition, even after a product receives orphan drug exclusivity, the FDA can subsequently approve the same product for the same condition if the FDA or such authorities conclude that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care; if the FDA determines that the holder of orphan drug exclusivity cannot ensure the availability of sufficient quantities of the product to meet the needs of patients with the rare disease or condition; or if the holder of orphan drug exclusivity consents to the approval of such subsequent product. Additionally, the FDA may revoke orphan drug designation if the FDA determines that the request for designation contained an untrue statement of material

fact, omitted material information, or the FDA subsequently finds that the drug in fact had not been eligible for orphan drug designation at the time of submission of the request for designation.

We face similar risks in the EU and other foreign jurisdictions that have comparable regulations concerning orphan drug exclusivity.

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 and costs associated with post-grant challenges. For example, such costs include *inter partes review* 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, other parties (e.g., licensors) may have the first right to maintain or defend intellectual property rights in which we have an interest, or may pursue strategies that are divergent to the interest of our Company.

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

Claims by other parties of alleged patent infringement could delay, stop or affect the development and commercialization of our products and product candidates. 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.

RISKS RELATED TO RELIANCE ON OTHER 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 vaccines and the specialty plasma in our hyperimmune specialty plasma products and certain ingredients for the ACAM2000 vaccine. We also rely on single-source suppliers for the materials necessary to produce NARCAN, 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 product candidates, and the complex nature of manufacturing processes. In addition, we may lose a sole-source supplier due to, among other things, 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 or other third party 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 NGOs 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 NGOs 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.

LEGAL AND REPUTATIONAL RISKS

Our financial condition and operating results could be adversely impacted by unfavorable results of legal proceedings or government investigations.

We are subject to various claims, legal proceedings and government investigations that have not yet been fully resolved, including stockholder derivative and putative class action lawsuits, and new matters may arise in the future. In addition, agreements entered into by us sometimes include indemnification provisions which can subject us to costs and damages in the event of a claim against an indemnified third party. The number of claims, legal proceedings and government investigations involving us, and the alleged magnitude of such claims, proceedings and government investigations, has generally increased over time and may continue to increase. Certain of these actions include, and future actual or threatened legal actions may include, claims for substantial and indeterminate amounts of damages, or may result in other actions adverse to us.

For example, multiple purported class action lawsuits have been filed against us and certain of our current and former senior officers in the United States District Court for the District of Maryland seeking unspecified damages on behalf of a putative class of persons who purchased or otherwise acquired shares of our common stock during various date ranges. The complaints, allege, among other things, that we made materially false and misleading statements regarding our procedures and quality controls relating to vaccine production, in violation of federal securities laws. As another example, multiple stockholder derivative lawsuits were filed in The Court of Chancery of the State of Delaware and the United States District Court for the District of Maryland on behalf of the Company against certain current and former officers and directors for breach of fiduciary duties, waste of corporate assets, unjust enrichment and insider trading, each allegation related to the Company's capabilities to manufacture COVID-19 vaccine bulk drug substance. In addition to monetary damages, the complaints seek the implementation of multiple corporate governance and internal policy changes.

Regardless of merit, litigation can be both time-consuming and disruptive to our operations and cause significant expense and diversion of management's attention. The outcome of litigation or government investigations is also inherently uncertain. If one or more legal matters were resolved against us or an indemnified third party in a reporting period for amounts above management's expectations, our financial condition and operating results for that reporting period could be materially adversely affected. Further, such an outcome could result in significant compensatory, punitive or trebled monetary damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief against us and could require us to change our business practices or limit our ability to offer certain products and services, all of which could materially adversely affect our financial condition and operating results. While we maintain insurance coverage for certain types of claims, such insurance coverage may be insufficient to cover all losses or all types of claims that may arise.

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 previously contracted with the USG and pharmaceutical companies for the development and manufacture of a significant quantity of COVID-19 vaccines which, 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 covering countermeasures for smallpox, mpox, and other orthopox; anthrax; and botulinum toxin. These declarations apply to certain of our products, namely BioThrax, ACAM2000, raxibacumab, Anthrasil, BAT and VIGIV products, as covered countermeasures. 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 under the SAFETY Act, which provides certain product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. Although BioThrax and RSDL are designated and certified under the SAFETY Act, the law 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 vaccine as a countermeasure to a bioterrorism threat. We rely on PREP Act protection for BioThrax, raxibacumab, ACAM2000, Anthrasil, BAT and VIGIV products, and SAFETY Act protection for BioThrax and RSDL products 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, 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.

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 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. We were not in compliance with the net leverage ratio and debt service coverage ratio covenants under our Senior Secured Credit Facilities as of December 31, 2022. We received a limited waiver from compliance with these covenants for the quarter ended December 31, 2022 and the quarter ending March 31, 2023. The Company does not expect to be in compliance with debt covenants in future periods without additional sources of liquidity or future amendments to the Credit Agreement. If we default under the Credit Agreement or our other debt arrangements, 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. If we are unable to refinance our Senior Secured Credit Facilities prior to their maturity in October 2023, our results of operations and financial condition may be adversely affected.

The Senior Secured Credit Facilities include a $450.0 million Term Loan Facility which had an outstanding principal balance of $362.8 million as of December 31, 2022 and the ability to borrow up to $600.0 million under our Revolving Credit Facility of which we had $598.0 million of outstanding borrowings as of December 31, 2022. On August 7, 2020, we completed an offering of $450.0 million aggregate principal amount of Senior Unsecured Notes, of which $353.0 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 Senior Secured Credit Facilities mature in October 2023. If we are unable to refinance our Senior Secured Credit Facilities prior to their maturity, we will be required to immediately repay the entire amount outstanding thereunder, which could adversely affect our results of operations and financial condition.

In addition, our Senior Secured Credit Facilities and our Senior Unsecured Notes each contain cross-default provisions whereby a default under one agreement would likely result in cross defaults under agreements covering other indebtedness. The occurrence of a default under any of these arrangements would permit the holders of the notes or the lenders under our Senior Secured Credit Facilities to declare all amounts outstanding under those borrowing arrangements to be immediately due and payable, and there is no assurance that we would have sufficient funds to satisfy any such accelerated obligations.

As of December 31, 2022, the Company was not in compliance with the debt service charge ratio and consolidated net leverage ratio covenants under the Credit Agreement. Pursuant to the Credit Agreement Amendment (as defined below) the requisite lenders have agreed to a limited waiver of any defaults or events of default that result from (a) any violation of

the financial covenants set forth in the Senior Secured Credit Facilities with respect to the fiscal quarter ending December 31, 2022 and the fiscal quarter ending March 31, 2023 and (b) the going concern qualification or exception contained in the audited financial statements for the fiscal year ending December 31, 2022. This limited waiver will expire on the earlier to occur of (i) any other event of default and (ii) April 17, 2023. During this period the Company is working with lenders under the Senior Secured Credit Facilities in connection with replacing such facilities before their October 2023 maturity with revised terms and conditions. The Company does not expect to be in compliance with debt covenants in future periods without additional sources of liquidity or future amendments to the Credit Agreement.

Our hedging program is subject to counterparty default risk.

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

We require significant additional funding to be able to continue as a going concern and we may be unable to raise capital when needed or on acceptable terms, which would harm our ability to grow our business, and our results of operations and financial condition. In addition, any capital we raise may result in dilution to our current stockholders.

As of December 31, 2022, we had unrestricted cash and cash equivalents of $642.6 million and remaining capacity under our Revolving Credit Facility of $0.7 million. Also as of December 31, 2022, there was $598.0 million outstanding under our Revolving Credit Facility and $362.8 million under our Term Loan Facility that mature in October 2023, which is within one year of the date that the Company's consolidated financial statements are issued for the year ended December 31, 2022. As a result, the Company determined that there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. We will need to obtain substantial additional funding in connection with our continuing operations, which cannot be assured.

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 2021, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer" under SEC rules, this shelf registration statement, effective until August 9, 2024, 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 the expiration of our automatic shell registration statement (whether by lapse of time due to us no longer qualifying as a "well-known seasoned issuer"), 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. 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.

Goodwill impairment charges in the future could have a material adverse effect on our business, results of operations and financial condition.

We have recorded a significant amount of goodwill on our consolidated balance sheet as a result of acquisitions. We review the recoverability of goodwill annually and whenever events or circumstances indicate that the carrying value of a reporting unit may not be recoverable. As of December 31, 2022, the only reporting unit that has goodwill associated with it is our MCM reporting unit.

The impairment tests require us to make an estimate of the fair value of our reporting units. An impairment could be recorded as a result of changes in assumptions, estimates or circumstances, some of which are beyond our control. Since a number of factors may influence determinations of fair value of goodwill, we are unable to predict whether impairments of goodwill will occur in the future, and there can be no assurance that continued conditions will not result in future impairments of goodwill. The future occurrence of a potential indicator of impairment could include matters such as (i) a decrease in expected net earnings, (ii) adverse equity market conditions, (iii) a decline in current market multiples, (iv) a decline in our common stock price, (v) a significant adverse change in legal factors or the general business climate, and (vi) an adverse action or assessment by a regulator. Any such impairment would result in us recognizing a non-cash charge in our consolidated balance sheets, which could adversely affect our business, results of operations and financial condition.

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.

On December 31, 2021, the International Exchange (ICE) Benchmark Association, which administrates LIBOR, ceased (i) entering into new contracts that use LIBOR as a reference rate and

(ii) publication of two LIBOR rates (one-week and two-month) and has announced that the remaining LIBOR rates (overnight, one-month, three-month, six-month and 12-month) will be retired on June 30, 2023. It is unclear if LIBOR will cease to exist at that time or if new methods of calculating LIBOR will be established such that it continues to exist after 2023. We have certain financial contracts, including the Amended Credit Agreement 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.

We have identified a material weakness in our internal control over financial reporting, and our ability to provide accurate and timely financial reporting could be affected if it is not effectively remediated or if additional material weaknesses are identified.

As described in Item 9A, "Controls and Procedures – Management's Report on Internal Control Over Financial Reporting" of this Annual Report on Form 10-K, during the process of preparing the financial statements as of and for the year ended December 31, 2022, our management [and auditor] determined that our internal control over financial reporting included a material weakness as of December 31, 2022 related to our inventory accounting. 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 consolidated financial statements will not be prevented or detected on a timely basis. The material weakness related to our internal control over financial reporting related to the capitalization of inventory. Due to the existence of this material weakness, our management concluded that as of December 31, 2022 our internal control over financial reporting was not effective.

We are taking steps to remediate this material weakness, including documenting a formal policy on the accounting for pre-paunch materials purchased for use in R&D activities, providing additional training related to the new policy, implementing a monthly control to review pre-launch inventory with corporate finance to ensure proper accounting treatment. However, we cannot provide any assurance that the measures we have taken to date and we intend to implement will be sufficient to remediate the material weakness we have identified or to avoid additional material weaknesses from occurring in the future. If we are unable to remediate the material weakness or any additional material weaknesses or other deficiencies in our internal control over financial reporting are identified in the future, or we otherwise fail to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, we may not be able to produce accurate and timely financial statements or certify that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms. Any failure of our internal control over financial reporting or disclosure controls and procedures could cause our investors to lose confidence in our publicly reported information, cause the market price of our stock to decline, harm our reputation, expose us to sanctions or investigations by the SEC or other regulatory authorities, or otherwise adversely impact our results of operations.

RISKS RELATED TO STRATEGIC ACQUISITIONS, DIVESTITURES 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. For example, in September 2022, we completed the acquisition from Chimerix, Inc. of its exclusive worldwide rights to brincidofovir,

including TEMBEXA® and related assets. 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, products, 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.

Our proposed sale of our travel health business to Bavarian Nordic may not be consummated and if the transaction is consummated we may not realize the benefit of the proposed transaction.

On February 15, 2023, we entered into the Sale Agreement with Bavarian Nordic, under which we agreed to sell our travel health business, including rights to Vaxchora and Vivotif, as well as our development-stage chikungunya vaccine candidate CHIKV VLP, our manufacturing site in Bern, Switzerland and certain of our development facilities in San Diego, California for a cash purchase price of $270.0 million, subject to certain customary adjustments. In addition, we may receive milestone payments of up to $80.0 million related to the development of CHIKV VLP and receipt of marketing approval and authorization in the U.S. and Europe, and sales-based milestone payments of up to $30.0 million based on aggregate net sales of Vaxchora and Vivotif in calendar year 2026. The transaction is expected to close in the second quarter of 2023, subject to certain customary closing conditions.

There can be no assurance that we will be able to close the sale of our travel health business to Bavarian Nordic. If we are unable to consummate the transaction or do not realize the expected strategic, economic, or other benefits of the transaction, it could adversely affect our business and financial position.

In addition, we have incurred, and will continue to incur, significant expenses in connection with the proposed sale of our travel health business to Bavarian Nordic. These expenses include fees and expenses for investment bankers, attorneys, accountants and other advisers in connection with our efforts and will be incurred whether or not an acquisition is consummated. The incurrence of these costs could adversely affect our financial results for particular quarterly or annual periods.

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, many institutional investors are increasingly focused on ESG factors. These investors may be seeking enhanced ESG disclosures or to 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.

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 size of our Board of Directors;
- limitations on the removal of directors;
- limitations on filling vacancies on the Board of Directors;

- advance notice requirements for stockholder nominations of candidates for election to the Board of Directors and other proposals;
- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue a new series of preferred stock without stockholder approval.

The affirmative vote of a majority of our Board of Directors or the 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 or by-laws. 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, 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 22, 2023, our common stock has traded as high as $137.61 per share and as low as $4.17 per share. 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 RISK FACTORS

The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. Any additional 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 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 2023 and 2034. Principal locations include:

Location	Use	Approximate square feet	Owned/ leased	Operating Segment
Lansing, Michigan	Manufacturing operations, office and laboratory space.	336,000	Owned	Products & Services
Winnipeg, Manitoba, Canada	Manufacturing operations, office and laboratory space.	315,000 (Owned); 15,800 (Leased)	Owned/ Leased	Products & Services
Gaithersburg, Maryland	Laboratory space, office space and rental real estate.	173,000	Owned	Products & Services
Canton, Massachusetts	Manufacturing operations and warehouse space.	122,508 (Owned); 27,000 (Leased)	Owned/ Leased	Products & Services
Baltimore, Maryland (Bayview)	Manufacturing facilities, office and laboratory space.	112,000	Owned	Products & Services
Elkridge, Maryland	Warehouse space.	103,182	Leased	Products & Services
Baltimore, Maryland (Camden)	Manufacturing facilities, office and laboratory space.	86,900 (Owned); 41,000 (Leased)	Owned/ Leased	Products & Services
Rockville, Maryland	Manufacturing facilities, office and warehouse space.	84,295	Owned	Products & Services
Bern, Switzerland	Manufacturing operations, office and laboratory space.	81,000	Owned	Products
San Diego, California	Manufacturing facilities and office space.	66,012	Leased	Products

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 17 ”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 22, 2023, the closing price per share of our common stock on the New York Stock Exchange was $13.98 and we had 18 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend Policy

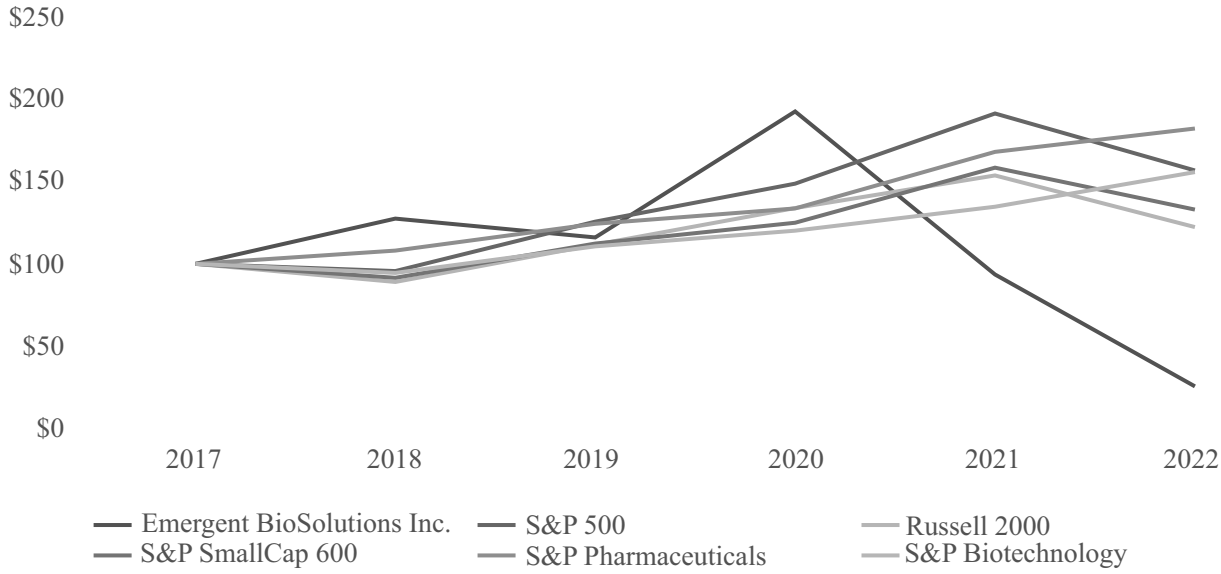
We have not declared or paid any cash dividends on our common stock since becoming a publicly traded company in November 2006. We currently have no plans to pay dividends.

The remaining information required by Item 5 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2023 Annual Meeting of the Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

Stock Performance Graph

The following graph provides a comparison of five year cumulative total stockholder returns of Emergent BioSolutions Inc.'s common stock, the Standard & Poor's ("S&P") 500 Stock Index, the Russell 2000 Index, the S&P SmallCap 600 Index, the S&P Pharmaceuticals Index and the S&P Biotechnology Index. The annual changes for the five-year period shown on the graph are based on the assumptions that $100 had been invested in Emergent BioSolutions Inc.'s common stock and each index on December 31, 2017, all fiscal years end December 31st and all dividends were reinvested.

Comparison of Five Year Cumulative Total Return



Company / Index	Market Performance 2017	2018	2019	2020	2021	2022
Emergent BioSolutions Inc.	$100.00	$127.57	$116.10	$192.81	$ 93.54	$ 25.41
S&P 500	$100.00	$ 95.62	$125.72	$148.85	$191.58	$156.89
Russell 2000	$100.00	$ 88.99	$111.70	$134.00	$153.85	$122.41
S&P SmallCap 600	$100.00	$ 91.52	$112.37	$125.05	$158.59	$133.06
S&P Pharmaceuticals	$100.00	$108.09	$124.40	$133.76	$168.21	$182.43
S&P Biotechnology	$100.00	$ 94.50	$110.67	$120.22	$134.80	$155.89

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis is meant to provide material information relevant to an assessment of the financial condition and results of operations of our company, including an evaluation of the amounts and uncertainties of cash flows from operations and from outside resources, so as to allow investors to better view our company from management's perspective. 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

Emergent BioSolutions Inc. ("Emergent," the "Company," "we," "us," and "our") is a global life sciences company focused on providing innovative preparedness and response solutions addressing accidental, deliberate, and naturally occurring Public Health Threats ("PHTs"). The Company's solutions include a product portfolio, a product development portfolio, and a contract development and manufacturing ("CDMO") services portfolio.

We are currently focused on the following five PHT categories: chemical, biological, radiological, nuclear and explosives ("CBRNE"); emerging infectious diseases ("EID"); travel health, which we have agreed to sell to Barvarian Nordic; public health crises; and acute, emergency and community care. We have a product portfolio of thirteen products that contribute a substantial portion of our revenue and are sold to government and commercial customers. We also have a product candidate, AV7909, which is procured under special circumstances by the United States ("U.S.") Government ("USG"), although it is not approved by the U.S. Food and Drug Administration ("FDA"). Additionally, we have a development pipeline consisting of a diversified mix of both pre-clinical and clinical stage product candidates. Finally, we have a fully integrated portfolio of CDMO services. Our CDMO service offerings cover development services, drug substance manufacturing and drug product manufacturing and packaging.

The Company structures the business with a focus on markets and customers. As such, the key components of the business structure include the following three product and service categories: Government—Medical Countermeasures ("MCM") Products, Commercial Products, and CDMO Services. The Company operates as two operating segments: (1) a products segment ("Products") consisting of the Government—MCM and Commercial products and (2) a services segment ("Services") consisting of our CDMO services.

Products Segment:

The majority of our product revenue comes from the following products and procured product candidates:

Government—MCM Products

- 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;
- Anthrasil® (Anthrax Immune Globulin Intravenous (human)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of inhalational anthrax in combination with appropriate antibacterial drugs;

- Anthrax vaccines, including our AV7909 (Anthrax Vaccine Adsorbed (AVA), Adjuvanted) 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. AV7909 has not been approved by the FDA, but is procured by certain authorized government buyers for their use;
- BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)), the only heptavalent antitoxin licensed by the FDA and Health Canada for the treatment of symptomatic botulism;
- CNJ-016® (Vaccinia Immune Globulin Intravenous (Human) (VIGIV)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination;
- Ebanga™ (ansuvimab-zykl) is a monoclonal antibody with antiviral activity provided through a single IV infusion for the treatment of Ebola. Under the terms of a collaboration with Ridgeback Biotherapeutics ("Ridgeback"). Emergent will be responsible for the manufacturing, sale, and distribution of Ebanga™ in the U.S. and Canada, and Ridgeback will serve as the global access partner for Ebanga™;
- Raxibacumab injection, the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax;
- RSDL® (Reactive Skin Decontamination Lotion Kit), 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;
- TEMBEXA®, an oral antiviral formulated as 100 mg tablets and 10 mg/mL oral suspension dosed once weekly for two weeks which has been approved by the FDA for the treatment of smallpox disease caused by variola virus in adult and pediatric patients, including neonates; and
- Trobigard® atropine sulfate, obidoxime chloride auto-injector, a combination drug-device auto-injector procured product candidate that contains atropine sulfate and obidoxime chloride. It was approved in Belgium in 2021 but has not been approved by the FDA. Trobigard is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure outside of the U.S.

Commercial Products

- NARCAN® (naloxone HCl) Nasal Spray, an intranasal 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;
- Vaxchora® (Cholera Vaccine, Live, Oral), the first vaccine approved by the FDA for the prevention of cholera, which we have agreed to sell as part of our travel health business; and
- Vivotif® (Typhoid Vaccine Live Oral Ty21a), a live attenuated vaccine for oral administration for the prevention of typhoid fever, which we have agreed to sell as part of our travel health business.

Services Segment:

Services—Contract Development and Manufacturing

Our services revenue consists of distinct but interrelated CDMO services: drug substance manufacturing; drug product manufacturing (also referred to as "fill/finish" services) and packaging; development services including technology transfer, process and analytical development services; and, when necessary, suite reservation obligations. These services, which we refer to as "molecule-to-market" offerings, employ diverse technology platforms (mammalian, microbial, viral and plasma) across a network of nine geographically distinct

development and manufacturing sites operated by us for our internal products and pipeline candidates and third-party CDMO services. We service both clinical-stage and commercial-stage projects for a variety of third-party customers, including government agencies, innovative pharmaceutical companies, and non-government organizations.

Full Year 2022 Executive Highlights

Asset Acquisition

During the year ended December 31, 2022, the Company acquired from Chimerix the exclusive worldwide rights to brincidofovir, including TEMBEXA® and other related assets. TEMBEXA is a medical countermeasure for smallpox approved by the FDA in June 2021.

Other Strategic Activities

2023 Organizational Restructuring Plan

On January 9, 2023, the Company announced an organizational restructuring plan (the "Plan") intended to reduce operating costs, improve operating margins, and continue advancing the Company's ongoing commitment to profitable growth. The Plan includes a reduction of the Company's current workforce by approximately five percent. Decisions regarding the elimination of positions are subject to local law and consultation requirements in certain countries, as well as the Company's business needs.

The Company estimates that it will incur approximately $9.0 million to $11.0 million of charges in connection with the Plan, which it expects to incur in the first quarter of fiscal 2023. These charges consist primarily of charges related to employee transition, severance payments, employee benefits, and share-based compensation. These actions, in combination with other cost reduction initiatives, are expected to result in annualized savings of over $60 million when fully implemented.

Agreement to Sell Travel Business Health

On February 15, 2023, we entered into the Sale Agreement with Bavarian Nordic, under which we agreed to sell our travel health business, including rights to Vaxchora and Vivotif, as well as our development-stage chikungunya vaccine candidate CHIKV VLP, our manufacturing site in Bern, Switzerland and certain of our development facilities in San Diego, California for a cash purchase price of $270.0 million, subject to certain customary adjustments. In addition, we may receive milestone payments of up to $80.0 million related to the development of CHIKV VLP and receipt of marketing approval and authorization in the U.S. and Europe, and sales-based milestones payments of up to $30.0 million based on aggregate net sales of Vaxchora and Vivotif in calendar year 2026. Approximately 280 employees are expected to join Bavarian Nordic as part of the transaction.

The transaction is expected to close in the second quarter of 2023, subject to certain customary closing conditions, including (1) the expiration or earlier termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (2) receipt of required clearances and approvals under Spain's competition laws, (3) receipt of certain Swiss real property approvals, (4) no material adverse effect having occurred with respect to the Business, and (5) certain other customary conditions.

Financial Operations Overview

Revenues

We generate product revenues from the sale of our marketed products and procured product candidates. The USG is the largest purchaser of our Government—MCM 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, generally with annual options. Our opioid overdose treatment product, NARCAN® Nasal Spray, and our travel health products, Vivotif and Vaxchora, are sold commercially through wholesalers and distributors, physician-directed or standing order prescriptions at retail pharmacies and to state and local community healthcare agencies, practitioners and hospitals.

We also generate revenue from our CDMO services, 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 large pharmaceutical and biotechnology industry and government agencies/ non-governmental organizations. From time to time, clients require suite reservations at our various manufacturing sites, which may be considered leases depending on the facts and circumstances.

We have received contracts and grant funding from the USG and other non-governmental organizations to perform R&D 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, the timing of manufacturing services performed and the nature of our business, which involves providing large scale bundles of products and services as needs arise. We expect continued variability in our quarterly financial results.

Cost of Product Sales and Services

Products - The primary expenses that we incur to deliver our products 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.

Services - The primary expenses that we incur to deliver our CDMO services consist of fixed and variable costs, including personnel, equipment, and facilities costs. Our manufacturing process includes the production of bulk material

and performing drug product work for containment and distribution of biological products. For drug product customers, we receive work in process inventory to be prepared for distribution.

Research and Development Expenses ("R&D")

We expense R&D costs as incurred. Our R&D 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 our clinical trial material; and
- costs of materials intended for use and used in clinical trials and R&D.

In many cases, we 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 R&D spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of R&D 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 R&D 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, 2022, income tax expense totaled $2.1 million. For every 1% change in the 2022 effective rate, income tax expense would have changed by approximately $2.2 million.

For additional information on our uncertain tax positions and income tax expense, please see Note 13, "Income taxes" to our consolidated financial statements included in this report.

RESULTS OF OPERATIONS

Consolidated and Segment Operating Results:

(in millions)	Year ended December 31, 2022	2021	$ Change	% Change
Revenues:				
Product sales, net:				
Nasal Naloxone Products	$ 373.7	$ 434.3	$ (60.6)	(14)%
Anthrax Vaccines	274.3	259.8	14.5	6%
ACAM2000	63.4	206.5	(143.1)	(69)%
TEMBEXA	117.6	—	—	NM
Other product sales	137.2	123.3	13.9	11%
Total product sales, net	966.2	1,023.9	(57.7)	(6)%
Services:				
CDMO—Services	108.4	334.9	(226.5)	(68)%
CDMO—Leases	4.9	299.7	(294.8)	(98)%
Total services revenues	113.3	634.6	(521.3)	(82)%
Contracts and grants	41.4	134.2	(92.8)	(69)%
Total revenues	1,120.9	1,792.7	(671.8)	(37)%
Operating expenses:				
Cost of product sales	424.1	382.0	42.1	11%
Cost of services	269.6	375.5	(105.9)	(28)%
Research and development	193.0	234.0	(41.0)	(18)%
Selling, general and administrative	340.3	348.4	(8.1)	(2)%
Goodwill impairment	6.7	41.7	(35.0)	(84)%
Amortization of intangible assets	59.9	58.5	1.4	2%
Total operating expenses	1,293.6	1,440.1	(146.5)	(10)%
Income (loss) from operations	(172.7)	352.6	(525.3)	NM
Other income (expense):				
Interest expense	(37.3)	(34.5)	(2.8)	8%
Other, net	(11.7)	(3.7)	(8.0)	NM
Total other income (expense), net	(49.0)	(38.2)	(10.8)	28%
Income (loss) before income taxes	(221.7)	314.4	(536.1)	NM
Income tax provision	2.1	83.5	(81.4)	(97)%
Net income (loss)	$(223.8)	$ 230.9	$(454.7)	NM

NM—Not meaningful

Year Ended December 31, 2022 Compared with Year Ended December 31, 2021

Revenues and gross margin

Total revenues decreased $671.8 million to $1.1 billion in 2022. The decrease was primarily due to a decrease in Services revenue of $521.3 million, coupled with decreases in Contracts and Grants revenue of $92.8 million and Products revenue of $57.7 million.

Consolidated gross margin percentage decreased 19% to 36%. The decrease was primarily due to decreases in the Services segment and Products segment gross margins of $415.4 million and $99.8 million, respectively. Consolidated gross margin percentage excludes contracts and grants revenues because the related costs are R&D expenses.

See “Segment Results” for an expanded discussion of revenues and gross profit.

Unallocated corporate expenses

Research and Development Expenses

R&D expenses decreased $41.0 million to $193.0 million in 2022. The decrease was largely due to the non-cash write-off in 2021 of $38.0 million of the contract asset associated with the completion of the BARDA COVID-19 Development Public Private Partnership, coupled with a decrease in spending for the Company’s COVID-19 therapeutic product candidates along with a number of other developmental activities, partially offset by an increase in costs associated with the Company’s Phase 3 study of our chikungunya virus-like particle vaccine candidate and pre-launch inventory related to CGRD-001.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased $8.1 million to $340.3 million in 2022. The decrease was due to lower professional services and marketing expenses partially offset by increased employee costs, primarily due to increased travel costs. Selling, general and administrative costs as a percentage of total revenue increased 10.9% to 30.4% for the year ended December 31, 2022. The increase was due to a decrease in revenues during the period, partially offset by a decrease in selling, general and administrative expenses during the period.

Amortization of Intangible Assets

Amortization of intangible assets increased $1.4 million to $59.9 million in 2022. Apart from the addition of the intangibles related to the Company’s acquisition of the worldwide rights to TEMBEXA in 2022, the composition of intangible assets amortized was largely consistent with 2021.

Goodwill Impairment

Goodwill impairment decreased $35.0 million to $6.7 million in 2022. The decrease was due to a smaller non-cash impairment charge taken in 2022 as compared with 2021. In 2022, as part of its annual goodwill impairment testing, the Company recognized a $6.7 million impairment charge to goodwill in the CDMO-Services reporting unit, reducing the goodwill balance to zero as of December 31, 2022.

There is the risk of future impairments in our reporting units as any further deterioration in their performance compared to forecast, changes in order volumes or delivery schedules for major customers, as well as any changes in economic forecasts and expected recovery in the biopharmaceutical industry, may require the Company to complete additional impairment tests in future quarters and could result in the reporting unit’s fair value falling below carrying value in subsequent quarters. In the event the Company experiences factors that it believes indicate a decline in fair value, including negative changes to long-term growth rates or if discount rates increase, we may be required to record impairments of goodwill and other identified intangible assets. Further, if the composition of the Company’s reporting unit’s assets and liabilities were to change and result in an increase in the reporting unit’s carrying value, it could lead to additional impairment testing and further impairment losses.

Total other income (expense), net

Total other income (expense), net decreased $10.8 million to an expense of $49.0 million in 2022. The decrease was due to a write-off of a tax indemnity receivable, which is offset in income tax provision, and unrealized foreign currency losses recorded related to the remeasurement of certain intercompany balances. Interest expense was largely consistent between periods.

Income tax provision

Income tax provision decreased $81.4 million to $2.1 million for the year ended December 31, 2022. The decrease was largely due to the decline in income before income taxes. The effective tax rate was (1)% for the year ended December 31, 2022 as compared to 27% in 2021. The effective annual tax rate decreased largely due to an increase in nondeductible expenses, specifically the impact of a valuation allowance charge in the U.S., state and foreign jurisdictions, a charge due the Company's indefinite reinvestment assertion, GILTI, and other permanent items. This is partially offset by tax credits, favorable rates in foreign jurisdictions, and the release of an indemnified unrecognized tax benefit.

SEGMENT RESULTS

PRODUCTS SEGMENT

	Products Segment		
	Year Ended December 31,		
(in millions)	2022	2021	% Change
Revenues	$966.2	$1,023.9	(6)%
Cost of sales	$424.1	$ 382.0	11%
Less: Changes in fair value of contingent consideration	2.6	2.9	(10)%
Less: Inventory step-up provision	51.4	—	NM
Adjusted cost of sales [1]	$370.1	$ 379.1	(2)%
Gross margin [2]	$542.1	$ 641.9	(16)%
Gross margin % [2]	56%	63%	(11)%
Adjusted gross margin [3]	$596.1	$ 644.8	(8)%
Adjusted gross margin % [3]	62%	63%	(2)%

(1) Adjusted cost of sales, which is a non-GAAP financial measure, is calculated as cost of sales less changes in fair value of contingent consideration and inventory step-up provision, both of which are non-cash items.

(2) Gross margin is calculated as revenues less cost of sales. Gross margin % is calculated as gross margin divided by revenues.

(3) Adjusted gross margin, which is a non-GAAP financial measure, is calculated as revenues less Adjusted cost of sales. Adjusted gross margin %, which is a non-GAAP financial measure, is calculated as Adjusted gross margin divided by revenues.

NM—Not meaningful

Year Ended December 31, 2022 Compared with Year Ended December 31, 2021

Nasal Naloxone Products

Nasal Naloxone Product sales decreased $60.6 million to $373.7 million in 2022. The decrease was primarily driven by a reduction in commercial retail sales and a decrease in the price per unit following the launch of a generic version of NARCAN Nasal Spray 4mg in December 2021, partially offset by an increase in U.S. public interest and Canadian sales.

Anthrax Vaccines

Anthrax vaccine sales increased $14.5 million to $274.3 million in 2022. The increase in anthrax vaccine sales was primarily due to an increase in the number of doses sold as a result of the timing of deliveries to the USG in 2022 as compared with 2021, as well as an increase in sales to non-USG customers at a higher price per unit in 2022. Anthrax vaccine product sales are primarily made under annual purchase options exercised by the USG. Fluctuations in revenues result from the timing of the exercise of annual purchase options and the USG purchases and Company delivery of orders that follow.

ACAM2000

ACAM2000 sales decreased $143.1 million to $63.4 million in 2022. The decrease was primarily due to a lower number of units sold to the USG, partially offset by an increased number of units sold to non-U.S. customers at a higher price per unit. We are currently negotiating with HHS the terms of a third contract option for ACAM2000. 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.

TEMBEXA

TEMBEXA sales, following the 2022 acquisition of worldwide rights to TEMBEXA, contributed $117.6 million in revenues in 2022.

Other Product Sales

Other product sales increased $13.9 million to $137.2 million in 2022. The increase was primarily due to increased sales of Anthrasil, Vivotif and RSDL products partially offset by decreased sales of VIGIV and BAT products.

Cost of Sales and Gross Margin

Cost of product sales increased $42.1 million, or 11%, to $424.1 million in 2022. The increase was primarily due to cost of sales for TEMBEXA following our 2022 acquisition of the worldwide rights for TEMBEXA. Excluding the acquisition related product costs, cost of product sales decreased $18.1 million, primarily due decreases in royalties paid for NARCAN sales and ACAM2000 product sales which were due to a reduced number of units sold to the USG and decreased expenses at our Bern facility due to higher facility utilization versus prior year. These were partially offset by inventory write-offs, primarily related to AV7909 and ACAM2000 and higher costs due to under-utilized capacity at our facilities.

Product gross margin percentage decreased 7% to 56% in 2022. The decrease was largely due to decreased sales volumes and inventory write-offs combined with a less favorable mix weighted more heavily to lower margin products. Adjusted gross margin percentage decreased 1% to 62% in 2022. Adjusted gross margin excludes the impact of non-cash items related to the changes in the fair value of contingent consideration of $2.6 million and the inventory step-up provision TEMBEXA inventory of $51.4 million.

SERVICES SEGMENT

	Services Segment		
	Year Ended December 31,		
(in millions)	**2022**	**2021**	**% Change**
Revenues	$ 113.3	$634.6	(82)%
Cost of sales	$ 269.6	$375.5	(28)%
Gross margin [1]	$(156.3)	$259.1	NM
Gross margin % [1]	(138)%	41%	NM

[1] Gross margin is calculated as revenues less cost of sales. Gross margin % is calculated as gross margin divided by revenues.

NM—Not meaningful

Year Ended December 31, 2022 Compared with Year Ended December 31, 2021

Services Revenues

CDMO services revenue decreased $226.5 million to $108.4 million in 2022. The decrease was primarily due to $201.4 million less of combined revenue related to reduced production activities at the Company's Bayview facility as a result of a halt in manufacturing under the Janssen contract in first quarter of 2022 and the cessation of manufacturing activities under the AstraZeneca contract which occurred in 2021. Additionally, the decrease also reflects reduced production at the Camden facility. The decreases were slightly offset by an increase in manufacturing activities at the Company's Winnipeg facility.

CDMO lease revenue decreased $294.8 million to $4.9 million in 2022. The decrease was primarily due to a reduction of $237.6 million associated with the completion of our COVID-19 development public-private partnership with BARDA in November 2021 and reduced lease revenues under the Janssen contract of $58.1 million.

Cost of Services and Gross Margin

Cost of Services decreased $105.9 million, or 28%, to $269.6 million in 2022. The decrease was primarily due to reduced production activities across our CDMO network, as well as a $41.5 million inventory write-off related to the Bayview facility in the second quarter of 2021, partially offset by increased costs at our Camden facility for additional investments in quality enhancement and improvement initiatives.

Services gross margin percentage decreased to (138)% in 2022. The decrease was primarily due to reduced production activities across our CDMO network including the completion of the Company's arrangement with BARDA in November 2021, the halt in manufacturing under the Janssen and AstraZeneca contracts and the decrease in margins at the Company's Camden facility due to additional investments in quality enhancement and improvement initiatives, including an increase in professional services costs.

OTHER REVENUE

Year Ended December 31, 2022 Compared with Year Ended December 31, 2021

Contracts and Grants

Contract and grants revenue decreased $92.8 million, or 69%, to $41.4 million in 2022. The decrease was primarily due to BARDA's completion of the CIADM agreement in November 2021 as well as decreases in development activities associated with various other externally funded research and development projects, most notably the Company's COVID-HIG therapeutic product candidate, as well as decreases in development activities for AV7909. Decreases were partially offset by revenue increases relating to indirect rate adjustments during the period.

Year Ended December 31, 2021 Compared with Year Ended December 31, 2020

Discussion and analysis of the year ended December 31, 2021 compared with the year ended December 31, 2020 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, 2021, as filed with the SEC on February 25, 2022.

Financial Condition, Liquidity and Capital Resources

Our financial condition is summarized as follows:

(in millions, except percentages)	Year Ended December 31, 2022	2021	Change %
Financial assets:			
Cash and cash equivalents	$ 642.6	$ 576.1	12%
Borrowings:			
Debt, current portion	$ 957.3	$ 31.6	NM
Debt, net of current portion	448.5	809.4	(45)%
Total borrowings	$1,405.8	$ 841.0	67%
Working capital:			
Current assets	$1,210.7	$1,272.1	(5)%
Current liabilities	1,229.9	373.8	229%
Total working capital	$ (19.2)	$ 898.3	(102)%

NM—Not Meaningful

Principal Sources of Capital Resources

We have historically financed our operating and capital expenditures through existing cash and cash equivalents, cash from operations, development contracts and grant funding and borrowings under our 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") and other lines of credit we have established from time to time. We also obtain financing from the sale of our common stock upon exercise of stock options. As of December 31, 2022, we had unrestricted cash and cash equivalents of $642.6 million and remaining capacity under our Revolving Credit Facility of $0.7 million.

Going Concern

The consolidated financial statements have been prepared on the going concern basis of accounting, which assumes the Company will continue to operate as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

As of December 31, 2022, there is $598.0 million outstanding on the our Revolving Credit Facility and $362.8 million on our Term Loan Facility that mature in October 2023, which is within one year of the date that the consolidated financial statements for the year ended December 31, 2022 are issued. The Company determined that there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued as a result of these pending maturities. This evaluation considered the potential mitigating effect of management's plans that have not been fully implemented. Management may evaluate the mitigating effect of its plans to determine if it is probable that (1) the plans will be effectively implemented within one year after the date the financial statements are issued, and (2) when implemented, the plans will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern. The Company's plan to alleviate the substantial doubt includes amending its existing Senior Secured Credit Facilities that are due October 2023.

On February 14, 2023, the Company entered into a Consent, Limited Waiver, and Third Amendment to the Amended and Restated Credit Agreement (the "Credit Agreement" and "Third Credit Agreement Amendment") relating to the Senior Secured Credit Facilities. Pursuant to the Third Credit Agreement Amendment, the requisite lenders consented to our sale of our travel health business to Bavarian Nordic substantially in accordance with the terms of the Sale Agreement. The proceeds from the transaction will be deposited into a cash collateral account with the Administrative Agent and will, unless otherwise agreed to by the Company and the

requisite lenders, be used to repay the outstanding Term Loan Facility on the expiration of the Limited Waiver (as described below). We currently expect the transaction to close in the second quarter of 2023, but we can provide no assurance that the transaction will close prior to the October 2023 maturity of the Term Loan Facility, or at all.

Pursuant to the Third Credit Agreement Amendment the requisite lenders have agreed to a limited waiver of any defaults or events of default that result from (a) any violation of the financial covenants set forth in the Senior Secured Credit Facilities with respect to the fiscal quarters ending December 31, 2022 and March 31, 2023 and (b) the going concern qualification or exception contained in the audited financial statements for the fiscal year ending December 31, 2022. This limited waiver will expire on the earlier to occur of (i) any other event of default and (ii) April 17, 2023. During this period the Company is working with lenders under the Senior Secured Credit Facilities in connection with replacing such facilities before their October 2023 maturity with revised terms and conditions. The Company does not expect to be in compliance with debt covenants in future periods without additional sources of liquidity or future amendments to the Credit Agreement.

While the Company is in the process of replacing and expects to replace the Senior Secured Credit Facilities before they mature, management cannot make the assumption that it is probable that the Company will be able to obtain such debt refinancing on commercially reasonable terms or at all until a new credit facility is in place. The Company is currently working with its lenders to refinance the Senior Secured Credit Facilities with revised terms and conditions. The extent to which the Company will be able to affect such refinancing, replacement or maturity extension on terms that are favorable or at all is dependent on a number of uncertain factors, including then-prevailing credit and other market conditions, economic conditions, particularly in the pharmaceutical and biotechnology industry, disruptions or volatility caused by factors such as COVID-19, regional conflicts, inflation, and supply chain disruptions. In addition, rising interest rates could limit our ability to refinance the Senior Secured Credit Facilities when they mature or cause us to pay higher interest rates upon refinancing.

The Company has $642.6 million of cash on hand at December 31, 2022. On January 9, 2023, the Company announced the 2023 organizational restructuring Plan (the "Plan") intended to reduce operating costs, improve operating margins, and continue advancing the Company's ongoing commitment to profitable growth. The Plan includes a reduction of the Company's current workforce by approximately five percent. These actions, in combination with other cost reduction initiatives, are expected to result in annualized savings of over $60.0 million when fully implemented.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2022 and 2021.

	Year Ended December 31,	
(in millions)	**2022**	**2021**
Net cash provided by (used in):		
Operating activities	$ (34.1)	$ 321.1
Investing activities	(381.3)	(225.0)
Financing activities	481.2	(141.0)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	0.5	(0.3)
Net change in cash, cash equivalents and restricted cash	$ 66.3	$ (45.2)

Operating Activities:

Net cash used in operating activities of $34.1 million in 2022 was due to net income excluding non-cash items of $34.6 million offset by positive working capital changes of $0.5 million primarily due an increase in

payments for our contingent consideration and other accrued expenses, an increase in prepaid expenses and an accumulation of inventory, partially offset by collections on receivables.

Net cash provided by operating activities of $321.1 million in 2021 was due to net income excluding non-cash items of $477.5 million offset by negative working capital changes of $156.4 million due to increases in receivables and associated changes in contract liabilities and the accumulation of inventory.

Net cash provided by (used in) operating activities decreased $355.2 million from 2021 to 2022. The decrease is due to a decrease in net income excluding non-cash items of $512.1 million offset by an increase in working capital changes of $156.9 million.

Investing Activities:

Net cash used in investing activities of $381.3 million in 2022 relates to payments for asset acquisitions, the purchases of property, plant and equipment and a royalty settlement payment.

Net cash used in investing activities of $225.0 million in 2021 relates to purchases of property, plant and equipment for increased capacity at our Rockville and Bayview facilities.

Net cash used in investing activities increased $156.3 million from 2021 to 2022. The increase is largely due the acquisition of worldwide rights to TEMBEXA® for $238.0 million, which closed in the third quarter of 2022.

Financing Activities:

Net cash provided by financing activities of $481.2 million in 2022 was largely from the $598.0 million of proceeds from our Revolving Credit Facility partially offset by repurchases of stock of $82.1 million and payments on our term loan of $33.8 million.

Net cash used in financing activities of $141.0 million in 2021 was primarily due to repurchases of stock of $106.0 million and payments on debt of $35.9 million.

Net cash provided by (used in) financing activities increased $622.2 million from 2021 to 2022. The increase is largely due to the proceeds from our Revolving Credit Facility of $598.0 million, partially offset by a decrease in cash payments on our Term Loan Facility.

Debt

As of December 31, 2022, the Company has $1.4 billion of fixed and variable rate debt with varying maturities, with $957.3 million payable within 12 months (see Note 8, “Debt” in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K).

Uncertainties and Trends Affecting Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures and debt service requirements from the following sources:

- existing cash and cash equivalents;
- net proceeds from the sale of our products and CDMO services;
- development contracts and grant funding;
- proceeds from the sale of our travel health business to Bavarian Nordic (see Note 18, “Subsequent events” in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K); and

- our Senior Secured Credit Facilities and any replacement or 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; and
- the costs of commercialization activities, including product marketing, sales and distribution.

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans, collaboration and licensing arrangements, cost reductions, assets sales or a combination of these options.

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 3.875% Senior Unsecured Notes due 2028 (the "Senior Unsecured Notes") 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. Any new debt funding, if available, may be on terms less favorable to us than our Senior Secured Credit Facilities or the Senior Unsecured Notes. If financing is unavailable or lost, our business, operating results, financial condition and cash flows would be adversely affected, and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

Unused Credit Capacity

Available room under the Revolving Credit Facility as of December 31, 2022 and December 31, 2021 was:

(in millions)	December 31, 2022	December 31, 2021
Total Capacity	$600.0	$600.0
Less:		
Outstanding Letters of Credit	1.3	2.3
Outstanding Indebtedness	598.0	—
Unused Capacity	$ 0.7	$597.7

Contractual Obligations

As of December 31, 2022, the Company has contractual obligations related to lease arrangements and purchase commitments. The lease arrangements are for certain equipment and facilities. As of December 31, 2022, the Company had fixed lease payment obligations of $23.5 million, with $6.5 million due within 12 months. The Company has non-cancelable purchase commitments of $132.8 million, with an estimated $125.7 million being due within 12 months.

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's product sales are recognized at a point-in-time generally upon delivery to the customer, depending on the performance obligation which the Company is delivering. The Company's CDMO arrangements are generally recognized on a percentage of completion basis utilizing a cost-to-cost method. Revenues are recognized as a percentage of the work completed during the period in an amount that reflects the percentage of the consideration which the Company expects to receive in exchange for the product or services.

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. Certain contracts may include lease components which are recognized under Accounting Standards Codification ("ASC") 842. 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, refer to Note 11, "Revenue recognition" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K.

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 of contingent consideration 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.

The Company's acquisitions accounted for as asset acquisitions may also include contingent consideration payments to be made for sales-based royalties, sales-based milestones and development and regulatory milestones. We assess whether such contingent consideration meets the definition of a derivative. Contingent consideration payments in an asset acquisition not required to be accounted for as derivatives are recognized when the contingency is resolved, and the consideration is paid or becomes payable. Contingent consideration payments required to be accounted for as derivatives are recorded at fair value on the date of the acquisition and are subsequently remeasured to fair value at each reporting date. For additional information on the Company's contingent consideration, refer to Note 6, "Fair value measurements" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K.

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 R&D 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. For additional information on the Company's income taxes, refer to Note 13, "Income taxes" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K.

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 2022 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 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 8, "Debt," in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K.

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, 2022 would increase our interest expense by approximately $6.1 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.

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, 2022 and 2021, the related consolidated statements of operations, comprehensive income (loss), changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 March 1, 2023 expressed an adverse opinion thereon.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company does not expect to be in compliance with debt covenants in future periods without additional sources of liquidity or future amendments to its Credit Agreement, has a working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that:

(1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue recognition

Description of the Matter

As described in Notes 2 and 11 to the consolidated financial statements, the Company recognized revenues of $373.7 million for the year ended December 31, 2022 related to the sale of nasal naloxone products. For these product sales, revenue is recognized at a point in time, and the Company's estimation of variable consideration includes allowances for returns, certain fees, discounts, rebates and chargebacks.

Auditing revenue recognition for nasal naloxone product sales involved significant auditor judgment because it involves subjective assumptions and estimates made by management. For example, auditing management's estimated rebates and returns for commercial arrangements are subject to significant judgment because their expected value is based on assumptions including sales or invoice data, expected utilization rates, historical payment experience, and changes in product pricing or customer contracts. These estimates 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 controls over the Company's revenue recognition for nasal naloxone product sales. For example, we tested controls over 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 revenue recognized, our audit procedures included the following primary procedures, amongst others. We estimated the rebates and returns accrual using the Company's historical data as well as externally available information and compared the result to the Company's estimated rebates and returns accrual. We evaluated the Company's ability to accurately estimate the accrual for rebates by comparing historically recorded accruals to the actual amount that was ultimately paid by the Company.

Evaluation of Goodwill for impairment

Description of the Matter

As of December 31, 2022, the Company's goodwill balance was $218.2 million. As discussed in Notes 2 and 5 of the consolidated financial statements, goodwill is tested annually for impairment at the reporting unit level. The Company evaluated goodwill for impairment as of October 1, 2022 using an income based (discounted cash flows) approach. As a result of the Company's annual goodwill impairment test, the Company recorded a $6.7 million goodwill impairment charge related to the CDMO – Services reporting unit of the Services reporting segment, which is included in "Goodwill impairment" in the Consolidated Statement of Operations for the year ended December 31, 2022.

Auditing management's goodwill impairment tests involved a high degree of auditor judgment due to the significant estimation required to determine the fair value of each reporting unit. In particular, the fair value estimate for certain reporting units was sensitive to significant assumptions such as the determination of guideline companies, discount rate, revenue growth rates and operating margins used to estimate future cash flows, which are affected by expectations about future market or economic conditions.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's goodwill impairment evaluation process. For example, we tested controls over management's review of the data used in their valuation models and reviewed significant assumptions discussed above used in determining the reporting unit fair values.

To test the estimated fair value of the Company's reporting units, with the assistance of our valuation professionals, our audit procedures included, among others, assessing fair value methodologies and testing the significant assumptions discussed above. We compared the significant assumptions used by management to current industry and economic trends, the Company's historical trends with consideration given to changes in the Company's business, customer base or product mix and other relevant factors. We assessed the historical accuracy of management's estimates and performed sensitivity analyses of significant assumptions to evaluate the changes in the fair value of the reporting units that would result from changes in the assumptions. We also evaluated the reconciliation of the estimated aggregate fair value of the reporting units to the Company's market capitalization.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2004.
Tysons, Virginia
March 1, 2023

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

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 642.6	$ 576.1
Restricted cash	—	0.2
Accounts receivable, net	158.4	274.7
Inventories, net	351.8	350.8
Prepaid expenses and other current assets	57.9	70.3
Total current assets	1,210.7	1,272.1
Property, plant and equipment, net	817.6	800.1
Intangible assets, net	728.8	604.6
Goodwill	218.2	224.9
Other assets	191.3	57.3
Total assets	$3,166.6	$2,959.0
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 103.5	$ 128.9
Accrued expenses	34.9	51.7
Accrued compensation	88.3	88.7
Debt, current portion	957.3	31.6
Other current liabilities	45.9	72.9
Total current liabilities	1,229.9	373.8
Debt, net of current portion	448.5	809.4
Deferred tax liability	71.8	94.9
Other liabilities	33.4	61.9
Total liabilities	1,783.6	1,340.0
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, 55.7 and 55.1 shares issued; 50.1 and 51.3 shares outstanding, respectively.	0.1	0.1
Treasury stock, at cost, 5.6 and 3.8 common shares, respectively	(227.7)	(152.2)
Additional paid-in capital	873.5	829.4
Accumulated other comprehensive income (loss), net	3.1	(16.1)
Retained earnings	734.0	957.8
Total stockholders' equity	1,383.0	1,619.0
Total liabilities and stockholders' equity	$3,166.6	$2,959.0

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,		
	2022	**2021**	**2020**
Revenues:			
Product sales, net	$ 966.2	$1,023.9	989.8
CDMO:			
Services	108.4	334.9	166.7
Leases	4.9	299.7	283.8
Total CDMO	113.3	634.6	450.5
Contracts and grants	41.4	134.2	115.1
Total revenues	1,120.9	1,792.7	1,555.4
Operating expenses:			
Cost of product sales	424.1	382.0	392.0
Cost of CDMO	269.6	375.5	132.0
Research and development	193.0	234.0	234.5
Selling, general and administrative	340.3	348.4	303.3
Goodwill impairment	6.7	41.7	—
Amortization of intangible assets	59.9	58.5	59.8
Total operating expenses	1,293.6	1,440.1	1,121.6
Income (loss) from operations	(172.7)	352.6	433.8
Other income (expense):			
Interest expense	(37.3)	(34.5)	(31.3)
Other, net	(11.7)	(3.7)	4.7
Total other income (expense), net	(49.0)	(38.2)	(26.6)
Income (loss) before income taxes	(221.7)	314.4	407.2
Income tax provision	2.1	83.5	102.1
Net income (loss)	$(223.8)	$ 230.9	$ 305.1
Net income (loss) per common share			
Basic	$ (4.47)	$ 4.32	$ 5.79
Diluted	$ (4.47)	$ 4.27	$ 5.67
Shares used in computing net income (loss) per common share			
Basic	50.1	53.5	52.7
Diluted	50.1	54.1	53.8

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

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

	Year Ended December 31,		
	2022	2021	2020
Net income (loss)	$(223.8)	$230.9	$ 305.1
Other comprehensive income (loss), net of tax:			
Foreign currency translation adjustment	1.0	(1.0)	(1.7)
Unrealized gains (losses) on hedging activities	10.7	6.5	(9.4)
Unrealized gain (losses) on pension benefit obligation	7.5	3.7	(4.3)
Total other comprehensive income (loss), net of tax	19.2	9.2	(15.4)
Comprehensive income (loss), net of tax	$(204.6)	$240.1	$ 289.7

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,		
	2022	**2021**	**2020**
Operating Activities			
Net income (loss)	$(223.8)	$ 230.9	$ 305.1
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Stock-based compensation expense	45.1	42.4	51.0
Depreciation and amortization	143.3	123.8	114.5
Change in fair value of contingent obligations, net	2.6	2.9	31.7
Amortization of deferred financing costs	4.1	4.1	3.5
Impairments	6.7	41.7	29.0
Deferred income taxes	(19.0)	46.9	(2.4)
Write off of contract asset and liability	—	(17.2)	—
Other	6.4	2.0	(5.2)
Changes in operating assets and liabilities:			
Accounts receivable	114.7	(48.2)	49.0
Inventories	(51.9)	(44.0)	(83.2)
Prepaid expenses and other assets	(19.9)	7.7	(29.2)
Accounts payable	(14.0)	(2.5)	18.7
Accrued expenses and other liabilities	(66.7)	(9.2)	19.4
Accrued compensation	0.1	4.0	21.8
Income taxes receivable and payable, net	28.6	(32.4)	1.1
Contract liabilities	9.6	(31.8)	11.2
Net cash provided by (used in) operating activities	(34.1)	321.1	536.0
Investing Activities			
Purchases of property, plant and equipment	(115.8)	(225.0)	(141.0)
Royalty settlement payment	(21.8)	—	—
Milestone payment from prior asset acquisition	—	—	(10.0)
Asset acquisitions	(243.7)	—	—
Net cash used in investing activities	(381.3)	(225.0)	(151.0)
Financing Activities			
Purchases of treasury stock	(82.1)	(106.0)	—
Proceeds from senior unsecured notes	—	—	450.0
Principal payments on convertible senior notes	—	(10.6)	—
Proceeds from revolving credit facility	598.0	—	—
Principal payments on revolving credit facility	—	—	(373.0)
Principal payments on term loan facility	(33.8)	(25.3)	(14.1)
Proceeds from stock-based compensation activity	5.0	15.9	31.6
Taxes paid for stock-based compensation activity	(5.9)	(13.8)	(13.8)
Debt issuance costs	—	—	(8.4)
Contingent consideration payments	—	(1.2)	(2.8)
Net cash provided by (used in) financing activities:	481.2	(141.0)	69.5
Effect of exchange rate changes on cash, cash equivalents and restricted cash	0.5	(0.3)	(1.0)
Net change in cash, cash equivalents and restricted cash	66.3	(45.2)	453.5
Cash, cash equivalents and restricted cash, beginning of period	576.3	621.5	168.0
Cash, cash equivalents and restricted cash, end of period	$ 642.6	$ 576.3	$ 621.5
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 33.0	$ 30.4	$ 21.0
Cash paid for income taxes	$ 6.2	$ 71.6	$ 109.3
Supplemental information on non-cash investing and financing activities:			
Purchases of property, plant and equipment unpaid at period end	$ 9.4	$ 20.0	$ 22.0
Purchases of treasury stock unpaid at period end	$ —	$ 6.6	$ —
Reconciliation of cash and cash equivalents and restricted cash:			
Cash and cash equivalents	$ 642.6	$ 576.1	$ 621.3
Restricted cash	—	0.2	0.2
Total	$ 642.6	$ 576.3	$ 621.5

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 Income (Loss)	Retained Earnings	Total Stockholders' Equity
	Shares	Amount		Shares	Amount			
Balance at January 1, 2020	53.0	$ 0.1	$716.1	(1.2)	$ (39.6)	$ (9.9)	$ 421.8	$1,088.5
Net income	—	—	—	—	—	—	305.1	305.1
Other comprehensive loss, net of tax	—	—	—	—	—	(15.4)	—	(15.4)
Share-based compensation activity	1.3	—	68.8	—	—	—	—	68.8
Balance at December 31, 2020	54.3	$ 0.1	$784.9	(1.2)	$ (39.6)	$(25.3)	$ 726.9	$1,447.0
Net income	—	—	—	—	—	—	230.9	230.9
Other comprehensive income, net of tax	—	—	—	—	—	9.2	—	9.2
Share-based compensation activity	0.8	—	44.5	—	—	—	—	44.5
Repurchases of common stock	—	—	—	(2.6)	(112.6)	—	—	(112.6)
Balance at December 31, 2021	55.1	$ 0.1	$829.4	(3.8)	$(152.2)	$(16.1)	$ 957.8	$1,619.0
Net loss	—	—	—	—	—	—	(223.8)	(223.8)
Other comprehensive income, net of tax	—	—	—	—	—	19.2	—	19.2
Share-based compensation activity	0.6	—	44.1	—	—	—	—	44.1
Repurchases of common stock	—	—	—	(1.8)	(75.5)	—	—	(75.5)
Balance at December 31, 2022	55.7	$ 0.1	$873.5	(5.6)	$(227.7)	$ 3.1	$ 734.0	$1,383.0

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. ("Emergent," the "Company," "we," "us," and "our") is a global life sciences company focused on providing innovative preparedness and response solutions addressing accidental, deliberate, and naturally occurring Public Health Threats ("PHTs"). The Company's solutions include a product portfolio, a product development portfolio, and a contract development and manufacturing ("CDMO") services portfolio.

The Company is focused on the following five PHT categories: chemical, biological, radiological, nuclear and explosives ("CBRNE"); emerging infectious diseases ("EID"); travel health; emerging health crises; and acute/emergency care. The Company has a product portfolio of thirteen products (vaccines, therapeutics, and drug-device combination products). The revenue generated by the products comprises a substantial portion of the Company's revenue. The Company has one product candidate that is procured under special circumstances by the United States government ("USG"), although it is not approved by the United States Food and Drug Administration ("FDA"). The Company structures the business with a focus on markets and customers. As such, the key components of the business structure include the following three product and service categories: Government—Medical Countermeasures ("MCM") Products, Commercial Products, and CDMO Services. The Company operates as two operating segments: (1) a products segment ("Products") consisting of the Government—MCM and Commercial product categories and (2) a services segment ("Services") focused on CDMO services (Note 16, "Segment information").

The Company's products and services include:

Government—MCM Products

- 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;
- Anthrasil® (Anthrax Immune Globulin Intravenous (human)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of inhalational anthrax in combination with appropriate antibacterial drugs;
- Anthrax vaccines, including our AV7909 (Anthrax Vaccine Adsorbed (AVA), Adjuvanted) 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. AV7909 has not been approved by the FDA, but is procured by certain authorized government buyers for their use;
- BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)), the only heptavalent antitoxin licensed by the FDA and Health Canada for the treatment of symptomatic botulism;
- CNJ-016® (Vaccinia Immune Globulin Intravenous (Human) (VIGIV)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination;
- Ebanga™ (ansuvimab-zykl) is a monoclonal antibody with antiviral activity provided through a single IV infusion for the treatment of Ebola. Under the terms of a collaboration with Ridgeback Biotherapeutics ("Ridgeback"). Emergent will be responsible for the manufacturing, sale, and distribution of Ebanga™ in the U.S. and Canada, and Ridgeback will serve as the global access partner for Ebanga™;

- Raxibacumab injection, the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax;
- RSDL® (Reactive Skin Decontamination Lotion Kit), 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;
- TEMBEXA®, an oral antiviral formulated as 100 mg tablets and 10 mg/mL oral suspension dosed once weekly for two weeks which has been approved by the FDA for the treatment of smallpox disease caused by variola virus in adult and pediatric patients, including neonates; and
- Trobigard® atropine sulfate, obidoxime chloride auto-injector, a combination drug-device auto-injector procured product candidate that contains atropine sulfate and obidoxime chloride. It was approved in Belgium in 2021 but has not been approved by the FDA. Trobigard is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure outside of the U.S.

Commercial Products

- NARCAN® (naloxone HCl) Nasal Spray, an intranasal 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;
- Vaxchora® (Cholera Vaccine, Live, Oral), the first vaccine approved by the FDA for the prevention of cholera, which we have agreed to sell as part of our travel health business; and
- Vivotif® (Typhoid Vaccine Live Oral Ty21a), a live attenuated vaccine for oral administration for the prevention of typhoid fever, which we have agreed to sell as part of our travel health business.

Services—Contract Development and Manufacturing

The Company's services line focused on CDMO offerings cover development services, drug substance manufacturing, drug product manufacturing, and when necessary, suite reservations, which depending on facts and circumstances could be considered a lease. These services are provided 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.

Asset Acquisition

During the year ended December 31, 2022, the Company acquired from Chimerix ("the Seller") the exclusive worldwide rights to brincidofovir, including TEMBEXA® and related assets (the "Transaction"). TEMBEXA is an oral antiviral medical countermeasure to treat smallpox approved by the FDA in June 2021. Under the terms of the Asset Purchase Agreement (the "Purchase Agreement"), the Company paid $238.0 million upon closing of the Transaction, and is subject to potential milestone payments of up to $124.0 million contingent on the potential exercise by the USG of procurement options. The closing payment and the milestone payments were based on the actual procurement value of the procurement contract (the "BARDA Contract") with the Biomedical Advanced Research and Development Authority ("BARDA"). Each milestone payment is associated with the exercise of future BARDA procurement options of TEMBEXA following the BARDA Contract base period. The Seller is also eligible to receive up to $12.5 million in regulatory milestones

associated with the SymBio Pharmaceuticals Ltd. brincidofovir licensing arrangements assumed by the Company in the Transaction. The milestone payments will be recorded when the associated procurement options have been exercised and/or the regulatory milestones have been met and the consideration is paid or becomes payable. The total consideration paid in the Transaction was allocated based on the proportionate fair value of the assets acquired. We recorded $156.9 million in intangible assets, net and $82.3 million in inventories, net upon execution of the Transaction on our consolidate balance sheet.

The Seller may also earn a 20% royalty on future gross profit of TEMBEXA in the United States associated with volumes above 1.7 million treatment courses of therapy during the exclusivity period of TEMBEXA. Outside of the United States, the Purchase Agreement also allows the Seller to earn a 15% royalty on all gross profit associated with TEMBEXA sales during the exclusivity period of TEMBEXA on a market-to-market basis. Refer to Note 5 “Intangible assets and goodwill” for additional information around the impacts of this asset acquisition on the current period results.

2. Summary of significant accounting policies

Basis of presentation and consolidation

Our financial statements are prepared in conformity with U.S. generally accepted accounting principles (“GAAP”). 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. Reclassifications of certain prior period amounts have been made to conform to the current period presentation.

During the year ended December 31, 2022, the Company revised the reporting that the chief operating decision maker (“the CODM”) reviews in order to assess Company performance. The CODM manages the business with a focus on two reportable segments: (1) Products segment consisting of Government—MCM and Commercial products and (2) Services segment focused on CDMO services.

Going Concern

The consolidated financial statements have been prepared on the going concern basis of accounting, which assumes the Company will continue to operate as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

As of December 31, 2022, there is $598.0 million outstanding on the our senior revolving credit facility (“Revolving Credit Facility”) and $362.8 million on our senior term loan facility (“Term Loan Facility” and together with the Revolving Credit Facility, the “Senior Secured Credit Facilities”) that mature in October 2023, which is within one year of the date that the consolidated financial statements for the year ended December 31, 2022 are issued. The Company determined that there is substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued as a result of these pending maturities. This evaluation considered the potential mitigating effect of management’s plans that have not been fully implemented. Management evaluated the mitigating effect of its plans to determine if it is probable that (1) the plans will be effectively implemented within one year after the date the financial statements are issued, and (2) when implemented, the plans will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern. The Company’s plan to alleviate the substantial doubt includes amending its existing Senior Secured Credit Facilities that are due October 2023.

On February 14, 2023, the Company entered into a Consent, Limited Waiver, and Third Amendment to the Amended and Restated Credit Agreement (the “Third Credit Agreement Amendment”, “Credit Agreement” and as amended, the “Amended Credit Agreement”) relating to the Senior Secured Credit Facilities. Pursuant to the Third Credit Agreement Amendment, the requisite lenders consented to our sale of our travel health business to

Bavarian Nordic substantially in accordance with the terms of the Sale Agreement. The proceeds from the transaction will be deposited into a cash collateral account with the Administrative Agent and will, unless otherwise agreed to by the Company and the requisite lenders, be used to repay the outstanding Term Loan Facility on the expiration of the Limited Waiver (as described below). We currently expect the transaction to close in the second quarter of 2023, but we can provide no assurance that the transaction will close prior to the October 2023 maturity of the Term Loan Facility, or at all.

Pursuant to the Third Credit Agreement Amendment the requisite lenders have agreed to a limited waiver of any defaults or events of default that result from (a) any violation of the financial covenants set forth in the Senior Secured Credit Facilities with respect to the fiscal quarters ending December 31, 2022 and March 31, 2023 and (b) the going concern qualification or exception contained in the audited financial statements for the fiscal year ending December 31, 2022. This limited waiver will expire on the earlier to occur of (i) any other event of default and (ii) April 17, 2023. During this period the Company is working with lenders under the Senior Secured Credit Facilities in connection with replacing such facilities before their October 2023 maturity with revised terms and conditions. The Company does not expect to be in compliance with debt covenants in future periods without additional sources of liquidity or future amendments to the Credit Agreement.

While the Company is in the process of replacing and expects to replace the Senior Secured Credit Facilities before they mature, management cannot conclude that it is probable that the Company will be able to obtain such debt refinancing on commercially reasonable terms or at all until a new credit facility is in place. The Company is currently working with its lenders to refinance the Senior Secured Credit Facilities with revised terms and conditions. The extent to which the Company will be able to affect such refinancing, replacement or maturity extension on terms that are favorable or at all is dependent on a number of uncertain factors, including then-prevailing credit and other market conditions, economic conditions, particularly in the pharmaceutical and biotechnology industry, disruptions or volatility caused by factors such as COVID-19, regional conflicts, inflation, and supply chain disruptions. In addition, rising interest rates could limit our ability to refinance the Senior Secured Credit Facilities when they mature or cause us to pay higher interest rates upon refinancing.

The Company has $642.6 million of cash on hand at December 31, 2022. On January 9, 2023, the Company announced the 2023 organizational restructuring Plan (the “Plan”) intended to reduce operating costs, improve operating margins, and continue advancing the Company’s ongoing commitment to profitable growth. The Plan includes a reduction of the Company’s current workforce by approximately five percent.

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), interest-rate swap arrangements and time deposits (Level 2) and contingent purchase consideration (Level 3) using fair value measurements in the accompanying financial statements. The carrying amounts of the Company's short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable approximate their fair values due to their short maturities. The carrying amounts of the Company's long-term 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. The Company's branded and generic 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 reserve for credit losses 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. 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 and the Company has a right to bill but invoicing has not yet occurred. Contract assets include revenues recognized in advance of billings and the Company does not have a right to invoice the customer under the terms of the contract. The Company has receivables from contracts containing lease components. At each reporting period, the Company assesses whether it is probable that the Company will collect all future lease payments. The Company considers payment history and current credit status when assessing collectability. The Company does 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.

Concentration Risk

Customers

The Company has long-term contracts with the USG that expire at various times from 2023 through 2036. The Company has derived a significant portion of its revenue from sales of our Government—MCM products 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 and other medical countermeasures products are subject to unilateral termination or modification by the government. The Company may fail to achieve significant sales of its medical countermeasures products, including ACAM2000

and Anthrax Vaccines to customers in addition to the USG, which would harm their growth opportunities. The Company's other product sales, largely Nasal Naloxone Products, 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. In 2022, we filed our supplemental New Drug Application for NARCAN® (naloxone HCl) Nasal Spray, as an over-the-counter emergency treatment which if approved would further broaden our customer base. Our CDMO customers are generally third-party pharmaceutical companies. Refer to Footnote 11, "Revenue recognition" for more information regarding significant customers.

Although the Company seeks to 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 receivable do not represent a significant concentration of credit risk. The USG accounted for approximately 43%, 50% and 64% of total revenues for 2022, 2021 and 2020, respectively. The Company's accounts receivable as of December 31, 2022 and 2021, consist primarily of amounts due from the USG or other large multinational 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, 2022, the Company does not anticipate nonperformance by any of its counterparties.

Inventories, net

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 short-dated, contaminated or 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 combinations 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, net

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.

The Company generally depreciates or amortizes the cost of its 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 basis and net operating loss and research and development ("R&D") 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 R&D 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.

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 components of our business for which discrete cash flow information is available one level below its operating segment. The Company evaluates goodwill and other indefinite-lived intangible assets for impairment annually as of October 1 and at interim 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 up to the total amount of goodwill included in the reporting unit.

When the Company has material indefinite lived intangible assets associated with in-process research and development ("IPR&D") a qualitative assessment is performed. If the qualitative assessment indicates 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 Note 5, "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, they 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 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. 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 in the period in which the increase is determined.

The Company's acquisitions accounted for as asset acquisitions may also include contingent consideration payments to be made for sales-based royalties, sales-based milestones and development and regulatory milestones. The Company assesses whether such contingent consideration meets the definition of a derivative. Contingent consideration payments in an asset acquisition not required to be accounted for as derivatives are

recognized when the contingency is resolved, and the consideration is paid or becomes payable. Contingent consideration payments required to be accounted for as derivatives are recorded at fair value on the date of the acquisition and are subsequently remeasured to fair value at each reporting date.

Leases

The Company has operating leases for corporate offices, R&D facilities and manufacturing facilities. The Company determines 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 $0.4 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 $0.4 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.

Revenue recognition

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.

Multiple performance obligations

At contract inception, the Company assesses the products or services promised in a contract 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. 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 more than one product, a lease, or options for customers to purchase additional products or services in the future for free or at a discount, which gives rise to separate performance obligations. 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 net profit received from sales of the Company's generic Nasal naloxone product, certain products sold on a net basis, cost-plus-fee contract terms and consideration transferred under its development contracts as consideration received can vary based on developmental progression of the product candidate. 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 year ended December 31, 2022.

Product sales

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. To indicate the transfer of control the Company will 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. 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 Government—MCM products include certain acceptance criteria before title passes to the customer. The primary customer for the Company's Government—MCM products and the primary source of funding for the development of its MCM product candidate portfolio is the USG. The USG contracts for the sale of the Company's Government—MCM products are normally multi-year contracts with annual options.

For the Company's commercial products, upon transfer of control of the goods the Company reflects estimates of the consideration that the Company expects. 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 include allowances for returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, chargebacks and rebates under managed care plans.

Revenue 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. 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 Company reassesses the Company's provisions for variable consideration at each reporting date.

CDMO services

The Company performs CDMO services for third parties. Under these contracts, activities can include drug substance and drug product manufacturing services for injectable and other sterile products, and development services such as pharmaceutical product process development, process design, technology transfer, manufacturing validations, laboratory analytical development support, aseptic filling, lyophilization, final

packaging, stability studies, and suite-reservations. These contracts vary in duration, activities, and number of performance obligations. Performance obligations identified under these arrangements may include drug substance and/or drug product manufacturing, technology transfer activities, and suite-reservations.

Drug substance, drug product manufacturing, development services and technology transfer performance obligations are recognized as revenue over-time because the Company's performance does not create an asset with an alternative use and the Company has an enforceable right to payment for performance completed as work is performed. In drug product arrangements, the customer typically owns and supplies the active pharmaceutical ingredient (API), that is used in the manufacturing process; in drug substance arrangements, the customer provides certain seed material that is used in the manufacturing process. The transaction price generally contains both a fixed and variable component. The fixed component is stated in the agreement as a fixed price per unit with no contractual provision for a refund or price concession and the variable component generally results from pass-through costs that are billed at cost-plus over the life of the contract. The Company uses an input method to measure progress toward the satisfaction of the related performance obligations based on costs incurred as a percentage of total costs to complete which the Company believes best depicts the transfer of control of goods or services promised to its customers.

Suite reservations are classified as leases when the customer directs the use of the identified suite and obtains substantially all the economic benefits from the manufacturing capacity. If a customer reserves more than one suite, the allocation of contract value is based on relative selling price which varies due to size, location, capacity, production capability for drug product or drug substance, and the time of planned use. The associated revenue is recognized on a straight-line basis over the period of performance. For arrangements that contain both lease and non-lease components, consideration in the contract is allocated on a relative standalone selling price basis.

The Company's CDMO customer contracts generally include provisions entitling the Company to a termination penalty when the contract is terminated prior to the contract's nominal end date. The termination penalties in the customer contracts vary but are generally considered substantive for accounting purposes and create enforceable rights and obligations throughout the stated duration of the contract. The Company accounts for a contract cancellation as a contract modification. The determination of the contract termination penalty is based on the terms stated in the related customer agreement. As of the modification date, the Company updates its estimate of the transaction price, subject to constraints, and recognizes the amount over the remaining performance period or measure of progress under the arrangement.

For contracts that contain lease components, the Company assesses the collectability of the lease payments. If the collectability of the lease payments is probable, the Company recognizes lease income over the term of the lease on a straight-line basis. If collectability is not deemed probable at any time during the term of the lease, the Company's lease income is limited to the lesser of (i) the lease payments that have been collected from the lessee, or the straight-line recognition of the contract value. If the collectability assessment changes to probable after the Company has determined collectability is not deemed probable, any difference between the lease income that would have been recognized if collectability had always been assessed as probable and the lease income recognized to date is recognized as a current-period adjustment to lease income. Changes to the collectability of operating leases are recorded as adjustments to lease income in the consolidated statements of operations in the period that they occur.

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 access to the development research

under these projects and benefits incrementally as R&D activities occur. When applicable, the Company considers fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract, the cost-to-cost measure of progress. The Company analyzes costs for contracts and reimbursable grants to ensure reporting of revenues gross versus net is appropriate. The USG contracts for the development of the Company's MCM product candidates are normally multi-year contracts.

Research and development

The Company expenses R&D costs as incurred. The Company's R&D 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 intended for use and used in clinical trials and R&D.

Comprehensive income (loss)

Comprehensive income (loss) is comprised of net income (loss) and other changes in equity that are excluded from net income (loss). 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 (loss) as well as gains and losses on its pension benefit obligation and derivative instruments.

Translation and Remeasurement 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 (loss) and are recorded in accumulated other comprehensive income (loss), 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 remeasured at the rate of exchange in effect on the date assets were acquired while monetary assets and liabilities are remeasured at current rates of exchange as of the balance sheet date. Income and expense items are remeasured at the average foreign currency rates for the period. Remeasurement adjustments of these subsidiaries are included in other income (expense), net in our consolidated statements of operations.

Net income (loss) per common share

Basic net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted net income (loss) per common share is computed using the treasury method by dividing net income (loss) 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.

Treasury stock

When stock is acquired for purposes other than formal or constructive retirement, the purchase price of the acquired stock is recorded in a separate treasury stock account, which is separately reported as a reduction of equity.

When stock is retired or purchased for formal or constructive retirement, the purchase price is initially recorded as a reduction to the par value of the shares repurchased, with any excess purchase price over par value recorded as a reduction to additional paid-in capital related to the series of shares repurchased and any remainder excess purchase price recorded as a reduction to retained earnings. If the purchase price exceeds the amounts allocated to par value and additional paid-in capital related to the series of shares repurchased and retained earnings, the remainder is allocated to additional paid-in capital related to other series of shares.

To determine the cost of treasury stock that is either sold or reissued, the Company uses the last in, first out method. If the proceeds from the re-issuance of treasury stock are greater than the cost, the excess is recorded as additional paid-in capital. If the proceeds from re-issuance of treasury stock are less than the cost, the excess cost first reduces any additional paid-in capital arising from previous treasury stock transactions for that class of stock, and any additional excess is recorded as a reduction of retained earnings.

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") under which the Company may grant various types of equity awards including stock options, restricted stock units and performance stock units. For all of our share-based awards, the Company recognizes forfeitures and compensation costs when they occur.

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. The Company records the estimated fair value of awards in expense 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 adjusted each reporting period 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 option 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 (loss), 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 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 payments of variable interest rate debt under its senior secured credit agreements.

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 (loss) and subsequently reclassified into interest expense in the same period during which the hedged transaction affects earnings. Amounts reported in accumulated other comprehensive income (loss) 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.

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, the Company incorporates credit valuation adjustments in the fair value measurements to appropriately reflect both its 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 the Company's derivative contracts for the effect of nonperformance risk, it has 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 7, "Derivative instruments" for further details on the interest rate swaps.

New Accounting Standards

Recently Adopted Accounting Standards

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

In March 2020, the Financial Accounting Standards Board issued ASU 2020-04, which was further amended in January 2021. ASU 2020-04 provides relief for impacted areas as it relates to impending reference rate reform. It 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 adopted ASU 2020-04 during the year ended December 31, 2022 with no material impact to our consolidated financial statements.

3. Inventories, net

Inventories, net consist of the following:

	December 31,	
	2022	2021
Raw materials and supplies	$143.4	$217.5
Work-in-process	116.2	95.8
Finished goods	92.2	37.5
Total inventories, net [1]	$351.8	$350.8

[1] During the year ended December 31, 2022, the Company acquired certain assets through an asset acquisition, the Transaction, and the related inventories of $28.6 million were included in the Company's inventories balances as of December 31, 2022.

Inventories, net is stated at the lower of cost or net realizable value.

During the year ended December 31, 2021, the Company recorded inventory write-offs related to its Bayview facility of $41.5 million and the charge was reflected as a component of cost of CDMO services on the Company's consolidated statements of operations. For additional information related the termination of the manufacturing services agreement (the "Agreement") with Janssen Pharmaceuticals, Inc. ("Janssen") as of December 31, 2022, refer to Note 11 "Revenue recognition".

4. Property, plant and equipment, net

Property, plant and equipment, net consists of the following:

	December 31,	
	2022	2021
Land and improvements	$ 54.9	$ 52.1
Buildings, building improvements and leasehold improvements	327.9	269.7
Furniture and equipment	567.5	513.5
Software	65.6	60.7
Construction-in-progress	185.5	223.2
Property, plant and equipment, gross	1,201.4	1,119.2
Less: Accumulated depreciation and amortization	(383.8)	(319.1)
Total property, plant and equipment, net	$ 817.6	$ 800.1

For the years ended December 31, 2022 and 2021, construction-in-progress primarily includes costs incurred related to construction to advance the Company's CDMO capabilities.

Property, plant and equipment, net is stated at cost, less accumulated depreciation and amortization. During the year ended December 31, 2022, the Company recorded accelerated depreciation of $12.7 million reflecting a shortening of the useful life of certain property, plant and equipment which were to be used in the manufacturing process to fulfill the Agreement with Janssen. For additional information related to the termination of the Agreement, refer to Note 11 "Revenue recognition".

Depreciation and amortization expense associated with property, plant and equipment was $83.4 million, $62.2 million and $50.1 million for the years ended December 31, 2022, 2021, and 2020, respectively.

5. Intangible assets and goodwill

The Company's intangible assets consist of products acquired via business combinations or asset acquisitions. Components of the Company's intangible assets, excluding goodwill, consisted of the following:

	December 31, 2022				December 31, 2021		
	Weighted Average Useful Life in Years	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Products [1][2]	14.4	$ 982.1	$253.3	$728.8	$798.0	$193.5	$604.5
Customer relationships	0.0	28.6	28.6	—	28.6	28.6	—
CDMO	0.0	5.5	5.5	—	5.5	5.4	0.1
Total intangible assets	14.4	$1,016.2	$287.4	$728.8	$832.1	$227.5	$604.6

(1) During the year ended December 31, 2022, the Company acquired certain assets through asset acquisitions, and the related intangible assets were assigned to the "Products" asset type, of which $156.9 million was related to the Transaction.

(2) During the year ended December 31, 2022, the Company acquired certain assets through a royalty settlement, and the related intangible assets of $21.8 million were assigned to the "Products" asset type.

For the years ended December 31, 2022, 2021, and 2020, the Company recorded amortization expense for intangible assets of $59.9 million, $58.5 million and $59.8 million, respectively, which is included in the amortization of intangible assets in the consolidated statements of operations.

The Company estimates its future amortization expense for our intangible assets as follows:

Year	As of December 31, 2022
2023	$ 71.5
2024	71.5
2025	71.5
2026	70.2
2027	67.0
Thereafter	377.1
Total remaining amortization	$ 728.8

The table below summarizes the changes in the carrying amount of goodwill by reportable segment:

	Products [1]	Services [2]	Total
Balance at December 31, 2020	$ 260.0	$ 6.7	$ 266.7
Goodwill impairment	(41.7)	—	(41.7)
Foreign currency translation adjustment	(0.1)	—	(0.1)
Balance at December 31, 2021	$ 218.2	$ 6.7	$ 224.9
Goodwill impairment	—	(6.7)	(6.7)
Foreign currency translation adjustment	—	—	—
Balance at December 31, 2022	$ 218.2	$ —	$ 218.2

(1) Amounts for the Company's Products segment include gross carrying values of $259.9 million as of December 31, 2022 and 2021, and $260.0 million as of December 31, 2020, and accumulated impairment losses of $41.7 million representing the aggregate impairment charges for the years ended December 31, 2022, 2021 and 2020.

(2) Amounts for the Company's Services segment include gross carrying values of $6.7 million as of December 31, 2022, 2021, and 2020, and accumulated impairment losses of $6.7 million representing the aggregate impairment charges for the year ended December 31, 2022.

As a result of the Company's annual goodwill impairment test on October 1, 2022 the Company recorded a $6.7 million non-cash goodwill impairment charge included in "Goodwill impairment" in the Statements of Operations during the year ended December 31, 2022 in the CDMO—Services reporting unit within the Services segment. The CDMO—Services reporting unit and Services segment had no remaining goodwill balance as of December 31, 2022. The goodwill impairment charge resulted from a reduction in the estimated fair value of the CDMO-Services reporting unit due to changes to the long-term operating plan that reflected lower expectations for growth and profitability than previous expectations. The Company used a quantitative assessment, utilizing a income based (discounted cash flows) approach, Level 3 non-recurring fair value measurement, for our goodwill impairment testing for all of our reporting units in 2022. Outside of our CDMO—Services reporting unit, the assessments completed for all other reporting units during the year ended December 31, 2022 indicated no impairment.

On October 1, 2021, the Company reorganized its lines of business resulting in a change in the composition of two of its reporting units and performed its annual impairment testing using quantitative tests to determine fair values of the reporting units both before and after the reorganization of the lines of business and its reporting units. Using both a market based (comparable company multiple) and income based (discounted cash flows) approach, each a Level 3 non-recurring fair value measurement, the Company determined that there was a goodwill impairment of $41.7 million included in "Goodwill impairment" in the Statements of Operations in the Commercial products reporting unit within our Products segment. The Company used a qualitative assessment for our goodwill impairment testing for all other reporting units in 2021. The assessments completed for all other reporting units during the year ended December 31, 2021 indicated no impairment.

6. Fair value measurements

The table below presents information about the Company's assets and liabilities that are regularly measured and carried at fair value and indicate the level within the fair value hierarchy of the valuation techniques we utilized to determine fair value:

	December 31, 2022				December 31, 2021			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Assets:								
Money market accounts	$320.8	$320.8	$ —	$—	$152.4	$152.4	$ —	$ —
Time deposits	170.7	—	170.7	—	200.0	—	200.0	—
Derivative instruments	$ 8.5	$ —	$ 8.5	$—	$ —	$ —	$ —	$ —
Total	$500.0	$320.8	$179.2	$—	$352.4	$152.4	$200.0	$ —
Liabilities:								
Contingent consideration	$ 6.8	$ —	$ —	$ 6.8	$ 37.2	$ —	$ —	$37.2
Derivative instruments	—	—	—	—	6.1	—	6.1	—
Total	$ 6.8	$ —	$ —	$ 6.8	$ 43.3	$ —	$ 6.1	$37.2

Contingent consideration

Contingent consideration liabilities associated with business combinations are measured at fair value. These liabilities represent an obligation of the Company to transfer additional assets to the selling shareholders and owners if future events occur or conditions are met. These liabilities associated with business combinations are measured at fair value at inception and at each subsequent reporting date. The changes in the fair value are primarily due to the expected amount and timing of future net sales, which are inputs that have no observable market. Any changes in fair value for the contingent consideration liabilities related to the Company's products are classified in the Company's statement of operations as cost of product sales. Any changes in fair value for the contingent consideration liabilities related to the Company's product candidates are recorded in R&D 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 during the years ended December 31, 2022, 2021 and 2020.

	Contingent Consideration
Balance at December 31, 2019	$ 29.2
Expense included in earnings	31.7
Settlements	(2.8)
Balance at December 31, 2020	$ 58.1
Expense included in earnings	2.9
Settlements	(23.8)
Balance at December 31, 2021	$ 37.2
Expense included in earnings	2.6
Settlements	(33.0)
Balance at December 31, 2022	$ 6.8

As of December 31, 2022 and 2021, the current portion of the contingent consideration liability was $3.1 million and $32.7 million, respectively, and was included in "other current liabilities" on the consolidated balance sheets. The non-current portion of the contingent consideration liability is included in "other liabilities" on the consolidated balance sheets.

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, 2022	Valuation Technique	Unobservable Input	Range
Royalty based	$6.8 million	Discounted cash flow	Discount rate	9.9%
			Probability of payment	25.0% - 50.0%
			Projected year of payment	2023 - 2028

Non-Variable Rate Debt

As of December 31, 2022 and 2021, the fair value of the Company's 3.875% Senior Unsecured Notes was $225.1 million and $433.3 million, respectively. The fair value was determined through market sources, which are Level 2 inputs and directly observable. The carrying amounts of the Company's other long-term variable interest rate debt arrangements approximate their fair values (see Note 8, "Debt").

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, 2022 and December 31, 2021, other than those outlined in Note 5 "Intangible assets and goodwill", there were no material assets or liabilities measured at fair value on a non-recurring basis.

7. 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 payments of variable interest rate debt associated with the Company's senior secured credit agreements.

If current fair values of designated interest rate swaps remained static over the next twelve months, the Company would reclassify $8.5 million of net deferred gains from accumulated other comprehensive income (loss) to the statement of operations over the next twelve month period. All outstanding cash flow hedges mature in October 2023.

As of December 31, 2022, 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.

	Fair Value of Asset Derivatives			Fair Value of Liability Derivatives		
		December 31,			December 31	
	Balance Sheet Location	2022	2021	Balance Sheet Location	2022	2021
Interest Rate Swaps	Other Current Assets	$ 8.5	$ —	Other Current Liabilities	$ —	$ 4.5
	Other Assets	$ —	$ —	Other Liabilities	$ —	$ 1.6

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. 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 not 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 (loss):

	Cumulative Amount of Gain/(Loss) Recognized in OCI on Derivatives		Location of Loss Reclassified from Accumulated OCI(L) into Income (Loss)	Amount of Loss Reclassified from Accumulated OCI(L) into Income (Loss)	
	December 31,			Year Ended December 31,	
	2022	2021		2022	2021
Interest Rate Swaps	$8.5	$(6.1)	Interest expense	$(0.1)	$(5.8)

8. Debt

The components of debt are as follows:

	December 31,	
	2022	2021
Senior secured credit agreement—Term loan due 2023	$ 362.8	$ 396.6
Senior secured credit agreement—Revolver loan due 2023	598.0	—
3.875% Senior Unsecured Notes due 2028	450.0	450.0
Other	3.0	3.0
Total debt	$1,413.8	$ 849.6
Current portion of long-term debt, net of debt issuance costs	(957.3)	(31.6)
Unamortized debt issuance costs	(8.0)	(8.5)
Non-current portion of debt	$ 448.5	$ 809.4

As of December 31, 2022 there was a $598.0 million outstanding revolver loan balance. There was no outstanding revolver loan balance as of December 31, 2021. During the year ended December 31, 2022, the

Company reclassified the debt issuance costs associated with the revolver loan to a contra account to directly offset the loan balance in other current liabilities on the Company's consolidated balance sheets. As of December 31, 2022, the Company had approximately $1.3 million debt issuance costs associated with the revolver loan that were classified as an offset to other current liabilities. Prior to 2022, the debt issuance costs associated with the revolver load were included in other current assets and other assets on the Company's consolidated balance sheets. As of December 31, 2021, the Company had approximately $2.0 million and $1.6 million of debt issuance costs associated with the revolver loan that were classified as other current assets and other assets, respectively.

3.875% Senior Unsecured Notes due 2028

On August 7, 2020, the Company completed its offering of $450.0 million aggregate principal amount of 3.875% Senior Unsecured Notes due 2028 (the "Senior Unsecured Notes") of which the majority of the net proceeds were used to pay down the Revolving Credit Facility (as defined below). Interest on the Senior Unsecured Notes is payable on February 15th and August 15th of each year until maturity, beginning on February 15, 2021. The Senior Unsecured Notes will mature on August 15, 2028.

On or after August 15, 2023, the Company may redeem the Senior Unsecured 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 Senior Unsecured Notes at a redemption price equal to 100% of the principal amount of the Senior Unsecured 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 Senior Unsecured 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 Senior Unsecured Notes at a purchase price of 101% of the principal amount of such Senior Unsecured Notes plus accrued and unpaid interest.

Negative covenants in the Indenture governing the Senior Unsecured 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 "Second 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 Revolving Credit Facility and Term Loan Facility, and together with the Revolving Credit Facility, the Senior Secured Credit Facilities. The Second 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 $600.0 million with a maturity date of October 13, 2023, and (ii) a Term Loan Facility with a principal amount of $450.0 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 1.3% to 2.3% 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 0.5%, and a eurocurrency rate for an interest period of one month plus 1.0% plus a margin

ranging from 0.3% to 1.3%, 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 0.2% to 0.4% 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, 5.0% 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 $100.0 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 2.5 to 1.0, and a maximum consolidated net leverage ratio of 4.5 to 1.0 (subject to an increase to 5.0 to 1.0 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.

On February 14, 2023, the Company entered into a Consent, Limited Waiver, and Third Amendment to the Amended and Restated Credit Agreement relating to the Senior Secured Credit Facilities. Pursuant to the Third Credit Agreement Amendment, the requisite lenders consented to our sale of our travel health business to Bavarian Nordic substantially in accordance with the terms of the Sale Agreement. The proceeds from the transaction will be deposited into a cash collateral account with the Administrative Agent and will, unless otherwise agreed to by the Company and the requisite lenders, be used to repay the outstanding Term Loan Facility on the expiration of the Limited Waiver (as described below). We currently expect the transaction to close in the second quarter of 2023, but we can provide no assurance that the transaction will close prior to the October 2023 maturity of the Term Loan Facility, or at all.

Pursuant to the Third Credit Agreement Amendment the requisite lenders have agreed to a limited waiver of any defaults or events of default that result from (a) any violation of the financial covenants set forth in the Senior Secured Credit Facilities with respect to the fiscal quarters ending December 31, 2022 and March 31, 2023 and (b) the going concern qualification or exception contained in the audited financial statements for the fiscal year ending December 31, 2022. This limited waiver will expire on the earlier to occur of (i) any other event of default and (ii) April 17, 2023. During this period the Company is working with lenders under the Senior Secured Credit Facilities in connection with replacing such facilities before their October 2023 maturity with revised terms and conditions. The Company does not expect to be in compliance with debt covenants in future periods without additional sources of liquidity or future amendments to the Credit Agreement. See Footnote 2 "Summary of significant accounting policies" for Going Concern considerations related to noncompliance with our debt covenants and the limited waiver.

Debt Maturity

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

Year	As of December 31, 2022
2023	$ 961.5
2024	0.3
2025	—
2026	2.0
2027	—
Thereafter	450.0
Total debt	$ 1,413.8

9. 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.

2021 Stock Repurchase program

On November 11, 2021, the Company announced that its Board of Directors authorized a stock repurchase program of up to an aggregate of $250.0 million of Common Stock (the "Share Repurchase Program"). The Share Repurchase Program expired on November 11, 2022. The Company utilized $187.9 million to purchase 4.4 million shares as of the program expiration date. The Share Repurchase Program did not obligate the Company to acquire any specific number of shares. Repurchased shares are available for use in connection with our stock plans and for other corporate purposes.

The following table details our stock repurchases under the Share Repurchase Program:

	Year Ended December 31,	
	2022	2021
Shares of common stock repurchased	1.8	2.6
Average price paid per share	$42.36	$42.67
Total cost	$ 75.5	$112.6

Accounting for share-based compensation

The Company has one share-based employee compensation plan, the Emergent Plan, which includes stock options and performance and restricted stock units.

As of December 31, 2022, an aggregate of 25.4 million shares of common stock were authorized for issuance under the Emergent Plan, of which a total of approximately 2.9 million shares of common stock remain

available for future awards to be made to plan participants. The exercise price of each option must be not less than 100% of the fair market value of the shares underlying such option on the date of grant. Options granted under the Emergent Plan have a contractual life of seven 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,		
	2022	2021	2020
Expected dividend yield	0%	0%	0%
Expected volatility	54%-62%	47-48%	39-48%
Risk-free interest rate	1.54%-4.31%	0.43-0.94%	0.27-1.42%
Expected average life of options	4.5 years	4.5 years	4.5 years

Stock options, restricted stock units and performance stock units

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

	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Stock options outstanding at December 31, 2021	1.2	$ 60.83		$ 3.0
Stock options granted	0.7	$ 39.11		
Stock options exercised	—	$ 27.71		
Stock options forfeited	(0.2)	$ 64.66		
Stock options outstanding at December 31, 2022	1.7	$ 51.74	4.1	$ —
Stock options exercisable at December 31, 2022	0.8	$ 54.14	2.3	$ —

Cash received from option exercises for the years ended December 31, 2022, 2021 and 2020 was $0.5 million, $10.4 million and $27.6 million, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2022, 2021, and 2020 was $17.85, $35.16 and $21.69 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2022, 2021, and 2020 was $0.3 million, $15.7 million and $38.2 million, respectively. As of December 31, 2022, there was $12.0 million of unrecognized compensation cost related to stock options.

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

	Number of Shares	Weighted-Average Grant Date Fair Value	Aggregate Intrinsic Value
Stock awards outstanding at December 31, 2021	1.1	$70.82	$47.6
Stock awards granted [1]	1.9	$34.49	
Stock awards released	(0.5)	$67.48	
Stock awards forfeited [1]	(0.3)	$55.46	
Stock awards outstanding at December 31, 2022	2.2	$42.30	$25.8

[1] Performance stock units granted and forfeited during the year ended December 31, 2022 are included at the target payout percentage, or 100%, of shares granted.

The total fair value of restricted stock unit awards released during the years ended December 31, 2022, 2021 and 2020 was $30.9 million, $26.9 million and $34.1 million, respectively. As of December 31, 2022, there was $54.5 million of unrecognized compensation cost related to unvested restricted stock units. That cost is expected to be recognized ratable over a weighted average period of 1.9 years.

Performance stock units represent common stock potentially issuable in the future, subject to achievement of performance conditions. Our current outstanding performance stock units vest based on certain financial metrics over the applicable performance period. The vesting and payout range for our performance stock units is typically between 50% and up to 150% of the target number of shares granted at the end of a three-year performance period. The total fair value of performance unit awards released during the years ended December 31, 2022, 2021 and 2020 was $2.5 million, $3.8 million and $1.2 million, respectively. As of December 31, 2022, there was $5.3 million of unrecognized compensation cost related to unvested performance stock units. That cost is expected to be recognized ratable over a weighted average period of 1.9 years.

Share-based Compensation Expense

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

	Year Ended December 31,		
	2022	2021	2020
Cost of product sales	$ 7.3	$ 6.4	$ 8.9
Cost of CDMO services	1.8	1.1	3.5
Research and development	5.4	5.0	8.4
Selling, general and administrative	30.6	29.9	30.2
Total share-based compensation expense	$45.1	$42.4	$51.0

Accumulated other comprehensive income (loss), net of tax

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

	Defined Benefit Pension Plan	Derivative Instruments	Foreign Currency Translation Adjustments	Total
Balance at December 31, 2020	$(7.7)	$(11.0)	$(6.6)	$(25.3)
Other comprehensive income (loss) before reclassifications	4.3	0.7	(1.0)	4.0
Amounts reclassified from accumulated other comprehensive income (loss)	(0.6)	5.8	—	5.2
Net current period other comprehensive income (loss)	3.7	6.5	(1.0)	9.2
Balance at December 31, 2021	$(4.0)	$ (4.5)	$(7.6)	$(16.1)
Other comprehensive income before reclassifications	8.7	10.8	1.0	20.5
Amounts reclassified from accumulated other comprehensive income (loss)	(1.2)	(0.1)	—	(1.3)
Net current period other comprehensive income	7.5	10.7	1.0	19.2
Balance at December 31, 2022	$ 3.5	$ 6.2	$(6.6)	$ 3.1

The tables below present the tax effects related to each component of other comprehensive income (loss):

	December 31, 2022			December 31, 2021			December 31, 2020		
	Pretax	Tax Benefit (Expense)	Net of tax	Pretax	Tax Benefit (Expense)	Net of tax	Pretax	Tax Benefit (Expense)	Net of tax
Defined benefit pension plan	$ 8.7	$(1.2)	$ 7.5	$ 4.3	$(0.6)	$ 3.7	$ (5.0)	$0.7	$ (4.3)
Derivative instruments	14.6	(3.9)	10.7	8.9	(2.4)	6.5	(13.0)	3.6	(9.4)
Foreign currency translation adjustments	0.6	0.4	1.0	(1.2)	0.2	(1.0)	(1.8)	0.1	(1.7)
Total adjustments	$23.9	$(4.7)	$19.2	$ 12.0	$(2.8)	$ 9.2	$(19.8)	$4.4	$(15.4)

10. Net income (loss) per common share

The following table presents the calculation of basic and diluted net income (loss) per common share:

	Year Ended December 31,		
	2022	2021	2020
Numerator:			
Net income (loss)	$(223.8)	$230.9	$305.1
Denominator:			
Weighted-average number of shares-basic	50.1	53.5	52.7
Dilutive effect of employee incentive plans	—	0.6	1.1
Weighted-average number of shares-diluted	50.1	54.1	53.8
Net income (loss) per common share—basic	$ (4.47)	$ 4.32	$ 5.79
Net income (loss) per common share—diluted	$ (4.47)	$ 4.27	$ 5.67

Basic net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted net income (loss) per common 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. No adjustment for the potential dilutive effect of dilutive securities is reported for the year ended December 31, 2022 as the effect would have been anti-dilutive due to the Company's net loss.

The following table presents the share-based awards that are not considered in the diluted net income (loss) per common 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, 2022, 2021 and 2020. 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,		
	2022	2021	2020
Anti-dilutive stock awards	2.8	1.0	—

11. Revenue recognition

The Company operates in two business segments (see Note 16, "Segment information"). The Company's revenues disaggregated by the major sources were as follows:

	Year Ended December 31,								
	2022			2021			2020		
	USG	Non-USG	Total	USG	Non-USG	Total	USG	Non-USG	Total
Product sales	$445.4	$520.8	$ 966.2	$530.0	$493.9	$1,023.9	$626.0	$363.8	$ 989.8
CDMO:									
Services	—	108.4	108.4	—	334.9	334.9	—	166.7	166.7
Leases	—	4.9	4.9	237.6	62.1	299.7	253.3	30.5	283.8
Total CDMO	—	113.3	113.3	237.6	397.0	634.6	253.3	197.2	450.5
Contracts and grants	37.2	4.2	41.4	130.2	4.0	134.2	109.2	5.9	115.1
Total revenues	$482.6	$638.3	$1,120.9	$897.8	$894.9	$1,792.7	$988.5	$566.9	$1,555.4

For the years ended December 31, 2022, 2021 and 2020, the Company's product sales from Anthrax Vaccines, Nasal Naloxone products, TEMBEXA, ACAM2000 and Other products as a percentage of total product sales were as follows:

	Year Ended December 31,		
	2022	2021	2020
% of product sales:			
Anthrax vaccines	28%	25%	38%
Nasal naloxone products	39%	43%	31%
TEMBEXA	12%	— %	— %
ACAM2000	7%	20%	20%
Other products	14%	12%	11%

For the year ended December 31, 2022 there were two customers in excess of 10% of total revenues. The USG accounted for 43% of total revenues and the second customer accounted for 10% of total revenues. Both customer's revenue is attributable to the Products segment. For the years ended 2021 and 2020, 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, 2022, 2021, and 2020, the Company's revenues from customers within the United States comprised 79%, 92% and 93%, respectively, of total revenues.

Termination of manufacturing services agreement with Janssen Pharmaceuticals, Inc.

On July 2, 2020, the Company, through its wholly-owned subsidiary, Emergent Manufacturing Operations Baltimore, LLC, entered into the Agreement with Janssen, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, for large-scale drug substance manufacturing of Johnson & Johnson's investigational SARS-CoV-2 vaccine, Ad26.COV2-S, recombinant based on the AdVac technology (the "Product").

On June 6, 2022, the Company provided to Janssen a notice (the "Notice") of material breach of the Agreement for, among other things, failure by Janssen (i) to provide the Company the requisite forecasts of the required quantity of Product to be purchased by Janssen under the Agreement and (ii) to confirm Janssen's intent to not purchase the requisite minimum quantity of the Product pursuant to the Agreement and instead, wind-down the Agreement ahead of fulfilling these minimum requirements. Later on June 6, 2022, the Company received from Janssen a purported written notice of termination (the "Janssen Notice") of the Agreement for asserted material breaches of the Agreement by the Company, including alleged failure by the Company to perform its obligations in compliance with current good manufacturing practices ("cGMP") or other applicable laws and regulations and alleged failure by the Company to supply Janssen with the Product. Janssen alleged that the Company's breaches were not curable and that, therefore, termination of the Agreement would be effective as of July 6, 2022. The Company disputes Janssen's assertions and allegations, including Janssen's ability to effect termination pursuant to the Janssen Notice. The Company and Janssen disagree on the monetary amounts that are due to the Company as a result of termination by any means. The Company believes the amounts due to the Company include, but are not limited to, compensation for services provided, reimbursement for raw materials purchased and non-cancelable orders, and fees for early termination. Janssen has alleged that no additional amount is due to the Company and that the Company should pay Janssen an unspecified amount as a result of the Company's alleged failure to perform under the Agreement. The Company has not recorded any contingent liabilities related to Janssen's allegations as the Company believes they are without merit and intends to vigorously defend the Company's position during the dispute resolution process through arbitration.

During the year ended December 31, 2022, there were no impacts on previously recognized revenue or depreciation related to the conclusion of the Agreement. As of December 31, 2022, the Company has no billed or unbilled net accounts receivable related to the Agreement.

Because the arbitration process may extend longer than one year, the Company reclassified $127.7 million from "Inventories, net" and $25.0 million from "Prepaid expenses and other current assets" to "Other assets" in

the fourth quarter resulting in $152.7 million in long-term assets related to the Janssen Agreement on the consolidated balance sheet as of December 31, 2022. These assets include termination penalties, certain inventory related items and raw materials inventory representing materials purchased for the Agreement which Janssen has not reimbursed. The Company evaluated the net realizable value of the inventory as of December 31, 2022, concluding that because the Agreement specifies the Company is entitled to, among other things, reimbursement of raw materials and non-cancelable orders in the event of a contract termination for any reason, the Company is entitled to payment from Janssen for these raw materials. Additionally, the Company has $6.2 million of non-cancelable orders as of December 31, 2022 which have not been received and Janssen has not reimbursed.

BARDA Center of Innovation and Advanced Development and Manufacturing Agreement

In 2020, the Company announced the issuance of a task order under its existing CIADM agreement with BARDA for COVID-19 vaccine development and manufacturing (the "BARDA COVID-19 Development Public Private Partnership"). The BARDA COVID-19 Development Public Private Partnership is considered a lease and is accounted for under ASC 842. The initial task order had a contract value of up to $628.2 million and included the reservation of manufacturing capacity and accelerated expansion of fill/finish capacity valued at $542.7 million and $85.5 million, respectively. Subsequently, the task order was expanded to include incremental capital activities which increased the value to $650.8 million. On November 1, 2021, the Company and BARDA mutually agreed to the completion of the Company's CIADM contract and associated task orders, including the BARDA COVID-19 Development Public Private Partnership. The Company did not recognize lease revenues under this arrangement during the year ended December 31, 2022. Total revenues associated with the base arrangement were $71.3 million and $15.8 million during the years ended December 31, 2021 and December 31, 2020, respectively, and are reflected as a component of contracts and grants revenue on the consolidated statements of operations. Revenues associated with the BARDA COVID-19 Development Public-Private Partnership were $237.6 million and $233.3 million during the years ended December 31, 2021 and December 31, 2020, respectively, and are recorded as CDMO leases on the consolidated statements of operations.

CDMO Operating Leases

Certain multi-year CDMO service arrangements with non-USG customers include operating leases whereby the customer has the right to direct the use of and obtain substantially all of the economic benefits of specific manufacturing suites operated by the Company. 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 components approximates 2.6 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, 2022, the Company's non-USG lease revenues were $4.9 million, which is included within CDMO leases in the consolidated statement of operations. Excluding future amounts related to the Agreement as discussed above, the Company estimates future operating lease revenues to be $5.1 million in 2023, $0.9 million in 2024, $0.9 million in 2025, and $2.7 million in years beyond 2025.

Transaction price allocated to remaining performance obligations

As of December 31, 2022, the Company expects future revenues of approximately $378.2 million associated with all arrangements entered into by the Company. The Company expects to recognize a majority of the $378.2 million of unsatisfied performance obligations within the next 24 months. The amount and timing of revenue recognition for unsatisfied performance obligations can change. The future revenues associated with unsatisfied performance obligations exclude the value of unexercised option periods in the Company's revenue arrangements. Often the timing of manufacturing activities changes based on customer needs and resource availability. Government funding appropriations can impact the timing of product deliveries. The success of the Company's development activities that receive development funding support from the USG under development contracts can also impact the timing of revenue recognition.

Contract assets

The Company considers accounts receivable and deferred costs associated with revenue generating contracts, which are not included in inventory or property, plant and equipment and the Company does not currently have a contractual right to bill, to be contract assets. As of December 31, 2022 and December 31, 2021, the Company had $34.8 million and $21.5 million, respectively, of contract assets recorded within accounts receivable, net on the consolidated balance sheets.

Contract liabilities

When performance obligations are not transferred to a customer at the end of a reporting period, cash received associated with the amount allocated to those performance obligations is reflected as contract liabilities on the consolidated balance sheets and is deferred until control of these performance obligations is transferred to the customer.

The following table presents the roll forward of the contract liabilities:

	Contract Liabilities
Balance at December 31, 2020	$ 100.1
Deferral of revenue	279.7
Revenue recognized	(363.4)
Balance at December 31, 2021	$ 16.4
Deferral of revenue	38.9
Revenue recognized	(23.6)
Balance at December 31, 2022	$ 31.7

As of December 31, 2022 and 2021, the current portion of contract liabilities was $26.4 million and $11.7 million, respectively, and was included in other current liabilities on the balance sheet.

Accounts Receivable and Allowance for Expected Credit Losses

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

	December 31,	
	2022	2021
Accounts receivable:		
Billed	$102.7	$228.1
Unbilled	56.4	49.8
Allowance for expected credit losses	(0.7)	(3.2)
Accounts receivable, net	$158.4	$274.7

12. Leases

The Company is the lessee for operating corporate leases for offices, R&D facilities and manufacturing facilities. The Company determines if an arrangement is a lease at inception. Operating leases are included in right-of-use ("ROU") assets and liabilities. For a discussion of lessor activities, see Note 11, "Revenue recognition".

The components of lease expense were as follows:

	Year Ended December 31,		
	2022	2021	2020
Operating lease cost:			
Amortization of right-of-use assets	$5.6	$5.6	$4.5
Interest on lease liabilities	1.1	1.3	1.1
Total operating lease cost	$6.7	$6.9	$5.6

Operating lease costs are reflected as components of cost of product sales, cost of contract development and manufacturing, research and development expense and selling, general and administrative expense.

Supplemental balance sheet information related to leases was as follows:

Leases	Classification	December 31, 2022	December 31, 2021
Operating lease right-of-use assets	Other assets	$ 19.4	$ 28.3
Operating lease liabilities, current portion	Other current liabilities	$ 5.8	$ 5.8
Operating lease liabilities	Other liabilities	14.8	24.2
Total operating lease liabilities		$ 20.6	$ 30.0
Operating leases:			
Weighted average remaining lease term (years)		5.9	7.0
Weighted average discount rate		4.1%	4.1%

During the year ended December 31, 2022, the Company exercised the option to purchase its Rockville manufacturing facility. As a result, the Company removed the related operating lease right-of-use asset and operating lease liability of $3.5 million and $3.4 million, respectively. The purchased assets have been properly included in "Property, plant and equipment, net" on the Company's consolidated balance sheet as of December 31, 2022.

The Company's leases have remaining lease terms of less than one year to approximately 11 years, some of which include options to extend the leases for up to five years, and some of which include options to terminate the leases within one year.

Lease maturities as of December 31, 2022, are as follows:

Year	As of December 31, 2022
2023	$ 6.5
2024	4.3
2025	2.7
2026	2.3
2027	1.8
Thereafter	5.9
Total undiscounted lease liabilities	23.5
Less: Imputed interest	2.9
Total Lease liabilities	$ 20.6

13. 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 Company establishes valuation allowances for deferred income tax assets in accordance with U.S. GAAP, which provides that such valuation allowances shall be established unless realization of the income tax benefits is more likely than not. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible.

As of December 31, 2022, the Company reassessed the valuation allowance and considered negative evidence, including its significant losses in the current year and the substantial doubt about the Company's ability to continue as a going concern through one year from the date that these financial statements are issued, positive evidence, scheduled reversal of deferred tax liabilities, available taxes in carryback periods, tax planning strategies and projected future taxable income. After assessing both the negative and positive evidence, the Company concluded that it should record a valuation allowance of $43.8 million on its global net operating losses, credits and other deferred tax assets.

The global intangible low-tax income ("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, 2022 and 2021. BEAT provisions do not have material impact on the consolidated financial statements.

For the year ended December 31, 2022, the Company has evaluated its historical indefinite reinvestment assertion in connection with the Company's going concern uncertainty. The Company recognized a deferred withholding tax liability for the undistributed earnings of the Company's international subsidiaries available cash and net working capital in the amount of $4.7 million. All other international subsidiaries' outside basis differences are indefinitely reinvested.

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

	Year Ended December 31,		
	2022	2021	2020
Current			
Federal	$ (9.6)	$(3.7)	$ 62.8
State	2.0	14.9	27.7
International	33.6	28.4	14.0
Total current	26.0	39.6	104.5
Deferred			
Federal	(39.0)	38.0	1.1
State	8.2	4.3	—
International	6.9	1.6	(3.5)
Total deferred	(23.9)	43.9	(2.4)
Income tax provision	$ 2.1	$ 83.5	$102.1

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

	Year Ended December 31,	
	2022	2021
Deferred tax assets		
Federal losses carryforward	$ 15.3	$ 7.6
State losses carryforward	5.4	3.3
R&D carryforward	18.4	16.6
Stock compensation	10.1	8.9
Foreign losses carryforward	9.1	10.2
Deferred revenue	2.0	0.4
Inventory reserves	10.5	2.9
Lease liability	4.6	6.5
IRC 263A capitalized costs	5.0	3.9
Capitalized R&D	25.9	—
IRC 163(j) Interest Limitation	7.6	—
Other	0.7	5.6
Gross deferred tax assets	114.6	65.9
Valuation allowance	(68.0)	(25.0)
Total deferred tax assets	46.6	40.9
Deferred tax liabilities		
Fixed assets	(62.4)	(75.1)
Intangible assets	(46.1)	(47.6)
Right-of-use asset	(4.3)	(6.1)
Foreign Withholding Tax	(4.7)	—
Other	(0.9)	(2.8)
Total deferred tax liabilities	(118.4)	(131.6)
Net deferred tax liabilities	$ (71.8)	$ (90.7)

As of December 31, 2022, the Company has approximately $73.0 million in U.S. federal net operating loss ("NOL") carryforwards, $36.0 million of NOL's which will expire in varying amounts in 2031 through 2035 and $37.0 million which will carryforward indefinitely, although, limited to eighty percent of taxable income annually. The Company has U.S. federal tax credit carryforwards of $13.4 million which will expire in 2027 through 2042.

As of December 31, 2022, the Company had pre-apportionment state NOLs totaling approximately $1.9 billion primarily in Maryland which will begin to expire in 2025 and post-apportionment NOLs totaling approximately $146.8 million that will begin to expire in 2028. The Company has state R&D tax credit carryforwards of $5.0 million which will expire in 2027 through 2038.

The deductibility of such US federal and state net operating losses and credits may be limited. Under Section 382/383 of the Internal Revenue Code of 1986, as amended (the "Code"), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which generally occurs if the percentage of the corporation's stock owned by 5% stockholders increases by more than 50% over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Certain of the net operating loss carryforwards and the credit carryforwards are subject to an annual limitation pursuant to Internal Revenue Code Section 382 and 383 as a result of historical acquisitions. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control, which may further limit our carryforwards. If we determine that an ownership change has occurred and our ability to use our historical NOL and credit

carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

The Company has approximately $51.5 million in net operating losses from foreign jurisdictions as of December 31, 2022, $14.5 million of losses which will expire in varying amounts in 2022 through 2028 and $37.0 million will carryforward indefinitely.

The Company's valuation allowance increased by $43.0 million due to the Company's determination that it is not more likely than not to realize its global net deferred income tax assets and the current year losses incurred within the U.S. The valuation allowance has been recorded primarily against the Company's net operating loss and credit carryforwards.

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:

	Year Ended December 31,		
	2022	2021	2020
U.S.	$(445.1)	$ 112.0	$362.0
International	223.4	202.4	45.2
Earnings (Losses) before taxes on income	(221.7)	314.4	407.2
Federal tax at statutory rates	$ (46.6)	$ 65.8	$ 85.5
State taxes, net of federal benefit	(10.2)	16.1	23.2
Impact of foreign operations	(7.0)	(16.8)	(7.8)
Change in valuation allowance	43.8	4.3	1.5
Tax credits	(3.5)	(4.7)	(7.6)
Stock compensation	4.7	(4.9)	(7.9)
Goodwill Impairments	1.8	8.3	—
Adjustment of prior year taxes	(0.5)	0.8	(0.7)
Transaction costs	—	0.3	6.0
Compensation limitation	0.7	2.9	2.2
Unrecognized tax benefit	(9.7)	0.3	(0.3)
GILTI, net	20.7	11.4	5.4
Foreign withholding tax	4.7	—	—
Permanent differences	3.2	(0.3)	2.6
Income tax provision (benefit)	$ 2.1	$ 83.5	$102.1

The effective annual tax rate for the years ended December 31, 2022, 2021, and 2020 was (1)%, 27% and 25%, respectively.

The effective annual tax rate of (1)% in 2022 is lower than the statutory rate primarily due to the impact of a valuation allowance charge in the US, state and Foreign Jurisdictions, a charge due the Company's indefinite reinvestment assertion, goodwill impairment, GILTI, and other permanent items. This is partially offset by tax credits, favorable rates in foreign jurisdictions, and the release of an indemnified unrecognized tax benefit.

The effective annual tax rate of 27% in 2021 is higher than the statutory rate primarily due to the impact of goodwill impairment, state taxes, GILTI and other non-deductible items. This is partially offset by stock option deduction benefits, tax credits, and favorable rates in foreign jurisdictions. The jurisdictional mix of profit has changed from the prior year largely due to lower U.S. CDMO margins, the termination of the CIADM arrangement in the U.S. and an increase in sales of NARCAN in which a portion of the profit is attributable to a foreign subsidiary.

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 the jurisdictional mix of earnings. This is partially offset by stock option deduction benefits, tax credits, and favorable rates in foreign jurisdictions.

The Company recognizes interest in interest expense and recognizes potential penalties related to unrecognized tax benefits in selling, general and administrative expense, and the total interest and penalties recognized are insignificant. The total unrecognized tax benefits recorded at December 31, 2022 and 2021 of $1.2 million and $9.8 million, respectively, is classified primarily as a non-current liability on the consolidated balance sheets.

The table below presents the gross unrecognized tax benefits activity for the years ended December 31, 2022, 2021 and 2020:

	Year Ended December 31,		
	2022	2021	2020
Gross unrecognized tax benefits, beginning of period	$ 9.8	$ 9.2	$ 10.4
Increases (decreases) for tax positions for prior years	(1.5)	0.4	—
Increases for tax positions for current year	0.9	0.2	0.6
Settlements	—	—	(1.8)
Lapse of statute of limitations	(8.0)	—	—
Gross unrecognized tax benefits, end of period	$ 1.2	$ 9.8	$ 9.2

The total gross unrecognized tax benefit of $1.2 million, includes the release of $8.0 million of liability that related to the 2018 acquisition of PaxVax Holdings Company, Ltd. The liability was offset by an indemnification receivable, both of which were released due to a lapse of the statute of limitation during the year.

The Company does not anticipate a significant change within the next twelve months for unrecognized tax benefits and when resolved, all of these liabilities would impact the effective tax rate. However, the Company maintains a full valuation allowance as of December 31, 2022 and the recognition of any unrecognized tax benefits would be offset with a change in the valuation allowance and therefore there would be no income statement impact.

The Company's federal and state income tax returns for the tax years 2019 and onwards remain open to examination. The Company's tax returns for Canada remain open to examination for the tax years 2014 through 2021. The Company's Irish tax returns remain open to examination for the tax years 2016 through 2021.

As of December 31, 2022, the Company's 2018 Canadian Scientific Research and Experimental Development Claim is under appeal and the Company's 2020 Canadian Scientific Research and Experimental Development Claim is under audit. The Company's 2016 and 2017 Canadian income tax returns for the Adapt entities are under audit. The Company's Irish group is under Level 1 Compliance Intervention review for 2021. In addition, the Company's 2019 and 2020 New York state income tax returns are under audit.

14. Defined benefit and 401(k) savings plan

The Company sponsors a defined benefit pension plan covering eligible employees in Switzerland (the "Swiss Plan"), which we have agreed to sell as part of our Travel Health business to Bavarian Nordic, described further in Note 18, "Subsequent events". 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 $0.8 million, $2.0 million and $2.4 million reflected as a component of selling, general and administrative expenses for the years ended December 31, 2022, 2021 and 2020, respectively.

The funded status of the Swiss Plan is as follows:

	Year Ended December 31,	
	2022	2021
Change in Plan Assets:		
Fair value of plan assets, beginning of period	$ 29.3	$ 27.6
Employer contributions	1.5	1.4
Employee contributions	0.9	0.9
Net benefits received	3.4	0.5
Actual return on plan assets	(0.4)	(0.1)
Settlements	(5.0)	—
Currency impact	(0.4)	(1.0)
Fair value of plan assets, end of period	$ 29.3	$ 29.3
Change in Benefit Obligation:		
Projected benefit obligation, beginning of period	$ 46.8	$ 49.2
Service cost	1.9	2.4
Interest Cost	0.1	—
Employee contributions	0.9	0.9
Actuarial gain	(10.0)	(4.6)
Net benefits received	3.4	0.5
Settlements	(5.0)	—
Currency impact	(0.9)	(1.6)
Projected benefit obligation, end of period	$ 37.2	$ 46.8
Funded status, end of period	$ (7.9)	$(17.5)
Accumulated benefit obligation, end of period	$ 34.0	$ 41.8

Components of net periodic pension cost incurred during the years ended December 31, 2022, 2021 and 2020 are as follows:

	Year Ended December 31,		
	2022	2021	2020
Service cost	$ 1.9	$ 2.4	$ 1.9
Interest cost	0.1	—	0.1
Expected return on plan assets	(0.8)	(0.8)	(0.6)
Amortization of loss	0.1	0.6	0.2
Amortization of prior service credit	(0.1)	(0.2)	(0.2)
Settlements	(0.4)	—	1.0
Net periodic benefit cost	$ 0.8	$ 2.0	$ 2.4

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

	December 31, 2022	December 31, 2021
Discount rate	2.1%	0.3%
Expected rate of return	3.5%	3.0%
Rate of future compensation increases	1.8%	1.4%

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, 2023 is $1.6 million.

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

	Year Ended December 31,	
	2022	2021
Net actuarial gain	$ 9.0	$ 5.9
Prior service cost	(0.3)	(1.3)
Total recognized in other comprehensive income (loss)	$ 8.7	$ 4.6

Future benefits expected to be paid as of December 31, 2022 are as follows:

Year	As of December 31, 2022
2023	$ 1.8
2024	1.8
2025	2.0
2026	1.9
2027	2.1
Thereafter	27.6
Total	$ 37.2

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"). 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, 2022, 2021 and 2020, the Company made matching contributions of approximately $8.8 million, $8.9 million and $6.6 million, respectively.

15. Purchase commitments

Purchase commitments are agreements to purchase raw materials and services that are enforceable, legally binding, and specify terms that (1) include fixed or minimum quantities to be purchased, (2) include fixed, minimum or variable price provisions and (3) are longer than one year.

As of December 31, 2022 the Company has approximately $132.8 million of purchase commitments associated with raw materials and CDMO services that will be purchased in the next five years, of which the Company estimates that approximately $125.7 million will be purchased within the next year. For the years ended December 31, 2022, 2021, and 2020, the Company purchased $199.6 million, $110.7 million and $108.0 million, respectively, of materials and services under these commitments.

16. Segment information

The Company reports segment information based on the internal reporting used by management for making decisions and assessing performance. During the first quarter of 2022, the Company revised the reporting that the

CODM reviews in order to assess Company performance. The CODM manages the business with a focus on two reportable segments: (1) Products segment consisting of the Government—MCM and Commercial product categories and (2) Services segment focused on CDMO services. The Company evaluates the performance of these reportable segments based on revenue and Adjusted Gross Margin, which is a non-GAAP financial measure. Segment revenue includes external customer sales, but it does not include inter-segment services. The Company defines Adjusted Gross Margin as segment revenue less segment cost of sales reduced for significant events, inventory step-up provisions and changes in fair value of contingent consideration. The Company does not allocate research and development, selling, general and administrative costs, amortization of intangibles assets, interest and other income (expense) or taxes to operating segments in the management reporting reviewed by the CODM. The accounting policies for segment reporting are the same as for the Company as a whole. The Company has recast the related historical information for consistency.

The Company manages its assets on a total company basis, not by operating segment, as the Company's operating assets are shared or commingled. Therefore, the Company's CODM does not regularly review any asset information by operating segment and, accordingly, the Company does not report asset information by operating segment.

The following table includes segment revenues and a reconciliation of the Company's segment adjusted gross margin to the consolidated statement of operations for each of the Company's reporting segments:

	Year Ended December 31,		
	2022	2021	2020
Revenues:			
Products	$ 966.2	$1,023.9	$ 989.8
Services [1]	113.3	634.6	450.5
Total segment revenues	1,079.5	1,658.5	1,440.3
Contracts and grants revenue	41.4	134.2	115.1
Total revenues	$1,120.9	$1,792.7	$1,555.4
Less: Cost of sales:			
Cost of Products	$ 424.1	$ 382.0	$ 392.0
Cost of Services	269.6	375.5	132.0
Total cost of sales	$ 693.7	$ 757.5	$ 524.0
Products gross margin	$ 542.1	$ 641.9	$ 597.8
Services gross margin [1]	$(156.3)	$ 259.1	$ 318.5
Consolidated gross margin [2]	$ 385.8	$ 901.0	$ 916.3
Adjustments to gross margin:			
Products:			
Changes in fair value of contingent consideration	$ 2.6	$ 2.9	$ 31.7
Inventory step-up provision	51.4	—	—
Products adjusted gross margin	$ 596.1	$ 644.8	$ 629.5
Services adjusted gross margin [1]	$(156.3)	$ 259.1	$ 318.5
Consolidated adjusted gross margin[3]	$ 439.8	$ 903.9	$ 948.0
Other reconciling items:			
Contracts and grants revenue	$ 41.4	$ 134.2	$ 115.1
Adjustments to gross margin	(54.0)	(2.9)	(31.7)
Research and development	(193.0)	(234.0)	(234.5)
Selling, general and administrative	(340.3)	(348.4)	(303.3)
Goodwill impairment	(6.7)	(41.7)	—
Amortization of intangible assets	(59.9)	(58.5)	(59.8)
Interest expense	(37.3)	(34.5)	(31.3)
Other, net	(11.7)	(3.7)	4.7
Income (loss) before income taxes	$(221.7)	$ 314.4	$ 407.2

(1) Services revenue, Services gross margin and Services Adjusted gross margin for the years ended December 31, 2021 and 2020 includes the impact of $237.6 million and $233.3 million, respectively of CDMO leases revenues related to the BARDA COVID-19 Development Public Private Partnership which ended in November 2021.

(2) Total segment revenues less total cost of sales.

(3) Consolidated gross margin plus adjustments to gross margin.

The following table includes depreciation expense for each segment:

	Year Ended December 31,		
	2022	2021	2020
Depreciation:			
Products	$32.9	$27.8	$27.2
Services	43.2	28.3	17.3
Other	7.3	6.1	5.6
Total	$83.4	$62.2	$50.1

The following table includes revenues by country. Revenues have been attributed based on the location of the customer:

	Year Ended December 31,		
	2022	2021	2020
Revenue:			
United States	$ 889.5	$1,642.5	$1,446.0
Canada	148.6	66.7	46.0
Other	82.8	83.5	63.4
Total revenues	$1,120.9	$1,792.7	$1,555.4

The following table included long-lived assets, net by country. Long-lived assets, net includes right-of-use assets, net and property, plant & equipment, net, excluding software, net:

	Year Ended December 31,	
	2022	2021
Long-lived assets, net:		
United States	$696.1	$705.5
Switzerland	88.1	73.1
Canada	37.5	35.0
Other	5.0	6.0
Total long-lived assets, net	$826.7	$819.6

17. Litigation

Securities and shareholder litigation

With respect to the specific legal proceedings and claims described below, unless otherwise noted, the amount or range of possible losses is not reasonably estimable. There can be no assurance that the settlement, resolution, or other outcome of one or more matters, including the matters set forth below, during any subsequent reporting period will not have a material adverse effect on the Company's results of operations or cash flows for that period or on the Company's financial condition.

On April 20, 2021, May 14, 2021, and June 2, 2021, putative class action lawsuits were filed against the Company and certain of its current and former senior officers in the United States District Court for the District of Maryland on behalf of purchasers of the Company's common stock, seeking to pursue remedies under the Securities Exchange Act of 1934. These complaints were filed by Palm Tran, Inc. – Amalgamated Transit Union Local 1577 Pension Plan; Alan I. Roth; and Stephen M. Weiss, respectively. The complaints allege, among other things, that the defendants made false and misleading statements about the Company's manufacturing capabilities with respect to COVID-19 vaccine bulk drug substance (referred to herein as "CDMO Manufacturing

Capabilities"). These cases were consolidated on December 23, 2021, under the caption In re Emergent BioSolutions Inc. Securities Litigation, No. 8:21-cv-00955-PWG (the "Federal Securities Class Action"). The Lead Plaintiffs in the consolidated matter are Nova Scotia Health Employees' Pension Plan and The City of Fort Lauderdale Police & Firefighters' Retirement System. The defendants filed a motion to dismiss on May 19, 2022 and the Lead Plaintiff filed an opposition to that motion on July 19, 2022. The defendants believe that the allegations in the complaints are without merit and intend to defend the matters vigorously. Given the uncertainty of litigation, the preliminary stage of the cases, and the legal standards that must be met for, among other things, class certification and success on the merits, the Company cannot reasonably estimate the possible loss or range of loss, if any, that may result from the consolidated action.

On June 29, 2021, Lincolnshire Police Pension Fund ("Lincolnshire"), and on August 16, 2021, Pooja Sayal, filed putative shareholder derivative lawsuits in the United States District Court for the District of Maryland on behalf of the Company against certain of the Company's current and former officers and directors for breach of fiduciary duties, waste of corporate assets, and unjust enrichment, each allegation related to the CDMO Manufacturing Capabilities. In addition to monetary damages, the complaints seek the implementation of multiple corporate governance and internal policy changes. On November 16, 2021, the cases were consolidated under the caption In re Emergent BioSolutions Inc. Stockholder Derivative Litigation, Master Case No. 8:21-cv-01595-PWG. On January 3, 2022, the Lincolnshire complaint was designated as the operative complaint in the consolidated action. On April 13, 2022 the Court approved the parties joint stipulation to and stay of the proceedings and discovery until the close of fact discovery in the Federal Securities Class Action. The defendants believe that the allegations in the complaints are without merit and intend to defend the matter vigorously.

On September 15, 2021, September 16, 2021 and November 12, 2021, putative shareholder derivative lawsuits were filed by Chang Kyum Kim, Mark Nevins and Employees Retirement System of the State of Rhode Island, North Collier Fire Control and Rescue District Firefighters Pension Plan, and Pembroke Pines Firefighters & Police Officers Pension Fund, respectively, in The Court of Chancery of the State of Delaware on behalf of the Company against certain of its current and former officers and directors for breach of fiduciary duties, unjust enrichment and insider trading, each allegation related to the CDMO Manufacturing Capabilities. In addition to monetary damages, the complaints seek the implementation of multiple corporate governance and internal policy changes. On February 2, 2022, the cases were consolidated under the caption In re Emergent BioSolutions, Inc. Derivative Litigation, C.A. No. 2021-0974-MTZ with the institutional investors as co-lead plaintiffs. On March 4, 2022, the defendants' filed a motion to dismiss the complaint. Ruling on this motion is stayed pursuant to a March 29, 2022 order staying all proceedings pending a final, non-appealable judgment in the Federal Securities Class Action.

On December 3, 2021, December 22, 2021 and January 18, 2022, putative shareholder derivative lawsuits were filed by Zachary Elton, Eric White and Jeffrey Reynolds in the Circuit Court for Montgomery County, Maryland on behalf of the Company against certain of its current and former officers and directors for breach of fiduciary duty, unjust enrichment, waste of corporate assets, failing to maintain internal controls, making or causing to be made false and/or misleading statements and material omissions, insider trading and otherwise violating the federal securities laws, each allegation related to the CDMO Manufacturing Capabilities. The complaints seek monetary and punitive damages. On February 22, 2022, the Court entered an order consolidating these actions under case number C-15-21-CV-000496. On March 9, 2022, the parties filed a Joint Stipulation of Stay of Proceedings and Discovery, pursuant to which the parties agreed to stay all proceedings until 30 calendar days after a ruling on the defendants' motion to dismiss the Federal Securities Class Action. The Court approved the Joint Stipulation on March 14, 2022.

In addition to the above actions, the Company has received inquiries and subpoenas to produce documents related to these matters from the Department of Justice, the SEC, the Maryland Attorney General's Office, and the New York Attorney General's Office. The Company produced or is producing documents as required in response and will continue to cooperate with these government inquiries. The Company also received inquiries and subpoenas from Representative Carolyn Maloney and Representative Jim Clyburn, members of the House

Committee on Oversight and Reform and the Select Subcommittee on the Coronavirus Crisis and Senator Murray of the Committee on Health, Education, Labor and Pensions. The Company produced documents and provided testimony and briefings as requested in response to these inquiries.

18. Subsequent events

2023 Organizational Restructuring Plan

On January 9, 2023, the Company announced an organizational restructuring plan (the "Plan") intended to reduce operating costs, improve operating margins, and continue advancing the Company's ongoing commitment to profitable growth. The Plan includes a reduction of the Company's current workforce by approximately five percent. Decisions regarding the elimination of positions are subject to local law and consultation requirements in certain countries, as well as the Company's business needs.

The Company estimates that it will incur approximately $9.0 million to $11.0 million in charges in connection with the Plan, which it expects to incur in the first quarter of fiscal 2023. These charges consist primarily of charges related to employee transition, severance payments, employee benefits, and share-based compensation.

Agreement to Sell Travel Business Health

On February 15, 2023, we entered into the Sale Agreement with Bavarian Nordic, under which we agreed to sell our travel health business, including rights to Vaxchora and Vivotif, as well as our development-stage chikungunya vaccine candidate CHIKV VLP, our manufacturing site in Bern, Switzerland and certain of our development facilities in San Diego, California for a cash purchase price of $270.0 million, subject to certain customary adjustments. In addition, we may receive milestone payments of up to $80.0 million related to the development of CHIKV VLP and receipt of marketing approval and authorization in the U.S. and Europe, and sales-based milestones payments of up to $30.0 million based on aggregate net sales of Vaxchora and Vivotif in calendar year 2026. Approximately 280 employees are expected to join Bavarian Nordic as part of the transaction.

The transaction is expected to close in the second quarter of 2023, subject to certain customary closing conditions, including (1) the expiration or earlier termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (2) receipt of required clearances and approvals under Spain's competition laws, (3) receipt of certain Swiss real property approvals, (4) no material adverse effect having occurred with respect to the Business, and (5) certain other customary conditions.

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, 2022. 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, 2022, our chief executive officer and chief financial officer concluded that, as of such date, that the disclosure controls and procedures were not effective due to a material weakness in internal control over financial reporting, described below.

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, 2022. 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). As a result of this assessment, our management concluded that, as of December 31, 2022, our internal control over financial reporting was not effective due to an identified material weakness related to the improper capitalization of inventory. 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. While this did not result in a material misstatement to our consolidated financial statements for any prior periods through and including December 31, 2022, there was a reasonable possibility that a material misstatement of our interim or annual financial statements would not be prevented or detected on a timely basis.

More specifically, the material weakness is due to insufficient controls to related to our assessment of pre-launch materials meeting the criteria for capitalization, which requires those materials to have economic value and a high probability of regulatory approval.

Remediation

We have initiated and begun to implement measures designed to improve our internal control over financial reporting related to the capitalization of inventory, including documenting a formal policy on the accounting for

pre-paunch materials purchased for use in R&D activities, providing additional training related to the new policy, implementing a monthly control to review pre-launch inventory with corporate finance to ensure proper accounting treatment. As a result of these efforts and given that the deficiencies relate to specific adjustments that were made during the period ended December 31, 2022, we believe that the Inventory Capitalization Issue may be remediated during the first quarter of 2023.

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, 2022, a copy of which is included in this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

Except for the material weakness described above, there has been no change in the Company's internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) that occurred during the quarter ended December 31, 2022 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, 2022, 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, because of the effect of the material weakness described below on the achievement of the objectives of the control criteria, Emergent BioSolutions Inc. and subsidiaries (the Company) has not maintained effective internal control over financial reporting as of December 31, 2022, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. Management has identified a material weakness in controls related to the Company's inventory process.

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, 2022 and 2021, the related consolidated statements of operations, comprehensive income (loss), changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes and financial statement schedule listed in the Index at Item 15. This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2022 consolidated financial statements, and this report does not affect our report dated March 1, 2023, which expressed an unqualified opinion that included an explanatory paragraph regarding the Company's ability to continue as a going concern.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting

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

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

/s/ Ernst & Young LLP

Tysons, Virginia
March 1, 2023

ITEM 9B. OTHER INFORMATION

Not applicable.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

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 SEC or the New York Stock Exchange concerning any amendment to, or waiver of, our code of business conduct and ethics. The reference to our website is intended to be an inactive textual reference only. Neither the information on or that can be accessed through our website are incorporated by reference in this Annual Report on Form 10-K.

The remaining information required by Item 10 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2023 Annual Meeting of Stockholders, to be filed with the U.S. Securities and Exchange Commission ("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 2023 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 2023 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 2023 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 2023 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 (PCAOB ID: 42)
- Consolidated Balance Sheets at December 31, 2022 and 2021
- Consolidated Statements of Operations for the years ended December 31, 2022, 2021 and 2020
- Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2022, 2021 and 2020
- Consolidated Statements of Cash Flows for the years ended December 31, 2022, 2021 and 2020
- Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2022, 2021 and 2020
- Notes to Consolidated Financial Statements

Financial Statement Schedules

Schedule II—Valuation and Qualifying Accounts for the years ended December 31, 2022, 2021 and 2020 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	Charged to Costs and Expenses	Deductions	Ending Balance
Year Ended December 31, 2022				
Inventory allowance	$42.7	79.1	(40.5)	$81.3
Prepaid expenses and other current assets allowance	$ 3.7	3.9	(0.5)	$ 7.1
Year Ended December 31, 2021				
Inventory allowance	$37.6	37.9	(32.8)	$42.7
Prepaid expenses and other current assets allowance	$ 3.9	0.2	(0.4)	$ 3.7
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

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		Exhibit Description
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		Agreement to Terminate Class A Stockholders Registration Rights Agreement, dated December 9, 2021 by and among Emergent BioSolutions Inc., Intervac, L.L.C. and BioVac, L.L.C. (incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
4.4		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).
4.5		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).
4.6		Form of 3.875% Senior Unsecured Note due 2028 (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 4.2 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
4.7		Description of the Company's Securities(incorporated by reference to Exhibit 4.6 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
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 (incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
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).

Exhibit Number		Exhibit Description
10.4	#	Consent, Limited Waiver, and Third Amendment to the Amended and Restated Credit Agreement, dated February 14, 2023.
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).
10.10	#	Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan Approved by the Compensation Committee of the Board of Directors of Emergent BioSolutions Inc. on January 4, 2023.
10.11	*	Emergent BioSolutions Inc. Stock Incentive Plan (incorporated by reference to Exhibit 99 to Registration Statement on Form S-8, filed on May 30, 2018).
10.12	*	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).
10.13	*	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).
10.14	*	Global Form of Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.15	*	Global Form of Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.16	*	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).
10.17	*	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).
10.18	*	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).
10.19	†*	Form of 2022-2024 Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to Current Report on Form 8-K filed on February 22, 2022).
10.20	*	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).

Exhibit Number		Exhibit Description
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 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 3, 2017).
10.30	†	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).

Exhibit Number		Exhibit Description
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).
10.40	†	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 10.1 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 (incorporated by reference to Exhibit 10.45 the Company's Annual Report on Form 10-K filed on February 19, 2021)
10.46	††	Modification No. 22 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 19, 2021)
10.47	††	Modification No. 23, effective September 30, 2020, 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 19, 2021)
10.48	††	Modification No. 24, effective February 2, 2021, 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 November 5, 2021).
10.49	††	Modification No. 25, effective September 29, 2021, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021).
10.50	††	Modification No. 26, effective November 1, 2021, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.48 the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.51	†	Modification No. 27, effective March 31, 2022, 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 April 29, 2022).

Exhibit Number		Exhibit Description
10.52	†	Modification No. 28, effective April 14, 2022, 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 August 2, 2022).
10.53	†	Modification No. 29, effective June 16, 2022, 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 2, 2022).
10.54	†	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).
10.55	†	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 5, 2021)
10.56	†	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 5, 2021).
10.57	††	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).
10.58	††	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).
10.59	††	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).
10.60	††	Modification No. 6, effective July 13, 2020, 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 6, 2020).
10.61	††	Modification No. 7, effective December 2, 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 July 30, 2021).
10.62	††	Modification No. 8, effective March 22, 2021, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.63	††	Modification No. 9, effective April 21, 2021, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.64	††	Modification No. 10, effective June 10, 2021 to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.65	††	Modification No. 11, effective September 30, 2021, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021).

Exhibit Number		Exhibit Description
10.66	††	Modification No. 12, effective December 2, 2021, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.61 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.67	†	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).
10.68	†	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).
10.69		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).
10.70	††	Award/Contract, effective August 30, 2019 (ACAM2000 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).
10.71	††	Modification No. 1, effective, May 28, 2020 to the ACAM2000 Contract (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).
10.72	††	Modification No. 2, effective, October 28, 2020 to the ACAM2000 Contract (incorporated by reference to Exhibit 10.60 the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.73	††	Modification No. 3, effective, April 1, 2021 to the ACAM2000 Contract (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.74	††	Modification No. 4, effective, July 13, 2021 to the ACAM2000 Contract (incorporated by reference to Exhibit 10.69 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.75	††	Modification No. 5, effective, September 29, 2021 to the ACAM2000 Contract (incorporated by reference to Exhibit 10.70 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.76	††	Modification No. 6, effective, November 1, 2021 to the ACAM2000 Contract (incorporated by reference to Exhibit 10.71 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.77	†	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).
10.78	††	Order for Supplies and Services Between Emergent Manufacturing Operations Baltimore LLC and the BioMedical Advance Research and Development Authority, dated April 2, 2020, under the BARDA ADM Contract (Task Order 75A50120F33006) (incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).

Exhibit Number		Exhibit Description
10.79	††	Modification No. 1, effective April 12, 2021, to Task Order 75A50120F33006 (incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.80	††	Modification No. 3, effective October 1, 2021, to Task Order 75A50120F33006 (incorporated by reference to Exhibit 10.75 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.81	††	Modification No. 4, effective November 1, 2021, to Task Order 75A50120F33006 (incorporated by reference to Exhibit 10.76 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.82	††	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).
10.83	††	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).
10.84	††	Modification No. 2, effective September 18, 2020, to Task Order 75A50120F33007 (incorporated by reference to Exhibit 10.64 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.85	††	Modification No. 3, effective October 7, 2020, to Task Order 75A50120F33007 (incorporated by reference to Exhibit 10.65 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.86	††	Modification No. 4, effective January 29, 2021, to Task Order 75A50120F33007 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.87	††	Modification No. 5, effective February 22, 2021, to Task Order 75A50120F33007 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.88	††	Modification No. 6, effective March 24, 2021, to Task Order 75A50120F33007 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.89	††	Modification No. 7, effective May 24, 2021, to Task Order 75A50120F33007 (incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.90	††	Modification No. 8, effective November 1, 2021, to Task Order 75A50120F33007 (incorporated by reference to Exhibit 10.85 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.91	††	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).
10.92	††	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).

Exhibit Number		Exhibit Description
10.93	††	Modification No. 2, effective November 17, 2020, to Task Order 75A50120F33008. (incorporated by reference to Exhibit 10.68 the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.94	††	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).
10.95	††	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).
10.96	††	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).
10.97	††	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).
10.98	††	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).
10.99	††	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).
10.100	††	Modification No. 25, effective September 23, 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).
10.101	††	Modification No. 26, effective November 2, 2020 to the BARDA ADM Contract (incorporated by reference to Exhibit 10.77 the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.102	††	Modification No. 27, effective May 6, 2021, to the BARDA ADM Contract (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.103	††	Modification No. 28, effective May 27, 2021, to the BARDA ADM Contract (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.104	††	Modification No. 30, effective September 30, 2021, 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 5, 2021).
10.105	††	Modification No. 31, effective October 20, 2021, to the BARDA ADM Contract (incorporated by reference to Exhibit 10.100 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.106	††	Modification No. 32, effective November 1, 2021, to the BARDA ADM Contract. (incorporated by reference to Exhibit 10.101 to the Company's Annual Report on Form 10-K filed on February 25, 2022).

Exhibit Number		Exhibit Description
10.107	††	Master 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).
10.108	††	Manufacturing Product Schedule, dated July 26, 2020 to AZ MSA (incorporated by reference to Exhibit 10.13 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.109	††	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).
10.110	††	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).
10.111	††	Amendment No. 2, effective October 30, 2020, to AZ MSA (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.112	††	Amendment No. 3, effective November 25, 2020, to AZ MSA (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.113	††	Amendment No. 4, effective January 21, 2021, to AZ MSA (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.114	††	Change Order No. 1 to Work Order #5997-01, effective July 31, 2020, to AZ MSA (incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.115	††	Change Order No. 2 to Work Order #5997-01, effective August 04, 2020, to AZ MSA (incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.116	††	Change Order No. 4 to Work Order #5997-01, effective November 17, 2020, to AZ MSA (incorporated by reference to Exhibit 10.13 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.117	††	Change Order No. 5 to Work Order #5997-01, effective September 16, 2020, to AZ MSA (incorporated by reference to Exhibit 10.14 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.118	††	Change Order No. 6 to Work Order #5997-01, effective October 13, 2020, to AZ MSA (incorporated by reference to Exhibit 10.15 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.119	††	Change Order No. 10 to Work Order #5997-01, effective March 10, 2021, to AZ MSA (incorporated by reference to Exhibit 10.16 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.200	††	Change Order No. 13 to Work Order #5997-01, effective April 23, 2021, to AZ MSA (incorporated by reference to Exhibit 10.17 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.201	††	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 (JNJ MSA) (incorporated by reference to Exhibit 10.16 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).

Exhibit Number		Exhibit Description
10.202	††	Amendment No. 1, effective February 25, 2021, to JNJ MSA (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.203	†	Asset Purchase Agreement, dated May 15, 2022, by and among Emergent BioSolutions Inc., the Sellers identified therein, Chimerix, Inc., (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on May 16, 2022).
10.204	#††	Purchase and Sale Agreement dated February 15, 2023 by and between Emergent BioSolutions Inc., through its wholly owned subsidiaries Emergent International Inc. and Emergent Travel Health Inc. and Bavarian Nordic.
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, 2022, 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; (vi) the related Notes to Consolidated Financial Statements; and (vii) the Cover Page.
104	#	Cover Page Interactive Data File, formatted in iXBRL and contained in Exhibit 101.

\# Filed herewith

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

†† 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.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

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: March 1, 2023

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)	March 1, 2023
/s/ Richard S. Lindahl Richard S. Lindahl	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 1, 2023
/s/ Zsolt Harsanyi, Ph.D. Zsolt Harsanyi, Ph.D.	Director	March 1, 2023
/s/ Kathryn Zoon, Ph.D. Kathryn Zoon, Ph.D.	Director	March 1, 2023
/s/ Ronald B. Richard Ronald B. Richard	Director	March 1, 2023
/s/ Louis W. Sullivan, M.D. Louis W. Sullivan, M.D.	Director	March 1, 2023
/s/ George Joulwan George Joulwan	Director	March 1, 2023
/s/ Jerome Hauer, Ph.D. Jerome Hauer, Ph.D.	Director	March 1, 2023
/s/ Marvin White Marvin White	Director	March 1, 2023
/s/ Sujata Dayal Sujata Dayal	Director	March 1, 2023
/s/ Keith Katkin Keith Katkin	Director	March 1, 2023

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BOARD OF DIRECTORS

Zsolt Harsanyi, Ph.D.[1,4,5,6,7]
Chairman of the Board, N-Gene Research Laboratories, Inc.

Sujata T. Dayal [3,6]
Vice President and Global Chief Compliance Officer, Medline Industries, LP

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.

Keith A. Katkin[3,5]
Former Chief Executive Officer, Urovant Sciences Ltd.

Robert G. Kramer[5]
President and Chief Executive Officer, Emergent BioSolutions Inc.

Ronald B. Richard[1,3*,5]
President and Chief Executive Officer, The Cleveland Foundation

Louis W. Sullivan, M.D.[1,2*,3,6]
President Emeritus, Morehouse School of Medicine; Former Secretary, Department of Health and Human Services

Marvin L. White[1*,4,5]
President and Chief Executive Officer, Aptevo Therapeutics Inc.

Kathryn C. Zoon, Ph.D.[2,3,4*,5,6*]
Scientist Emeritus, National Institute of Allergy and Infectious Diseases at the National Institutes of Health

1 Audit & Finance Committee
2 Compensation Committee
3 Nominating & Corporate Governance Committee
4 Scientific Review Committee
5 Strategic Operations Committee
6 Special Committee on Manufacturing and Quality Oversight
7 Chairman of the Board of Directors
* Chair of Committee
All titles are as of 4/1/23

EXECUTIVE OFFICERS

Robert G. Kramer
President, Chief Executive Officer and Director

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

Jennifer L. Fox
Executive Vice President, External Affairs, General Counsel and Corporate Secretary

Coleen Glessner
Executive Vice President, Quality and Ethics and Compliance

Adam R. Havey
Executive Vice President and Chief Operating Officer

Paul A. Williams
Senior Vice President, Products Business

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, 2022, 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 25, 2023, at 9:00 a.m. Eastern Time. Stockholders can attend the meeting online at www.virtualshareholdermeeting.com/EBS2023.

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®

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