

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, 2023

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

(State or Other Jurisdiction of  
Incorporation or Organization)

14-1902018

(I.R.S. Employer  
Identification No.)

300 Professional Drive

(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:**

<i>Title of Each Class</i>	<i>Trading Symbol(s)</i>	<i>Name of Each Exchange on Which Registered</i>
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, 2023 was approximately \$380.7 million 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 28, 2024, the registrant had 52,203,433 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement for its 2024 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, 2023, 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 2024 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. AND SUBSIDIARIES  
Annual Report on Form 10-K  
Fiscal Year Ended December 31, 2023

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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, are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "future," "goal," "intend," "may," "plan," "position," "possible," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions or variations thereof, or 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, assumptions and expectations regarding future events based on information that is currently available. 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 contained herein. 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 any obligation 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 ("MCM"), including CYFENDUS® (Anthrax Vaccine Adsorbed, Adjuvanted), previously known as AV7909, BioThrax® (Anthrax Vaccine Adsorbed) and ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) among others, as well as contracts related to development of medical countermeasures;
- the availability of government funding for our other commercialized products, including Ebanga™ (ansuvimab-zykl), BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)) and RSDL® (Reactive Skin Decontamination Lotion Kit);
- 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 MCM products that have expired or will be expiring;
- the commercial availability and acceptance of over-the-counter NARCAN® (naloxone HCl) Nasal Spray;
- the impact of a generic and competitive marketplace on NARCAN® Nasal Spray and future NARCAN® Nasal Spray sales;
- our ability to perform under our contracts with the USG, including the timing of and specifications relating to deliveries;
- our ability to provide bioservices 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 further commitments related to the collaboration and deployment of capacity toward future commercial manufacturing under our existing Bioservices contracts;
- our ability to collect reimbursement for raw materials and payment of service fees from our Bioservices customers;
- the results of pending stockholder litigation and government investigations and their potential impact on our business;
- our ability to comply with the operating and financial covenants required by our revolving credit facility (the "Revolving Credit Facility") and our term loan facility (the "Term Loan Facility" and, together with the Revolving Credit Facility, the "Senior Secured Credit Facilities") under a senior secured credit agreement, dated October 15, 2018, between the Company and multiple lending institutions, as amended from time to time, as well as our 3.875% Senior Unsecured Notes due 2028 ("Senior Unsecured Notes");
- our ability to remediate a material weakness in our internal control over financial reporting and to prepare accurate financial statements in a timely manner;

- our ability to resolve the going concern qualification in our consolidated financial statements and otherwise successfully manage our liquidity in order to continue as a going concern;
- the procurement of our product candidates by USG entities under regulatory authorities that permit government procurement of certain medical products prior to United States Food and Drug Administration (“FDA”) marketing authorization, and corresponding procurement by government entities outside of the United States;
- our ability to realize the expected benefits of the sale of our travel health business to Bavarian Nordic;
- the impact of the organizational changes we announced in January 2023 and August 2023;
- the success of our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- the impact of cybersecurity incidents, including the risks from the unauthorized access, interruption, failure or compromise of our information systems or those of our business partners, collaborators or other third parties; 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®, NARCAN®, CYFENDUS®, 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 Bioservices portfolio. The types of PHTs we are currently addressing are focused on the following four categories:

- chemical, biological, radiological, nuclear and explosives ("CBRNE");
- emerging infectious diseases ("EID");
- public health crises (such as the opioid crisis); 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 bioservices 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

In the fourth quarter of 2023, we realigned our reportable operating segments to reflect recent changes in our internal operating and reporting process. The revised reporting structure reflects the internal reporting and review process used by our Chief Operating Decision Maker, for making decisions and assessing performance, and is consistent with how we currently manage the business.

We now manage our business with a focus on three reportable segments:

- our Commercial Products Segment consisting of NARCAN<sup>®</sup> and other commercial products which were sold as part of our travel health business in the second quarter of 2023;
- our MCM Products Segment consisting of Anthrax—MCM products, Smallpox—MCM products and Other Products (as discussed below); and
- our Services Segment consisting of our Bioservices portfolio.

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

#### Commercial Products Segment

In the U.S. and international markets, our Commercial business primarily focuses on sales of NARCAN<sup>®</sup> (naloxone HCl) Nasal Spray. NARCAN<sup>®</sup> Nasal Spray is sold commercially over-the-counter at retail pharmacies and digital commerce websites as well as through physician-directed or standing order prescriptions at retail pharmacies, health departments, local law enforcement agencies, community-based organizations, substance abuse centers and other federal agencies.

On May 15, 2023, we completed the sale of our products segment's travel health business, including rights to Vivotif<sup>®</sup>, the licensed typhoid vaccine; Vaxchora<sup>®</sup>, the licensed cholera vaccine; the development-stage chikungunya vaccine candidate CHIKV VLP; the Company's manufacturing site in Bern, Switzerland; and certain of its development facilities in San Diego, California. In connection with the divestiture, the Company entered into a Transition Services Agreement ("TSA") with Bavarian Nordic to help support its ongoing operations. Under the TSA, the Company provides certain transition services to Bavarian Nordic, including information technology, finance and enterprise resource planning, research and development, human resources, employee benefits and other limited services. Services pursuant to the TSA remain ongoing. For additional information, refer to Note 3, "Divestiture."

#### MCM Products Segment

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.

### Services Segment

Our portfolio of Bioservices 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 Bioservices 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 Bioservices is primarily innovators in the biotechnology and pharmaceutical segments.

### OUR STRATEGY

The Company continues to execute the three-year strategic plan (2023-2025) adopted by management to strengthen the Company’s financial position and adapt to new strategic priorities. We expected this strategy would refocus the business and increase the Company’s ability to make more aggressive investments for future growth.

Specifically, throughout 2023 the Company has taken significant steps to strengthen our financial position and de-risk the business. We have executed the travel health divestiture, implemented actions intended to save over \$160 million of annualized operating expense, and announced a strategic shift to de-emphasize our CDMO business as a source of growth. At the same time, we have achieved a number of positive milestones in our core products business, including the receipt of approximately \$250 million of USG orders for ACAM2000® (discussed more fully below), VIGIV CNJ-016® and BAT®, the FDA approvals of CYFENDUS® and NARCAN® over-the-counter, new long-term contracts for RSDL® and Ebanga™ and the growth of NARCAN® Nasal Spray.

**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, Licenses or Clearances
ACAM2000 <sup>®</sup> , (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, Canada
ANTHRASIL <sup>®</sup> [Anthrax Immune Globulin Intravenous (human)]	Treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs.	United States, Canada
BAT <sup>®</sup> [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 <sup>®</sup> (Anthrax Vaccine Adsorbed)	Vaccine for active immunization for the prevention of disease caused by <i>Bacillus anthracis</i> in persons 18 through 65 years of age. BioThrax <sup>®</sup> 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 <i>Bacillus anthracis</i> exposure, when administered in conjunction with recommended antibacterial drugs.	United States, Canada, France (where it is known as BaciThrax <sup>®</sup> ), Germany, Italy, the Netherlands, Poland, Singapore and UK
CYFENDUS <sup>®</sup> (Anthrax Vaccine Adsorbed Adjuvanted)	Previously known as AV7909, approved by the FDA for post-exposure prophylaxis of disease following suspected or confirmed exposure to <i>Bacillus anthracis</i> in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs.	United States
Ebanga <sup>™</sup> (ansuvimab-zykl), for injection	Treatment of infection caused by <i>Zaire ebolavirus</i> in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for <i>Zaire ebolavirus</i> infection.	United States
Raxibacumab injection	Treatment of adult and pediatric patients with inhalational anthrax due to <i>Bacillus anthracis</i> 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 <sup>®</sup> (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 <sup>®</sup> (brincidofovir), (tablet and oral suspension)	Treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates.	United States, Canada
Trobigard <sup>®</sup> 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*
VIGIV CNI-016 <sup>®</sup> [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 postvaccinal encephalitis.	United States, Canada

\*TROBIGARD<sup>®</sup> is not approved by the 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<sup>®</sup> (Smallpox (Vaccinia) Vaccine, Live). ACAM2000<sup>®</sup> vaccine is a smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection and comprises the largest percentage of the current USG stockpile in the Strategic National Stockpile ("SNS") designated for use in a bioterrorism emergency. On December 5, 2023, ACAM2000<sup>®</sup> vaccine received a Notice of Compliance from Health Canada for its Extraordinary Use New Drug Submission (EUNDS) for the indication of active immunization against smallpox disease for persons determined to be at high risk for smallpox infection. On October 27, 2023, Emergent submitted a supplemental Biological License Application (sBLA) to the US FDA seeking approval for the expansion of the indication for ACAM2000<sup>®</sup> to include immunization against mpox virus. ACAM2000<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> vaccine. We completed the delivery of all ACAM2000<sup>®</sup> doses in 2022. The USG chose to not exercise its option year in 2022. On May 26, 2023, the Company, through its wholly-owned subsidiary, Emergent Product Development Gaithersburg Inc., received a contract modification from the Office of the Assistant Secretary for Preparedness and Response ("ASPR"), an agency of the U.S. Department of Health and Human Services ("HHS"), exercising and funding the third of nine annual contract term extension options (the "Third Option Exercise") for Emergent to supply ACAM2000<sup>®</sup> to the SNS. The Third Option Exercise is valued at approximately \$120 million and was made under a bilateral modification of Emergent's existing 10-year contract awarded by ASPR on August 30, 2019. The period of performance under the Third Option Exercise required Emergent to deliver doses of ACAM2000<sup>®</sup> into the SNS by June 30, 2023 and the Company achieved delivery in this period.

ANTHRASIL<sup>®</sup>. ANTHRASIL<sup>®</sup> (Anthrax Immune Globulin Intravenous (human)) 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: 1) a development and procurement contract which has been extended to expire in September 2024 for possible additional scope, and 2) 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; such contract covered extended plasma storage, and the options for manufacturing and delivery of finished product into the SNS to be exercised by HHS through September 2023. We anticipate that the direct disposition of the plasma and close out activities will be completed before July 31, 2025. In addition to domestic USG sales, Anthrasil solution has been sold to several foreign governments, including the Canadian government.

BAT<sup>®</sup> [Botulinum Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine)]. BAT<sup>®</sup> antitoxin is the only equine plasma antitoxin licensed by the FDA and Health Canada for the treatment of all seven botulinum neurotoxin serotypes. BAT<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> antitoxin continues to be sold internationally, with deliveries to 15 foreign governments in 2023.

BioThrax<sup>®</sup> (Anthrax Vaccine Adsorbed). BioThrax<sup>®</sup> vaccine is the only vaccine licensed by the FDA for pre-exposure prophylaxis of anthrax disease in persons at high risk of exposure. BioThrax<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> vaccine as well as CYFENDUS<sup>®</sup> vaccine (formerly known as 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<sup>®</sup> 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<sup>®</sup> 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. On January 11, 2024, the Company announced that it has secured an indefinite-delivery, indefinite-quantity ("IDIQ") procurement contract with a maximum value up to \$235.8 million to supply BioThrax<sup>®</sup> vaccine for use by all branches of the U.S. military as Pre-Exposure Prophylaxis (PrEP) for anthrax disease. The new contract with the U.S. Department of Defense ("DoD") and led by the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, is comprised of a five-year base agreement ending on September 30, 2028, and an additional five-year option that would extend the contract to September 30, 2033.

CYFENDUS<sup>®</sup> (Anthrax Vaccine Adsorbed, Adjuvanted) (known as AV7909 prior to FDA approval in July 2023). CYFENDUS<sup>®</sup> vaccine was approved by the FDA 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 CYFENDUS<sup>®</sup> elicits a stronger immune response using fewer doses than BioThrax<sup>®</sup> vaccine, which is expected to allow patients to reach a protective level of immunity more rapidly. CYFENDUS<sup>®</sup> is designed to provide protection with a two-dose regimen (versus the BioThrax<sup>®</sup> 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 Biomedical Advanced Research and Development Authority ("BARDA"), which included a five-year base period of performance to develop CYFENDUS<sup>®</sup> 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 CYFENDUS<sup>®</sup> 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 CYFENDUS<sup>®</sup>. Following this submission, BARDA began procuring CYFENDUS<sup>®</sup>, 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 July 2020 (valued at \$258.0 million) to procure additional doses of CYFENDUS<sup>®</sup> for delivery into the SNS over 12 months, in September 2021 funding another contract option (valued at approximately \$399.0 million) to deliver doses of CYFENDUS<sup>®</sup> to the SNS over 18 months. Two contract modifications (each valued at \$75 million) were executed with BARDA in 2023; the first modification was filed during 2023 and the second modification expires in March 2024. In April 2022, we completed our submission of a Biologics License Application ("BLA") for CYFENDUS<sup>®</sup> to the FDA and received BLA approval in July 2023. When we report the revenue associated with "anthrax vaccines," it reflects the combined revenue from the procurement and sale of CYFENDUS<sup>®</sup> as well as BioThrax<sup>®</sup> (described above).

Ebanga<sup>™</sup> (ansuvimab-zykl), for injection. Ebanga<sup>™</sup> (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 asset purchase agreement and a license agreement with Ridgeback Biotherapeutics ("Ridgeback") to expand the availability of Ebanga<sup>™</sup> (ansuvimab-zykl). This included a license to the Ebanga<sup>™</sup> trademark and to certain patent rights related to Ebanga<sup>™</sup> (ansuvimab-zykl). We will be responsible for manufacturing, selling and distributing Ebanga<sup>™</sup> (ansuvimab-zykl) in the U.S. and Canada and Ridgeback will serve as the global access partner. In July 2023, the Company announced it was awarded a 10-year contract by BARDA, valued at up to a maximum of \$704 million, for advanced development, manufacturing scale-up, and procurement of Ebanga<sup>™</sup>.

Raxibacumab injection. 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<sup>®</sup> (Reactive Skin Decontamination Lotion Kit). RSDL<sup>®</sup> kit is cleared by the FDA and 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<sup>®</sup> 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<sup>®</sup> kits have been agencies of the USG, including the DoD and the National Guard. 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<sup>®</sup> kits for use by all branches of the U.S. military. We also sold RSDL<sup>®</sup> kits to ten foreign countries outside the U.S. in 2023. In November 2022, three lots of our RSDL<sup>®</sup> 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. We identified and remediated the cause leading to the November 2022 recall, as well as completed all required actions, notices and report submissions related to the recalled batch. We are currently awaiting formal closure of the recall from FDA.

TEMBEXA<sup>®</sup> (brincidofovir) tablets and oral suspension. TEMBEXA<sup>®</sup> 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 BARDA, valued at up to \$680.0 million, to supply up to 1.7 million tablet and suspension formulations of TEMBEXA<sup>®</sup> was novated to the Company. On December 11, 2023, Emergent received a Notice of Compliance from Health Canada for its Extraordinary Use New Drug Submission (EUNDS) for indication of the treatment of human smallpox disease in adults and pediatric patients, including newborn infants. The Company has 2 patent families relating to the TEMBEXA<sup>®</sup> product including but not limited to, those listed in the Orange Book: 8,962,829, 9,303,051, 9,371,344, 10,112,909, and 10,487,061. The latest expiring United States composition of matter patents expires in 2034.

TROBIGARD<sup>®</sup> atropine sulfate, obidoxime chloride auto-injector. TROBIGARD<sup>®</sup> auto-injector was approved by the Federal Agency for Medicines and Health Products of the Belgium Health Authority on February 18, 2021. TROBIGARD<sup>®</sup> auto-injector is not currently approved or cleared by the FDA. TROBIGARD<sup>®</sup> auto-injector is only distributed to authorized government buyers for use outside the U.S. In Belgium, the TROBIGARD<sup>®</sup> 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<sup>®</sup> product, training auto-injectors and RSDL<sup>®</sup> 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<sup>®</sup> (Vaccinia Immune Globulin Intravenous (Human)). 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 <sup>®</sup> (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

#### Description of Commercial Products

NARCAN<sup>®</sup> Nasal Spray. NARCAN<sup>®</sup> 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. We have rights to formulations of naloxone used in NARCAN<sup>®</sup> Nasal Spray from Indivior PLC (f/k/a Opiant Pharmaceuticals Inc.). The primary customers for NARCAN<sup>®</sup> Nasal Spray are state health departments, local law enforcement agencies, community-based organizations, substance abuse centers, federal agencies, and consumers. We completed two important product life cycle improvements in 2020. First, we launched the Generation II NARCAN<sup>®</sup> Nasal Spray device, which has a claim for enhanced temperature excursions and storage below 25°C. Second, we gained FDA approval for an extension of the shelf life of NARCAN<sup>®</sup> Nasal Spray from 24 months to 36 months. On January 18, 2024, the Company announced that the FDA has acknowledged the shelf-life extension of NARCAN<sup>®</sup> Nasal Spray from 36 months to 48 months based on the company's four-year stability data.

In the fourth quarter of 2022, we filed our supplemental New Drug Application ("sNDA") for NARCAN<sup>®</sup> 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. 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<sup>®</sup> Nasal Spray was supportive of its use as a nonprescription opioid overdose reversal agent.

NARCAN® Nasal Spray was approved as an OTC medication on March 29, 2023. It was the first 4 mg naloxone nasal spray available OTC in the U.S. The new OTC product was shipped out to retailers and e-commerce providers nationwide in August of 2023. Emergent is prepared to supply all segments and customers of the business with OTC product.

**Product Candidates**

The table below highlights our current portfolio of product candidates:

PRODUCT CANDIDATES	
Product Candidate	Target Indication
CGRD-001 (Pralidoxime chloride/atropine auto-injector)	Treatment of poisoning by organophosphorus nerve agents or organophosphorus compounds.
EBS-LASV (rVSV-vectored vaccine for Lassa fever)	Active immunization to prevent Lassa fever.
EBS-MARV (rVSV-vectored vaccine for Marburg virus disease)	Active immunization to prevent Marburg virus disease.
EBS-SUDV (rVSV-vectored vaccine for Sudan virus disease)	Active immunization to prevent Sudan virus disease.
Pan-Ebola mAbs	Treatment of ebola virus disease caused by infection in patients with confirmed Sudan virus.
SIAN (stabilized isoamyl nitrite)	Antidote for initial treatment of certain or suspected acute cyanide poisoning.
UniFlu (Universal influenza vaccine)	Intended to induce broad and supra-seasonal immunity against influenza A and B viruses.
WEVEE-VLP	To prevent disease caused by Western, Eastern, and Venezuelan equine encephalitis virus infections.

Description of Product Candidates

**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.

**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"). We have completed our Phase 1 clinical trial and are currently analyzing the data.

**EBS-MARV.** This vaccine candidate is a recombinant, vesicular stomatitis virus vectored, monovalent vaccine encoding the surface glycoprotein precursor gene of Marburg virus. The development program is partnered with Auro Vaccines and is currently in IND-enabling stage. NIAID is funding Auro Vaccines program with contract options through Phase 1 development.

**EBS-SUDV.** This vaccine candidate is a recombinant, vesicular stomatitis virus vectored, monovalent vaccine encoding the surface glycoprotein precursor gene of Sudan virus. The development program is partnered with Auro Vaccines and is currently in IND-enabling stage. NIAID is funding Auro Vaccines program with contract options through Phase 1 development.

**Pan-Ebola mAbs.** IBT-T02 is a cocktail comprised of two chimeric mAbs, FVM04 and CA45. The mAb cocktail candidate targets two highly conserved and non-overlapping epitopes on the glycoprotein of Sudan ebolavirus (SUDV) and other ebolaviruses. The preclinical program is in partnership with Integrated Biotherapeutics with a BARDA funded non-human primate study in progress.

**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. We have completed our Phase 1 clinical trial to assess the safety, tolerability, pharmacokinetics and pharmacodynamics, and are currently analyzing the data.

**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. We have completed our Phase 1 clinical trial to assess safety, tolerability, and immunogenicity and are currently analyzing the data.

WEVEE-VLP. WEVEE VLP vaccine is a recombinant VLP vaccine. The development program is in partnership with NIAID Vaccine Research Center (VRC), who has already completed a Phase 1 clinical trial of the trivalent vaccine, in addition to a monovalent Phase 1 clinical study of the VEEV VLP component only.

#### **Description of Services**

**Bioservices.** Our Bioservices 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 Bioservices 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 8 development and manufacturing sites located in the U.S. and Canada. These sites allow us to meet our internal manufacturing needs as well as performing services for our external customers. Six of these sites currently provide bioservices to customers.

- Our Winnipeg and Gaithersburg sites house our development services expertise;
- Our Lansing and Winnipeg 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 55 active Bioservices 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.

The following table lists the registered trademarks for our MCM products:







Trademark	Country of Origin
ACAM2000®	Australia, Brazil, Canada, EU, Hong Kong, Israel, Singapore, United Kingdom, U.S.
Anthrasil®	Australia, Canada, Egypt, EU, Israel, Lebanon, Republic of Korea, Qatar, Saudi Arabia, Singapore, Turkey, United Kingdom, United Arab Emirates, U.S.
	U.S.
	EU, UK
BAT®	Canada, China, EU, Japan, Mexico, Republic of Korea, United Kingdom, U.S.
BioThrax®	Australia, Brazil, Canada, EU, India, Malaysia, Saudi Arabia, Singapore, United Kingdom, U.S.
CYFENDUS®	U.S.
RSDL®	Australia, EU, United Kingdom, U.S.
TEMBEXA®	Argentina, Australia, Brazil, Canada, Chile, China, EU, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Norway, Russia, Singapore, Switzerland, Taiwan, Turkey, Ukraine, United Kingdom, U.S.
CNJ-016®	U.S.

### Commercial Products

In the U.S. market, NARCAN<sup>®</sup> (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<sup>®</sup> Nasal Spray is sold to consumers online and through retailers nationwide. In 2022, we submitted a supplemental New Drug Application (sNDA) requesting that FDA switch NARCAN<sup>®</sup> Nasal Spray (4mg) from a prescription drug to an over-the-counter medicine. 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<sup>®</sup> Nasal Spray was supportive of its use as a nonprescription opioid overdose reversal agent. NARCAN<sup>®</sup> Nasal Spray was approved as an OTC medication on March 29, 2023. It was the first 4 mg naloxone nasal spray available OTC in the U.S.

In the Canadian market, NARCAN<sup>®</sup> (naloxone HCl) Nasal Spray is sold directly to federal, provincial and local governments and agencies for use by first responders, public health and harm reduction agencies, and indigenous communities. In addition, NARCAN<sup>®</sup> Nasal Spray is sold to businesses and consumers online and through pharmacies nationwide. On November 24, 2023, we submitted a Medical Device Establishment License (MDEL) Application to Health Canada that would permit Emergent to distribute Narcan<sup>®</sup> Nasal Spray (4mg) in kitted-format with other medical devices as well as in standard approved packaging to comply with provincial legislative requirements. The performance standard to issue a decision is 120 calendar days from submission. On December 22, 2023, the Health Canada MDEL Review Committee granted Emergent BioSolutions Canada Inc. the MDEL, enabling the direct sale of kitted NARCAN<sup>®</sup> Nasal Spray across Canada.

The following table lists the registered trademarks for NARCAN<sup>®</sup> (naloxone HCl) Nasal Spray:

Trademark	Country of Registration
NARCAN <sup>®</sup>	Benelux, Canada, Denmark, Estonia, EU, Finland, Germany, Ireland, Italy, Norway, Spain, Sweden, United Kingdom, U.S.
	EU, Norway, United Kingdom, U.S.
	Canada, U.S.
	Canada, U.S.
	Canada

### Bioservices

We market our bioservices to the global pharmaceutical and biotechnology industry, governments and NGOs. We also provided bioservices to the USG, which ended in 2021. Our bioservices 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<sup>®</sup>*. ACAM2000<sup>®</sup> vaccine, which is licensed by the FDA and recently licensed by Health Canada, 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<sup>®</sup> vaccine faces competition from JYNNEOS<sup>™</sup> 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<sup>®</sup> vaccine is also approved in Canada and in the EU under the trade names IMVAMUNE<sup>®</sup> and IMVANEX<sup>®</sup>, respectively.

- **CYFENDUS<sup>®</sup> and BioThrax<sup>®</sup>.** CYFENDUS<sup>®</sup> and BioThrax<sup>®</sup> vaccines are currently procured, primarily by the USG, for prevention of anthrax disease. BioThrax<sup>®</sup> and CYFENDUS<sup>®</sup> vaccines are currently the only two anthrax vaccine approved by the FDA for prevention of anthrax disease, and CYFENDUS<sup>®</sup> and BioThrax<sup>®</sup> 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. GC Pharma, Blue Willow Biologics/Porton Biopharma, and Greffex are each currently developing anthrax vaccine product candidates, which are in various stages of clinical development. Of these product candidates, GC Pharma and Blue Willow Biologics have completed Phase 1 trials.
- **BAT<sup>®</sup>.** 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<sup>®</sup>.** 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<sup>®</sup> (tecovirimat), an oral therapy, for the treatment of complications following vaccination against smallpox. TPOXX<sup>®</sup> is currently procured by the USG for the SNS.
- **Ebanga<sup>™</sup> (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<sup>®</sup> (atoltivimab, mafivimab and odesivimab-ebgn), which was approved by the FDA in October 2020 with the same indication. Inmazeb<sup>®</sup> is currently procured by the USG for the SNS.
- **NARCAN<sup>®</sup>.** NARCAN<sup>®</sup> (naloxone HCl) 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<sup>®</sup> Nasal Spray 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<sup>®</sup> Nasal Spray approved by the FDA. Padagis launched its generic naloxone nasal spray. NARCAN<sup>®</sup> Nasal Spray also faces branded competition: Kloxxado<sup>™</sup> (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<sup>™</sup> (naloxone), a branded injectable product developed by Adamis and RiVive<sup>™</sup> a 3mg naloxone nasal spray formulation intended for use in opioid overdose reversal by Harm Reduction Therapeutics. On May 22, 2023, FDA granted approval of Opvee<sup>®</sup> (nalmefene) Nasal Spray to Opiant Pharmaceuticals Inc. (now a wholly owned subsidiary of Indivior PLC), which was released in the market during fourth quarter of 2023. Teva Pharmaceutical Industries Ltd. also received a notice of compliance (NOC) from Health Canada on January 2, 2024. NARCAN<sup>®</sup> Nasal Spray may face additional generic and branded competition in the future.
- **Raxibacumab and Anthrasil<sup>®</sup> [Anthrax Immune Globulin Intravenous (human)].** Our raxibacumab product is the first FDA-licensed fully human anthrax monoclonal antibody therapeutic and Anthrasil<sup>®</sup> [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<sup>®</sup> (oblitoximab) injection, a chimeric (or partially human) antibody indicated for the treatment and prophylaxis of inhalational anthrax. Oblitoximab is also approved in Canada and the EU.
- **RSDL<sup>®</sup>.** In the U.S., the RSDL<sup>®</sup> Kit is 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<sup>®</sup> (brincidofovir).** TEMBEXA<sup>®</sup> is the first oral antiviral approved by the FDA, in June 2021, for all age groups for the treatment of smallpox. In December 2023, TEMBEXA<sup>®</sup> received approval by Health Canada. TEMBEXA<sup>®</sup> faces competition from TPOXX<sup>®</sup> (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<sup>®</sup> is also approved in Canada and the EU. In the EU, TPOXX<sup>®</sup> 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.

**Bioservices**

We also compete for bioservices with several biopharmaceutical product R&D organizations, contract manufacturers of biopharmaceutical products, other bioservices organizations, and university research laboratories.

Companies with which we compete to provide bioservices include, among others: Lonza Group Ltd., Catalent, Inc., Thermo Fisher Scientific, Curia Global, Inc., Resilience, Grand River Aseptic Manufacturing, Berkshire Sterile Manufacturing, Jubilant HollisterSteirVetter Pharma, and FUJIFILM Diosynth Biotechnologies. We also compete with in-house research, development and support service departments of other biopharmaceutical companies.

## MANUFACTURING OPERATIONS

**Manufacturing Network:** Emergent relies on an internal and external network of manufacturers and other third parties to produce its commercial and clinical supply of products. The following products are manufactured internally: ACAM2000®, Anthrasil®, BAT®, VIGIV CNJ-016®, RSDL®.

NARCAN® Nasal Spray, EBANGA™, TEMBEXA, CYFENDUS® and BioThrax® are produced externally in whole or in part by contract manufacturers. However, we perform the majority of the work internally to produce CYFENDUS® and BioThrax®.

For example, 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.

**Supplies and Raw Materials:** We place purchase orders for quantities of raw material and supplies in advance of their use in manufacturing in quantities believed to be sufficient to meet upcoming demand requirements. Once received into our facilities or our contract manufacturer's facility, these materials are subject to rigorous testing to ensure they are appropriate for use.

We obtain Alhydrogel® adjuvant 2%, used to manufacture CYFENDUS® 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 we believed to be sufficient to meet our expected manufacturing needs. We also utilize single-source suppliers for other raw materials in our manufacturing processes.

In addition, we utilize single source suppliers for all components of NARCAN® Nasal Spray.

We also rely on single source suppliers for our plasma collection to support the VIGIV CNJ-016® and BAT® programs. We work closely with our suppliers for these specialty programs and operate under long-term agreements.

## 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, know-how, 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 valid and enforceable 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 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<sup>®</sup>, ACAM2000<sup>®</sup>, Anthrasil<sup>®</sup>, BAT<sup>®</sup>, 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 an Emergency Use Authorization ("EUA") 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, or a disease or condition that may be attributable to 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 an attack with a CBRN agent or an agent that may cause, or is otherwise associated with, an imminently life-threatening and specific risk to United States military forces; 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 (the EUA Declaration) that circumstances exist justifying EUAs for MCMs to respond to the threat or emergency at issue. Once the relevant determination and EUA 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 a serious or life-threatening disease or condition related to the threat or emergency and that there are no adequate, approved, and available alternatives to the product for diagnosing, preventing, or treating the disease or condition. EUAs are subject to additional conditions and restrictions, are product-specific, and terminate when the EUA is revoked or the EUA declaration is terminated because the Secretary of HHS has determined that the circumstances that led to the emergency determination have ceased or because the authorized use has been approved.

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 the 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<sup>®</sup>, ACAM2000<sup>®</sup>, raxibacumab, Anthrasil<sup>®</sup>, BAT<sup>®</sup> 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<sup>®</sup> and RSDL<sup>®</sup> in 2006 and has continued to renew those determinations. Any future renewals of the SAFETY Act designation and certification for BioThrax<sup>®</sup> and RSDL<sup>®</sup> 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 efficacy data from animal studies. In assessing the sufficiency of animal data, the FDA may take into account other available data, including human data. 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 application ("IND"). 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 an 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 each approved product 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, 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 FDA's review of 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 RLD, 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 RLD.

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 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) the patent 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 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 product 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 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 marketing authorization 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 (for drugs and biologics), 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 for the same indication. Orphan drug exclusivity will not bar approval of the same drug marketed by a different manufacturer under certain circumstances, including if the company with orphan drug exclusivity is not able to meet market demand, grants consent to the FDA's approval of the subsequent product 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.

In September 2021, the U.S. Court of Appeals for the Eleventh Circuit held in *Catalyst Pharmaceuticals, Inc. v. Becerra* that the FDA had erred by limiting the scope of orphan drug exclusivity for FIRDAPSE® (amifampridine) to the product's approved indication, an action that the FDA took in accordance with its regulations interpreting the Orphan Drug Act. The court held that under the Orphan Drug Act, FIRDAPSE's orphan drug exclusivity instead protected the rare disease or condition that received orphan drug designation. Following this court decision in the Catalyst case, the FDA announced in January 2023 that it would continue to apply the FDA's regulations limiting the scope of orphan drug exclusivity to a product's approved uses or indications. As a result of the FDA's announcement, the scope of orphan drug exclusivity and other issues relating to the FDA's implementation of the Orphan Drug Act with respect to previously approved and future products may be the subject of further litigation or legislation.

*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 and/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 are not authorized to be legally marketed in the U.S. are subject to FDA export requirements.

## Manufacturing Requirements

The FDA's statutory provisions and regulations require that drugs be manufactured in FDA-registered 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/or QSRs and other requirements.

The FDA uses a "risk-based approach" to inspections, whereby the agency prioritizes medical product surveillance inspections deemed high risk based on a variety of specific criteria, such as facility type, compliance history, and inherent risks of product manufactured at the facility. 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. Each foreign country has its own regulatory requirements for medicines and medical devices. 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. 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 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

high 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 privacy requirements on U.S. companies similar to the requirements reflected in the General Data Protection Regulation ("GDPR") in the EU ("State Consumer Privacy Laws"). As of December 31, 2023, State Consumer Privacy Laws were effective in five U.S. states. Three more State Consumer Privacy Laws become effective in 2024. 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 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.

During 2023, our number of employees declined by approximately 900 due to organizational restructurings announced in January and August 2023 and the sale of our travel health business to Bavarian Nordic in May. As of December 31, 2023, we had approximately 1,600 employees.

#### **Health and Wellness**

At our company, we are deeply committed to the health and wellbeing of our employees. We provide a comprehensive range of benefits and resources to support their physical, mental, and financial wellness. This includes access to mindfulness tools, online therapy apps, fitness apps, and programs focused on financial literacy and wellbeing. Additionally, our safety programs comply with regional requirements and are designed to ensure a safe and comfortable work environment, incorporating measures such as ergonomics, COVID-19 prevention protocols, and a strong culture of safety in our day-to-day operations.

#### **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, leadership and technical training programs, tuition assistance professional memberships and professional conference attendance. We continue to 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 comprehensive benefits and salaries, bonuses, and for employees in eligible roles, equity awards. 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 within our company.

## 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 demonstrate respect for the individual by providing fair and equal treatment to all our employees and identifying ways to recognize their various needs and interests. Our three inaugural Emergent Resource Groups ("ERGs") for black, women and veteran employees continue to open pathways of communication, help to expand learning opportunities, and offer avenues to give back to communities. In 2023, the ERGs brought guest speakers and learning opportunities on important topics such as imposter syndrome, maintaining mental fitness and challenges faced by women in the workplace. Another important initiative has been implementing and planning to expand the SkillBridge internship program and other efforts that support veterans' successful transition into the private sector. 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.

## 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. Since 2020, Emergent has annually reported on ESG matters under the responsibility of the Vice President, Assistant Treasurer reporting into the Chief Financial Officer ("CFO"), with oversight from the Nominating and Corporate Governance Committee. In 2023, we created a dedicated role within our organization to manage this work full time, reinforcing our commitment to ESG progress at Emergent. In addition to creating and publishing Emergent's annual ESG report, this new role will work with core stakeholders across the organization to evolve and implement a multiyear ESG strategy that supports our mission. Our Nominating and Corporate Governance Committee will continue to oversee ESG efforts, with executive sponsorship from the CFO and Executive Vice President of External Affairs and General Counsel.

Our strategy is influenced by the Task Force on Climate-Related Disclosures framework ("TCFD") as well as the Sustainability Accounting Standards Board's 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. Our most recent ESG Report can be found at: [www.emergentbiosolutions.com/wp-content/uploads/2023/10/EBSI\\_2022\\_ESG\\_Report](http://www.emergentbiosolutions.com/wp-content/uploads/2023/10/EBSI_2022_ESG_Report). The information contained in the ESG report is not a part of, or incorporated by reference into, this Annual Report on Form 10-K.

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

Since conducting our first materiality assessment in 2020, Emergent and the world have changed significantly. To ensure our priority issues support business needs and meet stakeholder expectations, we conducted a materiality refresh in 2023 with input from internal and external stakeholders. Our updated priority issues are:

- Top Priorities
  - Talent Attraction, Engagement & Development
  - Ethics & Compliance
  - Product Quality & Patient Safety
  - Sustainable Innovation
  - Product Affordability & Accessibility
  - Responsible Supply Chain

- Relative Priorities
  - Carbon Emissions
  - Climate Policy and Risk Management
  - Clinical Trial Practices
  - Diversity, Equity and Inclusion
  - Employee Health and Safety
  - Energy Use and Efficiency
  - Environmental Policy and Management
  - ESG Oversight
  - Supplier Product Quality, Reliability and Compliance
  - Waste 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 our 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.

We expect these efforts will also allow us to make informed decisions on setting targets and creating an accompanying strategy and road map for meeting our goals. 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 Nominating and Corporate Governance Committee of the Company's board of directors. ESG executive sponsors provide regular updates on ESG initiatives and progress at both the committee and full board meetings. Each director serves on at least 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 300 Professional Drive, Gaithersburg, Maryland 20879. Our telephone number is (240) 631-3200, and our website address is [www.emergentbiosolutions.com](http://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 CYFENDUS® 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.

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 Bioservices 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 bioservices.
- 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® (naloxone HCl) Nasal Spray is currently subject to generic and branded competition in the U.S. and may be subject to branded and generic competition in Canada. In addition, the success of NARCAN® Nasal Spray, including in over-the-counter form, is subject to commercial availability of the product and our ability to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community.



- 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.
- Potential discrepancies or challenges with respect to licenses, including our failure to comply with obligations under such licenses.
- Potential loss or misappropriation of proprietary information, know-how, and trade secrets 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.
- Cybersecurity incidents involving us, our business partners, collaborators or other third parties could 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, Public Readiness and Emergency Preparedness Act (the "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 Revolving Credit Facility, Term Loan Facility, Senior Unsecured Notes and any other debt agreements to which we may be a party.
- Our ability to remediate a material weakness in our internal control over financial reporting and to prepare accurate financial statements in a timely manner.

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:

- We may not be successful in identifying, structuring or acquiring businesses and products to drive our growth.
- 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 realize the full benefits from the sale of our travel health business to Bavarian Nordic.

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 stockholders.
- 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 CYFENDUS<sup>®</sup> vaccine and the TEMBEXA<sup>®</sup>, oral antiviral and have historically derived a substantial portion of our revenue from USG procurement of the ACAM2000<sup>®</sup> vaccine and of BioThrax<sup>®</sup>. If the USG's demand for and/or funding for procurement of CYFENDUS<sup>®</sup>, BioThrax<sup>®</sup>, ACAM2000<sup>®</sup> and/or TEMBEXA<sup>®</sup> 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 CYFENDUS<sup>®</sup>. As with any approved product, there is a risk that we may encounter challenges causing delays or an inability to deliver CYFENDUS<sup>®</sup>, 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 CYFENDUS<sup>®</sup> or BioThrax<sup>®</sup> vaccines may be delayed, limited or not available, BARDA may never complete the anticipated full transition to stockpiling CYFENDUS<sup>®</sup> 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<sup>®</sup> vaccine to the USG. If priorities for the SNS change with respect to ACAM2000<sup>®</sup> vaccine or the USG decides not to exercise additional options under our ACAM2000<sup>®</sup> contract, our future business, financial condition, operating results and cash flows could be materially harmed.

*Our USG procurement and development contracts require ongoing funding decisions by the USG. 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 MCMs and the primary source of funds for the development of most of our product candidates in our development pipeline. 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 CYFENDUS<sup>®</sup> 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. On July 31, 2023, we were awarded a 10-year contract by BARDA for the advanced development, manufacturing scale-up, and procurement of Ebanga<sup>™</sup> (ansuvimab-zykl) treatment for Ebola. The contract consists of a base period of performance with two option periods valued at approximately \$121 million, and option periods for procurement of Ebanga<sup>™</sup> over five years valued at up to \$583 million. If all option periods are exercised, the total contract value will be valued at up to approximately \$704 million. 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 this contract or our other 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 and other commercialized products. 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 and other commercialized products upon the expiration of a related procurement contract, but there can be no assurance that we will be successful obtaining any follow-on contracts. Even if we are successful in negotiating a follow-on procurement contract, it may be for a lower product volume, over a shorter period of performance or be on less favorable pricing or other terms. An inability to secure follow-on procurement contracts for our 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 and other commercialized 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 & Human Services (“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 requirements. The Company's failure to maintain compliance with CGMP requirements at our manufacturing facilities has hindered and could continue to hinder our ability to continue manufacturing for our own products and for Bioservices customers, which could adversely affect our business, financial condition, operating results and cash flows. For example, in February 2022, the FDA inspected Emergent's Camden facility located in Baltimore, Maryland and issued a Form FDA 483. In August 2022, the 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. In July and August of 2023, the FDA inspected the Camden facility, and in October 2023, the FDA determined that the inspection classification of the Camden facility was "voluntary action indicated" or VAI. A VAI classification indicates that, although investigators found and documented objectionable conditions during the inspection, the FDA would not take or recommend any administrative or regulatory action. Furthermore, the FDA concluded that the Camden facility inspection was "closed" under 21 CFR 20.64(d)(3) and issued to the Company a "Warning Letter close-out letter". In August 2023, the FDA inspected Emergent's Canton facility located in Canton, Massachusetts and issued a Form FDA 483. The Canton facility inspection was classified as VAI. In December 2023, the FDA inspected Emergent's Lansing facility located in Lansing, Michigan and issued a Form FDA 483. At this point, the Lansing facility inspection has not been classified and we are not aware of specific timing regarding the classification decision.

The failure to remedy any remaining objectionable conditions at Emergent's manufacturing facilities, or any additional failures to maintain compliance with CGMP requirements at any of our manufacturing facilities, could adversely affect our business, financial condition, operating results and cash flows.

*Disruption at, damage to or destruction of, our manufacturing facilities could impede our ability to manufacture anthrax vaccines, our ACAM2000<sup>®</sup> vaccine or our other products or product candidates, as well as impact the delivery of bioservices, 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;
- 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; 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 our Lansing, Michigan facility as 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 Bioservices 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 Form FDA 483s 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 certain 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 Centers for Disease Control and Prevention (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.

## **PRODUCT DEVELOPMENT AND COMMERCIALIZATION RISKS**

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

We provide bioservices 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 Bioservices programs 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 Bioservices customers and the November 2021 termination of the termination of the Center for Innovation in Advanced Development and Manufacturing agreement with BARDA for COVID-19 vaccine development and manufacturing caused us to suffer considerable reputational and financial damage and resulted in the instigation of stockholder litigation and government investigations described elsewhere in this Annual Report. Further, our announcement in the third quarter of 2023 that we are de-emphasizing focus on our Bioservices business may raise concerns regarding our ability to fulfill manufacturing commitments to our Bioservices customers. 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 Quality System Regulation ("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.

In particular, the success of NARCAN® (naloxone HCl) Nasal Spray, including in over-the-counter form, is subject to commercial availability of the product and our ability to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community.

*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 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 Public Health Service Act (the "PHSA") and the Federal Food, Drug, and Cosmetic Act (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 and other approved products 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 the FDA to market and sell any of our future drug, biologic, or vaccine products, we will be required to submit a New Drug Application (an "NDA") or Biologics License Application (a "BLA") to the FDA. Under the FDCA, the PHSA, and the 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, the 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 premarket approval application ("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, the 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 product candidates 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, the 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; and 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 drug 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 or 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 condition.

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

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.

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 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 the 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. A growing number of state attorneys general are filing legal challenges, including antitrust challenges, related to drug pricing and reimbursement against various supply chain entities, such as pharmacy benefit managers, and such litigation may also involve drug manufacturers in the future. 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 laws, 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 Children's Health Insurance Program to report certain payments and transfers of value made to U.S. physicians, prescribers and teaching hospitals, as well as ownership or investment interests held by physicians, 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.

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 federal 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 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 applicable 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. 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 or reimbursed 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 all federal purchasers. In addition, for the “Big Four” federal agencies—the DVA, the DoD, the PHS (including the Indian Health Service), and the Coast Guard—we must make covered drugs available at pricing that is capped at the statutory federal ceiling price (“FCP”). The FCP is calculated using the formula set forth in Section 603 of the Veterans Health Care Act of 1992 (the “VHCA”) and 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 Tricare program agreements, 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 TROBIGARD® (and CYFENDUS®, prior to its approval by the FDA) 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. The 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®. 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 alleging, 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, three lots of our RSDL<sup>®</sup> kits was recalled due to leakage (the "November 2022 Recall"), which could cause the product not to perform as effectively as intended. We identified and remediated the cause leading to the November 2022 Recall, as well as completed all required actions, notices and report submissions related to the recalled batch. We are currently awaiting formal closure of the November 2022 Recall from the FDA, Center for Devices and Radiological Health.

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 continues to be subject to European Union rules under the Northern Ireland Protocol. The MHRA relies 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 U.S. Foreign Corrupt Practices Act (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 United States, also have various lobbying laws and regulations governing the conduct of individuals and companies who interact with government officials. These laws and regulations typically include certain restrictions and disclosure obligations. If we, our employees, or third parties acting on our behalf do not comply with these laws and regulations, we may be subject to civil and criminal penalties.

Many countries, including the United States, restrict the export or import of products to or from certain countries through, for example, bans, sanction programs, and boycotts. Such restrictions may preclude us from supplying products in certain countries.



which could limit our growth potential. Furthermore, if we, or third parties acting on our behalf, do not comply with these restrictions, we may be subject to civil and criminal penalties.

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

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties, 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 CYFENDUS<sup>®</sup>, BioThrax<sup>®</sup>, and ACAM2000<sup>®</sup>. 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<sup>®</sup> (naloxone HCl) Nasal Spray is currently subject to generic and branded competition and may be subject to additional generic and branded competition in the future. If demand for over-the-counter NARCAN<sup>®</sup> Nasal Spray outpaces current estimations, there could be supply challenges to meet demand.*

NARCAN<sup>®</sup> Nasal Spray was approved as an over-the-counter ("OTC") medication on March 29, 2023. The new OTC product was shipped out to retailers and e-commerce providers nationwide in August of 2023. Emergent is prepared to supply all segments/customers of the business with OTC product. If demand for NARCAN<sup>®</sup> Nasal Spray increases beyond our current estimates, there could be supply interruptions. Should this occur, Emergent has contingency plans to continue to provide product to those at the highest need and increase production to meet the new demand.

NARCAN<sup>®</sup> Nasal Spray currently faces generic competition. In 2016, Teva Pharmaceuticals Industries Limited and Teva Pharmaceuticals USA (collectively, "Teva") filed an Abbreviated New Drug Application (an "ANDA") seeking regulatory approval to market a generic version of NARCAN<sup>®</sup> Nasal Spray. 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 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<sup>®</sup> Nasal Spray also faces generic competition from Padagis LLC ("Padagis"). Prior to Padagis' separation from Perrigo UK FINCO Limited Partnership ("Perrigo") in 2021, Perrigo filed its own ANDA for generic naloxone nasal spray 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 ANDA and Padagis launched its prescription generic naloxone nasal spray. On July 18, 2023 the FDA approved an Rx-to-OTC switch of Padagis' product. In March 2023, Amneal Pharmaceuticals, Inc. ("Amneal") announced that the FDA had accepted for review Amneal's ANDA for generic naloxone nasal spray.

Sales of generic versions of NARCAN<sup>®</sup> Nasal Spray at prices lower than our branded product or provided at no cost by Teva, Padagis and Amneal (pending approval) have the potential to erode our sales and could impact our product revenue related to NARCAN<sup>®</sup> Nasal Spray.

NARCAN<sup>®</sup> Nasal Spray also faces branded competition from RiVive<sup>™</sup> (naloxone HCl nasal spray 3mg), a branded product developed by Harm Reduction Therapeutics; Kloxxado<sup>™</sup> (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<sup>™</sup> (naloxone), a branded injectable product developed by Adamis Pharmaceuticals Corporation.

NARCAN<sup>®</sup> (naloxone HCl) Nasal Spray may also 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 indication 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, the 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 indication. In addition, even after a product receives orphan drug exclusivity, the FDA can subsequently approve the same product for the same indication 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, know-how and proprietary confidential information, through defense and enforcement of existing rights and pursuit of protection on new and arising innovations.

Obtaining, maintaining and enforcing 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 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 challenges may have the potential to materially harm our business, financial condition, operating results, and cash flows.*

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 proprietary confidential information, know-how, and trade secrets can be difficult to protect, and potential loss or misappropriation of this information generally carries the risk of reducing the value of our technology and products. We seek to protect this confidential information, in part, through agreements with our employees, consultants, and third parties, as well as through internal policies and audits, although these may not always be successful in protecting our proprietary confidential information, know-how, and trade secrets.

Certain of our products are approved as drug products 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 Act 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<sup>®</sup> in sufficient quantities to meet our needs to manufacture CYFENDUS<sup>®</sup> and BioThrax<sup>®</sup> vaccines and the specialty plasma in our hyperimmune specialty plasma products and certain ingredients for the ACAM2000<sup>®</sup> vaccine. We also rely on single-source suppliers for the materials necessary to produce NARCAN<sup>®</sup> (naloxone HCl) Nasal Spray, such as the naloxone active pharmaceutical ingredient and other excipients, along with the vial, stopper and device.

Where a particular single-source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation of materials prior to use in our products and 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 non-governmental organizations ("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 cyber security incidents, unauthorized access or other failure, inadequacy, interruption or security lapse of that technology could harm our ability to operate our business effectively or result in data leakage of proprietary or confidential business or 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 and those of many of our business partners, collaborators and other third parties make them potentially vulnerable to interruption, invasion, computer viruses, destruction, unauthorized or malicious intrusion and additional related disruptions, which may result in the impairment of production and key business processes. Our systems and information are also potentially vulnerable to cyber security incidents through user error, phishing scams, or malfeasance, as well as cyber security incidents involving our employees, business partners, collaborators or other third parties, any of which may expose sensitive data to unauthorized persons. Our systems and those of our business partners and collaborators have in the past been, and in the future likely will be subject to computer viruses, malicious codes, unauthorized access and other cyber security incidents. We are not aware of any significant impact on our operations or financial results from such incidents although, as of the date of this report, we are assessing the potential impact of a cyber security incident involving misuse of authorized access by a business partner of which we became aware in October 2023.

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. Cyber security incidents 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. Any such unauthorized access to our information, whether through an incident involving our information technology systems or those of our business partners, collaborators or other third parties, could disrupt our business operations, result in the loss of assets, and have a material adverse effect on our reputation, business, financial condition, or results of operations. While the Company has experienced non-material cyber incidents involving third-party vendors, the Company's continued use of third parties in its business yields the potential for material cyber security incidents that may harm business operations.

A significant business disruption or a breach in security resulting in misappropriation, theft or sabotage with respect to proprietary or confidential business or 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<sup>®</sup>, ACAM2000<sup>®</sup>, raxibacumab, Anthrasil<sup>®</sup>, BAT<sup>®</sup> 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<sup>®</sup> and RSDL<sup>®</sup>, 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<sup>®</sup> and RSDL<sup>®</sup> 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<sup>®</sup> vaccine as a countermeasure to a bioterrorism threat. We rely on PREP Act protection for BioThrax<sup>®</sup>, raxibacumab, ACAM2000<sup>®</sup>, Anthrasil<sup>®</sup>, BAT<sup>®</sup> and VIGIV products, and SAFETY Act protection for BioThrax<sup>®</sup> and RSDL<sup>®</sup> 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<sup>®</sup> (naloxone HCl) Nasal Spray, 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, debt service coverage ratio, consolidated EBITDA level, minimum liquidity level and required liquidity raise under our Senior Secured Credit Facilities, and the additional terms and conditions imposed by the Forbearance Agreement and Sixth Amendment to Amended and Restated Credit Agreement, dated February 29, 2024 (the "Forbearance Agreement and Amendment") 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.

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

The Senior Secured Credit Facilities include the Term Loan Facility, which had an outstanding principal balance of \$198.2 million as of December 31, 2023 and the ability to borrow up to \$300.0 million under our Revolving Credit Facility under which we had \$219.2 million of outstanding borrowings as of December 31, 2023. On August 7, 2020, we completed an offering of \$450.0 million aggregate principal amount of Senior Unsecured Notes. 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 bioservices;
- 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.

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.

*Our hedging programs have been, and any hedging program we initiate in the future will be, subject to counterparty default risk.*

From time to time, 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, when we are party to such interest rate swaps, 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, 2023, we had unrestricted cash and cash equivalents of \$111.7 million and remaining capacity under our Revolving Credit Facility of \$80.3 million. Also as of December 31, 2023, there was \$219.2 million outstanding on our Revolving Credit Facility and \$198.2 million on our Term Loan Facility that mature in May 2025. We are not in compliance with certain provisions of the Senior Credit Facilities, most notably that we comply with the minimum consolidated EBITDA covenant and that our financial statements not contain a "going concern" qualification. In addition, it is unlikely that we will be able to comply with the requirement in the Credit Agreement Amendment (as defined below) that we raise not less than \$75.0 million through the issuance of equity and/or unsecured indebtedness by April 30, 2024. 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 included in this Annual Report on Form 10-K were issued. On February 29, 2024, the requisite lenders under the Senior Credit Facilities agreed to enter into the Forbearance Agreement and Amendment to, among other things, (a) provide that the Administrative Agent and the Lenders forbear from exercising all rights and remedies under the Existing Credit Agreement and the other related loan documents arising from the occurrence and continuation of certain specified events of default during a forbearance period (the "Forbearance Period") between the forbearance effective date until the earlier to occur of (x) 5:00 p.m. on April 30, 2024 and (y) the occurrence of any event of default (other than the specified events of default) or default under the Forbearance Agreement and Amendment and notice by the Administrative Agent to the Company of the termination of the Forbearance Period and (b) provide consent by the required revolving credit lenders to make further loans to the Company or other extensions of credit to the credit parties during the Forbearance Period, notwithstanding the occurrence of the specified events of default, subject to certain conditions set forth in the Forbearance Agreement and Amendment, including a limit on Revolving Credit Facility indebtedness of \$270 million. The Company does not expect to be in compliance with debt covenants in future periods without additional sources of liquidity or future amendments to or forbearance arrangements under the Credit Agreement. 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 a shelf registration statement, which immediately became effective under SEC rules. As a result of the delayed filing of certain of our periodic reports with the SEC, we are not currently eligible to register the offer and sale of our securities using the shelf registration statement and we will not become eligible until we have timely filed certain periodic reports required under the Securities Exchange Act of 1934 for 12 consecutive calendar months. There can be no assurance that we will be eligible to file a shelf registration statement or to have such a shelf registration statement become effective after such period, which may inhibit our ability to access the capital markets to raise funds.

If we raise funds by issuing equity securities, including through our ATM Program, 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.*

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.

*Impairment charges to our intangible assets or property, plant and equipment could have a material adverse effect on our business, results of operations and financial condition.*

In accordance with GAAP, we are required to assess the value of our intangible assets and goodwill annually, or more frequently whenever events or changes in circumstances indicate potential impairment, such as changing market conditions or any changes in key assumptions. If the testing performed indicates that an asset may not be recoverable, we are required to record a non-cash impairment charge for the difference between the carrying value of the asset and its implied fair value in the period the determination is made.

We also periodically monitor the remaining net book values of our property, plant and equipment, or whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. For example, we performed recoverability tests on certain asset groups within the Bioservices reporting unit during the three months ended June 30, 2023, and allocated and recognized a non-cash impairment charge of \$306.7 million during the three months ended June 30, 2023 related to certain Bioservices long-lived assets.

In addition, we annually perform a goodwill impairment evaluation, during the fourth quarter, or sooner if triggering events are identified. During the three months ended September 30, 2023 as a result of continued market volatility, including significant declines in our market capitalization and revised financial outlook, we determined that a triggering event had occurred that required an evaluation of our goodwill for potential impairment. As a result of the quantitative assessments, we determined that our goodwill, which related to the MCM reporting unit within the Products segment, was fully impaired and recorded a \$218.2 million non-cash goodwill impairment charge during the three months ended September 30, 2023.

We have a significant amount of intangible assets and property, plant and equipment on our balance sheet. 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, we are unable to predict whether impairments of intangible assets and property, plant and equipment will occur in the future, and we can provide no assurance that continued conditions will not result in future impairments of these assets. 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 accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. We have identified material weaknesses in our internal control over financial reporting and have restated prior period financial statements that resulted from one of these material weaknesses, which may raise questions regarding the accuracy and reliability of our financial statements and our ability to report accurately in the future.*

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. During the process of preparing the financial statements as of and for the year ended December 31, 2022, we determined that we had a material weakness related to our inventory accounting. Subsequently, in connection with the preparation of the financial statements as of and for the periods ended September 30, 2023, we determined that we had a material weakness related to the calculation and review of the Company's net state deferred tax liability and that this material weakness had existed as of December 31, 2022 and resulted in a material misstatement to our consolidated financial statements for the period ended December 31, 2022. Due to the existence of these material weaknesses, our management concluded that as of December 31, 2022 our internal control over financial reporting was not effective and we were required to restate the financial statements included in our Original Form 10-K and filing Amendment No. 1 to the Original Form 10-K for the fiscal year ended December 31, 2022.

We determined that we remediated our internal weakness with respect to inventory accounting as of March 31, 2023 and we are taking steps to remediate the material weakness related to the calculation and review of the Company's net state deferred tax liability. In addition, we have restated our financial statements for the fiscal year ended December 31, 2022 to correct the errors that were identified as a result of the material weakness regarding our calculation and review of the Company's net state deferred tax liability, and corrected other unrelated errors that were either unrecorded or addressed as out-of-period adjustments in previously filed financial

statements that were not material, individually or in the aggregate, to those financial statements. 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 regarding state deferred taxes that we have identified, or to avoid additional material weaknesses from occurring in the future. The material weaknesses in our internal control over financial reporting and the restatement of our prior financial statements may raise significant questions regarding the accuracy and reliability of our filed financial statements and our ability to report in an accurate and timely manner in the future. These material weaknesses and resulting errors in our financial statements, or those that may occur in the future, could have an adverse effect on our ability to meet our reporting obligations, which could cause our investors to lose confidence in our publicly reported information, cause the market price of our stock to decline, harm our reputation, business and financial results, and expose us to stockholder litigation and sanctions or investigations by the SEC or other regulatory authorities.

*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.

#### **RISKS RELATED TO STRATEGIC ACQUISITIONS, DIVESTITURES AND COLLABORATIONS**

*We may not be successful in identifying, structuring or acquiring businesses and products to drive our growth.*

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 identify and 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, including but not limited to, license rights, freedom-to-operate, litigation, and loss of proprietary confidential information, know-how, and trade secrets.

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.

*We may not realize the expected benefits of the sale of our travel health business to Bavarian Nordic.*

On May 15, 2023, pursuant to the Purchase and Sale Agreement, we completed the previously announced sale to Bavarian Nordic of 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 \$270.2 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.

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

#### **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 stockholders.*

In recent years, some stockholders 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 environmental, social, and corporate governance ("ESG") factors. These investors may be seeking enhanced ESG disclosures or to implement policies adverse to our business. There can be no assurances that stockholders will not publicly advocate for us to make corporate governance changes or engage in certain corporate actions. Responding to challenges from stockholders, 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 of directors, which could have an adverse effect on our business and operational results. Any such stockholder actions or requests, or the mere public presence of stockholders with a reputation for taking such actions among our investor 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 to be voted on at meetings of stockholders;
- 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 adopt 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 adopt 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 December 31, 2023, our common stock has traded as high as \$137.61 per share and as low as \$1.81 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;
- 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 sales of our common stock or other securities convertible into common stock, or the perception that such sales or issuances could occur, could result in dilution of our stockholders and could cause our share price to decline.*

Our board of directors is authorized, without stockholder approval, to cause us to issue additional shares of our common stock or to raise capital through the issuance of preferred shares or the sale of debt securities that are convertible into common stock, options, warrants and other rights, on terms and for consideration as our board of directors in its sole discretion may determine. In addition, under the Credit Agreement Amendment, we are required to increase our liquidity by April 30, 2024 by raising at least \$75 million of equity or unsecured indebtedness. We also require substantial additional funding to be able to continue as a going concern and we may seek to achieve such funding through future sales of our common stock or other securities convertible into our common stock. Sales of substantial amounts of our common stock or the issuance of preferred shares, convertible debt, options, restricted stock units, performance stock units, warrants and other rights, or the perception that such sales or issuances could occur could cause the market price of our common stock to decrease significantly. As of December 31, 2023, we had 52,167,256 shares of common stock issued and outstanding. We cannot predict the effect, if any, of future sales of our common stock or any preferred shares, convertible debt securities, options, restricted stock units, performance stock units, warrants or other rights or the availability of our common stock for future sales on the value of our common stock.

#### **GENERAL RISK FACTORS**

*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. From time to time, there may be changes in our senior management team resulting from the hiring or departure of executives. For example, we hired a new Chief Executive Officer in February 2024. Our new Chief Executive Officer will be critical to executing on and achieving our vision, strategic direction, and business objectives. If we are unable to successfully transition leadership to our new Chief Executive Officer, our business, results of operations and financial conditions could be adversely affected. In addition, 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 IB. UNRESOLVED STAFF COMMENTS

Not applicable.

## ITEM IC. CYBERSECURITY

### CYBERSECURITY

The Company's cybersecurity program is aligned and integrated into the overall company risk management process through its Enterprise Risk Management Program ("ERM"). At Emergent, ERM is a centralized process that prioritizes, and groups the top risks to our organization into 12 categories, one of which is Cybersecurity. We conduct an Enterprise Risk Assessment ("ERA") annually to proactively identify, assess, respond, monitor, and report risks to our enterprise. Identified risks are assessed and we accordingly will either accept the risk or take action to reduce or avoid the risk. Mitigations against risks are developed, as necessary, and all risks are monitored, reviewed quarterly, and reported to executive leadership and the Board of Directors.

The ERM program and ERA process is described in the company's Enterprise Risk Management Policy which was released this year. The program includes enterprise level risks grouped in 12 risk categories. Cybersecurity is included as a standing risk category. The ERM program does not itself independently review cybersecurity policies and practices. In first quarter 2024, ERM, in collaboration with Emergent's Policy and Training Center of Excellence, provided training on Emergent's Enterprise Risk Management Policy to all employees who are at the vice president level and above. We are currently working on an all-employee awareness communication to further educate the full employee population about the ERM program, policy and intranet page. Timing for this communication is expected in first half of 2024. Annually, an ERM training will be provided to all participants in advance of the Company's annual ERA. Full retraining on the ERM policy will occur every three years. The Company leverages the Committee of Sponsoring Organizations' ("COSO") guidelines as the foundation for our ERM program and leverage external expertise.

The Company proactively reviews threats landscape, impacts to the company, and address any gaps where necessary. Also, we maintain security operations metrics, incident response plan and conduct tabletop exercises. The Company engages outside consultants to review both its Cybersecurity posture, and maturity, and perform for a cyber assessments of the Company's manufacturing/operational technology environments. The Company has a process in place to oversee and identify material risks from cybersecurity threats associated with its use of any third-party service provider, namely its Third-Party Risk Management Assessment Process. We utilize the NIST framework when assessing third parties. The framework covers 23 categories. When applicable, we may request if the third party vendor is SOC1/2, GDPR, certified.

The Company's Chief Information Security Officer ("CISO") is responsible for assessing and managing the Cybersecurity risks with comprehensive oversight of information security functions with an emphasis on strategic leadership, governance, risk management and technical proficiency. Moreover, the Company's CISO provides cyber security updates to the entire board of directors and the board's Quality Compliance Management Risk Committee (the "Committee"). The purpose of the Committee is to assist the Board in fulfilling its oversight responsibilities relating to the Company's compliance with laws, regulations, and industry standards that, if breached, may cause significant business, regulatory, or reputational damage to the Company, including oversight of the Company's:

- Compliance with good ("x" = manufacturing, clinical, laboratory, pharmacovigilance, storage, distribution etc.) (GxP) and medical device Quality Systems Regulations (QSR);
- Healthcare compliance, anti-corruption, privacy and data security landscape, medical product safety, supply chain, employee health and safety, political expenditures and lobbying activities, and government contracting;
- Enterprise Risk Management program;
- Cyber and information security risks.

The Committee is the primary oversight body to monitor the Company's cybersecurity and related information technology risks and receives periodic updates from Company management (including, the Chief Information Officer and the CISO) on the Company's policies, processes, procedures, and any significant developments related to the identification, mitigation, and remediation of cybersecurity risks. The Chair or Vice-Chair of the Committee meet as necessary with the Chief Information Officer and the CISO to engage in a more detailed review of the Company's cybersecurity and information security activities. The Committee charter also requires that the Committee ensure that Company management provides an annual cyber and information security update to the full Board. Current Committee members are: Zsolt Harsanyi, Ph.D., Sujata Dayal and Kathryn C. Zoon, Ph.D., all of whom are independent directors.

The Company's CISO is a Certified Information Systems Security Professional (CISSP) and Certified Information Security Manager (CISM), and is certified in Risk and Information Systems Control® (CRISC). The CISO reports to the Quality Compliance Management Risk Committee twice per year and also reports to the Board twice per year.

The Company has not incurred material cybersecurity incidents over the past three years. The Company is not aware that any risks from cybersecurity threats, including because of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect the company. The Company proactively reviews threats landscape, impacts to the company, and address any gaps where necessary. Also, we maintain security operations metrics, incident response plan and conduct tabletop exercises. In addition, the Company has:

- Managed Security Service Provider (MSSP) that maintains 24 hours per day, 7 days per week, monitoring of the Company's environment;
- Formed partnership with Cybersecurity Infrastructure Security Agency (CISA), to monitor the Company's external traffic and external facing web environment;
- Performed an internal red campaign;
- Been audited by internal and external auditors.

## ITEM 2. PROPERTIES

We own and lease approximately 1.4 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 16 locations in North America and Europe. Properties that have been leased expire on various dates between 2024 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.	160,000 (Owned); 15,800 (Leased)	Owned/Leased	Products & Services
Gaithersburg, Maryland	Laboratory space, office space and rental real estate.	173,000 (Owned); 11,547 (Leased)	Owned/Leased	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
San Diego, California	Office space.	18,012	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 19, "Litigation."

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

## PART II



**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Market Information and Holders

Our common stock trades on the New York Stock Exchange under the symbol "EBS".

As of February 28, 2024, the closing price per share of our common stock on the New York Stock Exchange was \$3.20 and we had 19 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend Policy

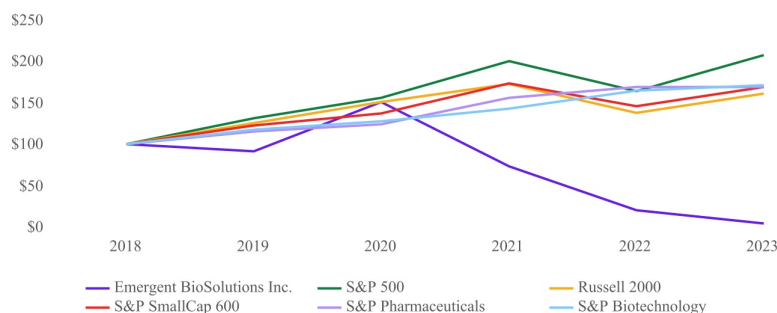
We have not declared or paid any cash dividends on our common stock since becoming a publicly traded company in November 2006. We currently have no plans to pay dividends.

The remaining information required by Item 5 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2024 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, 2018, all fiscal years end December 31<sup>st</sup> and all dividends were reinvested.

**Comparison of Five Year Cumulative Total Return**



Company / Index	Market Performance									
	2018	2019	2020	2021	2022	2023				
Emergent BioSolutions Inc.	\$ 100.00	\$ 91.01	\$ 151.15	\$ 73.33	\$ 19.92	\$ 4.05				
S&P 500	\$ 100.00	\$ 131.49	\$ 155.68	\$ 200.37	\$ 164.08	\$ 207.21				
Russell 2000	\$ 100.00	\$ 125.52	\$ 150.58	\$ 172.90	\$ 137.56	\$ 160.85				
S&P SmallCap 600	\$ 100.00	\$ 122.78	\$ 136.64	\$ 173.29	\$ 145.39	\$ 168.73				
S&P Pharmaceuticals	\$ 100.00	\$ 115.09	\$ 123.75	\$ 155.62	\$ 168.77	\$ 169.33				
S&P Biotechnology	\$ 100.00	\$ 117.11	\$ 127.21	\$ 142.64	\$ 164.95	\$ 171.29				

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 (the "Annual Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, 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 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 services ("CDMO") portfolio.

We are currently focused on the following four PHT categories: chemical, biological, radiological, nuclear and explosives ("CBRNE"); emerging infectious diseases ("EID"); public health crises; and acute, emergency and community care. We have a product portfolio of 12 products that contribute a substantial portion of our revenue and are sold to government and commercial customers. 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 which 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 four product and service categories: Anthrax - Medical Countermeasures ("MCM") Products, NARCAN<sup>®</sup>, Smallpox - MCM products and Emergent Bioservices (CDMO) services ("Bioservices"). In the fourth quarter of 2023, we realigned our reportable operating segments to reflect recent changes in our internal operating and reporting process. The revised reporting structure reflects the internal reporting and review process used by our Chief Operating Decision Maker, for making decisions and assessing performance, and is consistent with how we currently manage the business. We now manage our business with a focus on three reportable segments: (1) a Commercial Products segment consisting of our NARCAN<sup>®</sup> and Other Commercial Products; (2) a MCM Products segment consisting of the Anthrax - MCM, Smallpox - MCM and Other Products and (3) a Services segment consisting of our Bioservices offerings.

#### Commercial Products Segment:

The majority of our Commercial product revenue comes from the following products:

##### NARCAN<sup>®</sup>

- NARCAN<sup>®</sup> (naloxone HCl) Nasal Spray, an intranasal formulation of naloxone approved by the FDA (including in over-the-counter form) and Health Canada for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression.

##### Other Commercial Products (Sold to Bavarian Nordic as part of our travel health business in Mar 2023)

- Vaxchora<sup>®</sup> (Cholera Vaccine, Live, Oral), the first vaccine approved by the FDA for the prevention of cholera, which we sold to Bavarian Nordic as part of our travel health business; and
- Vivotif<sup>®</sup> (Typhoid Vaccine Live Oral Ty21a), a live attenuated vaccine for oral administration for the prevention of typhoid fever, which we sold to Bavarian Nordic as part of our travel health business.

## MCM Products Segment:

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

### Anthrax - MCM Products

- Anthrasi® (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;
- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the United States Food and Drug Administration ("FDA") for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- CYFENDUS® (Anthrax vaccine adsorbed (AVA), adjuvanted), previously known as AV7909, which was recently approved by the FDA 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. CYFENDUS® is procured by certain authorized government buyers for their use; and
- Raxibacumab injection, the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax.

### Smallpox - 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;
- 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; and
- 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.

### Other Products

- 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;
- Ebanga™ (ansuvimab-zykl), 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™;
- 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; and
- Trobigard® atropine sulfate, obidoxime chloride auto-injector, a combination drug-device auto-injector procured product candidate that contains atropine sulfate and obidoxime chloride. Trobigard® 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.

## Services Segment:

### *Bioservices - contract development and manufacturing*

Our services revenue consists of distinct but interrelated Bioservices: 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 eight geographically distinct development and manufacturing sites operated by us for our internal products and pipeline candidates and third-party Bioservices. 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. In August 2023, we initiated an organizational restructuring plan (the “August 2023 Plan”) which included actions to reduce investment in and de-emphasize focus on our Bioservices business.

## Other Strategic Activities

### *January 2023 Organizational Restructuring Plan*

In January 2023, the Company initiated an organizational restructuring plan (the “January 2023 Plan”) intended to reduce operating costs, improve operating margins, and continue advancing the Company’s ongoing commitment to profitable growth. As part of the January 2023 Plan, the Company reduced its workforce by approximately 125 employees. The Company incurred approximately \$9.3 million in charges in connection with the January 2023 Plan during the year ended December 31, 2023. These charges consist primarily of charges related to employee transition, severance payments and employee benefits. All activities related to the January 2023 Plan were substantially completed during the first quarter of 2023.

### *Sale of Travel Health Business to Bavarian Nordic*

On May 15, 2023, pursuant to the Purchase and Sale Agreement (the “Purchase and Sale Agreement”), by and between the Company, through its wholly owned subsidiaries Emergent International Inc. and Emergent Travel Health Inc., and Bavarian Nordic, the Company completed the previously announced sale of the Company’s travel health business, including rights to Vivotif<sup>®</sup>, the licensed typhoid vaccine; Vaxchora<sup>®</sup>, the licensed cholera vaccine; the development-stage chikungunya vaccine candidate CHIKV VLP; the Company’s manufacturing site in Bern, Switzerland; and certain of its development facilities in San Diego, California.

At the closing, Bavarian Nordic paid a cash purchase price of \$270.2 million, exclusive of customary closing adjustments for cash, indebtedness, working capital and transaction expenses of the business at closing. Bavarian Nordic may also be required to pay 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 earn-out payments of up to \$30.0 million based on aggregate net sales of Vaxchora and Vivotif in calendar year 2026.

As a result of the divestiture, the Company recognized a pre-tax gain of \$74.2 million during year ended December 31, 2023, net of transaction costs of \$4.0 million, which was recorded within “Gain on sale of business” on the Consolidated Statements of Operations.

### *FDA Approval of CYFENDUS<sup>®</sup>*

On July 20, 2023, the FDA approved CYFENDUS<sup>®</sup> 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 December 2018, CYFENDUS<sup>®</sup> vaccine was the subject of a pre-emergency use authorization package submitted to the FDA. The following year, the USG began procuring this product for national preparedness efforts.

### *Ebanga<sup>™</sup> Procurement Contract*

On July 31, 2023, the Company was awarded a 10-year contract by the Biomedical Advanced Research and Development Authority (“BARDA”) for advanced development, manufacturing scale-up, and procurement of Ebanga<sup>™</sup> treatment for Ebola. The contract consists of a base period of performance with two option periods valued at approximately \$121.0 million, and five option periods for procurement of Ebanga<sup>™</sup> over five years valued at up to \$583.0 million. If all option periods are exercised, the total contract value will be valued at up to approximately \$704.0 million.

Emergent is responsible for the manufacturing, sale, and distribution of Ebanga<sup>™</sup> in the U.S. and Canada pursuant to a collaboration agreement with Ridgeback, the developer of the treatment.

Emergent paid Ridgeback \$6.3 million in contingent consideration as a result of the award of the BARDA contract in the third quarter of 2023. In addition, the Company could owe up to \$50.4 million in contingent consideration to Ridgeback if activities under the awarded contract have not ceased by June 1, 2026.

#### *August 2023 Organizational Restructuring Plan*

In August 2023, the Company initiated the August 2023 Plan intended to strengthen its core business and financial position by reducing investment in and de-emphasizing focus on its Bioservices business for future growth. As part of the August 2023 Plan, the Company reduced its workforce by approximately 400 employees. The Company incurred approximately \$20.0 million in charges in connection with the August 2023 Plan during the year ended December 31, 2023. These charges consist primarily of charges related to severance payments, transition services, and employee benefits. All activities related to the August 2023 Plan were substantially completed during the third quarter of 2023.

#### *Launch of NARCAN<sup>®</sup> Naloxone HCl Nasal Spray 4 mg Over-The-Counter ("NARCAN<sup>®</sup> OTC")*

In the third quarter of 2023, the Company launched NARCAN<sup>®</sup> OTC, which was approved by the FDA as an over-the-counter emergency treatment of opioid overdose, broadening our customer base and sales channels to retail pharmacies and digital commerce websites. The Company's Nasal Naloxone products are now sold commercially over-the-counter at retail pharmacies and digital commerce websites as well as through physician-directed or standing order prescriptions at retail pharmacies, health departments, local law enforcement agencies, community-based organizations, substance abuse centers and other federal agencies.

#### **2023 Triggering Events**

##### *Long-Live Asset Impairment Testing*

The Company tests its long-lived assets that are held and used for recoverability whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable.

During the second quarter of 2023, due to deterioration in performance and resulting downward revisions to our internal Bioservices forecast made during the second quarter, including future expected cash flows, the Company determined there were sufficient indicators of impairment on certain asset groups within the Bioservices reporting unit to require an impairment analysis. As a result, the Company performed recoverability tests on certain asset groups within the Bioservices reporting unit and concluded that the impacted asset groups were not recoverable as the undiscounted expected cash flows did not exceed their carrying values.

Asset groups are written down only to the extent that their carrying value is higher than their respective fair value. The Company, with the assistance of a third-party valuation firm, applied valuation methods to estimate the fair values for each of the assets within the different asset classes. For the intangible assets, an option pricing model was applied to estimate the assets' fair value. An orderly liquidation value was applied to estimate the fair value of the personal property assets and market and cost based approaches were applied to estimate the fair value of the real property assets, each representing Level 3 non-recurring fair value measurements. Based on this analysis, the Company allocated and recognized a non-cash impairment charge of \$306.7 million during the year ended December 31, 2023.

##### *Goodwill Impairment Testing*

The Company performs its goodwill impairment evaluation annually, during the fourth quarter, or sooner if triggering events are identified. During the third quarter of 2023, the Company observed continued market volatility including significant declines in its market capitalization and revised its financial outlook during the third quarter, which was identified as a triggering event. As a result of the quantitative assessments performed in connection with the preparation of the financial statements as of and for the quarter ended September 30, 2023, the Company recorded a \$218.2 million non-cash goodwill impairment charge for the MCM reporting unit within the Products segment, which is included in "Goodwill impairment" on the Condensed Consolidated Statement of Operations for the year ended December 31, 2023. The MCM reporting unit and Products segment had no remaining goodwill as of December 31, 2023. The goodwill impairment charge resulted from a reduction in the estimated fair value of the MCM reporting unit due to changes in the risk profile of the Company as well as revisions to the long-term operating plan that reflected lower expectations for growth and profitability than previous expectations. The Company used a quantitative assessment, utilizing an income-based (discounted cash flows) approach, Level 3 non-recurring fair value measurement, for our goodwill impairment testing.

## FINANCIAL OPERATIONS OVERVIEW

### Revenues

We generate Commercial Product revenues through sale of NARCAN<sup>®</sup> Nasal Spray, which is sold commercially over-the-counter at retail pharmacies and digital commerce websites as well as through physician-directed or standing order prescriptions at retail pharmacies, health departments, local law enforcement agencies, community-based organizations, substance abuse centers and other federal agencies. In addition we previously generated Commercial product revenues through sale of the Company's travel health products, which we sold to Bavarian Nordic in May 2023. We generate MCM 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.

We also generate revenue for our Services segment through our Bioservices portfolio, which is based on our established development and manufacturing infrastructure, technology platforms and expertise. Our services include a fully integrated molecule-to-market bioservices 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

**Commercial and MCM Products** - The primary expenses that we incur to deliver NARCAN<sup>®</sup> and MCM and other commercial 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, shipping, and logistics.

**Services** - The primary expenses that we incur to deliver our Bioservices offerings 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 Bioservices 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 Bioservices 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, 2023, income tax expense totaled \$29.3 million. For every 1% change in the 2023 effective rate, income tax expense would have changed by approximately \$7.3 million.

The OECD ("Organization for Economic Co-operation and Development") has proposed a global minimum tax of 15% of reported profits (Pillar 2) that has been agreed upon in principle by over 140 countries. During 2023, many countries took steps to incorporate Pillar 2 model rule concepts into their domestic laws. On December 18, 2023, Ireland enacted laws related to this minimum tax, effective January 1, 2024.

Under the Pillar Two rules, a company would be required to determine a combined effective tax rate for all entities located in a jurisdiction. If the jurisdictional effective tax rate determined under the Pillar Two is less than 15%; a top-up tax will be due to bring the jurisdictional effective tax rate up to 15%. We continue to evaluate the potential impacts of proposed and enacted legislative changes on our business in future periods in Ireland and elsewhere.

For additional information on our uncertain tax positions and income tax expense, refer to Note 15, "Income taxes" to our consolidated financial statements included in this report.

**RESULTS OF OPERATIONS**
**Consolidated and Segment Operating Results:**

<i>(in millions, except %)</i>	Year Ended December 31,		\$ Change	% Change
	2023	2022		
<b>Revenues:</b>				
<b>Commercial Product sales, net:</b>				
NARCAN®	\$ 487.5	\$ 373.7	\$ 113.8	30 %
Other Commercial Products	9.8	12.9	(3.1)	(24)%
<b>Total Commercial Product sales, net</b>	<b>497.3</b>	<b>386.6</b>	<b>110.7</b>	<b>29 %</b>
<b>MCM Product sales, net:</b>				
Anthrax MCM	187.6	290.1	(102.5)	(35)%
Smallpox MCM	167.4	234.4	(67.0)	(29)%
Other Products	92.2	55.1	37.1	67 %
<b>Total MCM product sales, net</b>	<b>447.2</b>	<b>579.6</b>	<b>(132.4)</b>	<b>(23)%</b>
<b>Services:</b>				
Bioservices - Services	72.8	105.0	(32.2)	(31)%
Bioservices - Leases	5.7	4.9	0.8	16 %
<b>Total Services revenues</b>	<b>78.5</b>	<b>109.9</b>	<b>(31.4)</b>	<b>(29)%</b>
<b>Contracts and grants</b>	<b>26.3</b>	<b>41.4</b>	<b>(15.1)</b>	<b>(36)%</b>
<b>Total revenues</b>	<b>\$ 1,049.3</b>	<b>\$ 1,117.5</b>	<b>\$ (68.2)</b>	<b>(6)%</b>
<b>Operating expenses:</b>				
Cost of Commercial product sales	210.3	160.3	50.0	31 %
Cost of MCM product sales	305.6	264.3	41.3	16 %
Cost of Bioservices	189.5	268.5	(79.0)	(29)%
Goodwill impairment	218.2	6.7	211.5	NM
Impairment of long-lived assets	306.7	—	306.7	NM
Research and development	111.4	188.3	(76.9)	(41)%
Selling, general and administrative	368.4	339.5	28.9	9 %
Amortization of intangible assets	65.6	59.9	5.7	10 %
<b>Total operating expenses</b>	<b>1,775.7</b>	<b>1,287.5</b>	<b>488.2</b>	<b>38 %</b>
<b>Loss from operations</b>	<b>(726.4)</b>	<b>(170.0)</b>	<b>(556.4)</b>	<b>NM</b>
<b>Other income (expense):</b>				
Interest expense	(87.9)	(37.3)	(50.6)	136 %
Gain on sale of business	74.2	—	74.2	NM
Other, net	8.9	(11.7)	20.6	(176)%
<b>Total other income (expense), net</b>	<b>(4.8)</b>	<b>(49.0)</b>	<b>44.2</b>	<b>(90)%</b>
Loss before income taxes	(731.2)	(219.0)	(512.2)	NM
Income tax provision (benefit)	29.3	(7.4)	36.7	NM
<b>Net loss</b>	<b>\$ (760.5)</b>	<b>\$ (211.6)</b>	<b>\$ (548.9)</b>	<b>NM</b>

NM - Not meaningful



Year Ended December 31, 2023 Compared with Year Ended December 31, 2022

Revenues and gross margin

(dollars in millions)	Year Ended December 31,		% Change
	2023	2022	
<b>Total revenues</b>	\$ 1,049.3	\$ 1,117.5	(6)%
Contracts and grants	26.3	41.4	(36)%
<b>Total segment revenues <sup>(1)</sup></b>	<b>\$ 1,023.0</b>	<b>\$ 1,076.1</b>	<b>(5)%</b>
Cost of Commercial Product sales	210.3	160.3	31 %
Cost of MCM Product sales	305.6	264.3	16 %
Cost of Bioservices	189.5	268.5	(29)%
<b>Total cost of sales or services</b>	<b>705.4</b>	<b>693.1</b>	<b>2 %</b>
<b>Total segment gross margin <sup>(1)</sup></b>	<b>\$ 317.6</b>	<b>\$ 383.0</b>	<b>(17)%</b>
<b>Total segment gross margin % <sup>(1)</sup></b>	<b>31 %</b>	<b>36 %</b>	

<sup>(1)</sup> We define total segment revenues, which is a non-GAAP financial measure, as our total revenues, less contracts and grants revenue, which is also equal to the sum of the revenues of our operating segments. We define total segment gross margin, which is a non-GAAP financial measure, as total segment revenues less our aggregate cost of sales or services. We define total segment gross margin %, which is a non-GAAP financial measure, as total segment gross margin as a percentage of total segment revenues.

Total revenues decreased \$68.2 million, or 6%, to \$1.0 billion in 2023. The decrease was due to a decrease in MCM Products revenue of \$132.4 million, Bioservices revenue of \$31.4 million and Contracts and Grants revenue of \$15.1 million, offset by an increase in Commercial Products revenue of \$110.7 million.

Total segment gross margin decreased \$65.4 million, or 17%, to \$317.6 million in 2023. Total segment gross margin percentage decreased 5 percentage points to 31%. The decrease was primarily due to a decrease in the MCM Products segment gross margin of \$173.7 million, partially offset by increases in the Commercial Products segment gross margin and Bioservices segment gross margin of \$60.7 million and \$47.6 million, respectively. Total segment gross margin and 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 operating expenses

Goodwill Impairment

Goodwill impairment increased \$211.5 million to \$218.2 million in 2023. During the third quarter of 2023, the Company recognized a \$218.2 million impairment charge to goodwill in the MCM reporting unit, reducing the goodwill balance of the reporting unit and segment to zero as of December 31, 2023.

Impairment of long-lived assets

During the year ended December 31, 2023, the Company recorded a non-cash impairment charge of \$306.7 million related to certain asset groups within our Bioservices reporting unit. The asset groups were written down only to the extent their carrying value was higher than their respective fair values. The Company, with the assistance of a third-party valuation firm, applied valuation methods to estimate the fair values for each of the assets within the different asset classes to determine the amount of the impairment.

R&D Expenses

R&D expenses decreased \$76.9 million, or 41%, to \$111.4 million in 2023. The decrease was primarily due to the sale of our development program for CHIKV VLP to Bavarian Nordic and reduction in related overhead costs driven by the headcount reductions, which were significant contributors to prior period R&D expense, partially offset by write-offs related to program terminations during the period.

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses increased \$28.9 million, or 9%, to \$368.4 million in 2023. The increase was primarily due to higher professional services fees related to general corporate initiatives, including organizational transformation consulting fees and legal remediation services fees as well as an increase in marketing expenses related to the launch of NARCAN® OTC. The increase was partially offset by decreases in compensation and other employee costs related to the restructuring initiatives during 2023. Selling, general and administrative costs as a percentage of total revenue increased 5 percentage points to 35% for the year ended December 31, 2023. The increase was due to an increase in selling, general and administrative expenses coupled with a decrease in revenues during the period.

#### Amortization of Intangible Assets

Amortization of intangible assets increased \$5.7 million, or 10%, to \$65.6 million in 2023. The increase was primarily due to amortization expense for intangible assets related to TEMBEXA®, NARCAN®, and Ebanga™ which were acquired during the second half of 2022. The increase was partially offset by a decrease in amortization expense resulting from the intangibles sold as part of our travel health business to Bavarian Nordic.

#### *Interest expense*

Interest expense increased \$50.6 million, or 136%, to \$87.9 million in 2023. The increase was primarily due to higher interest costs related to our syndicated borrowings and debt service costs attributable to the negotiation of the Fourth Amendment to Amended and Restated Credit Agreement, Waiver and First Amendment to Amended and Restated Collateral Agreement (the "Credit Agreement Amendment"), partially offset by reduced interest expense related to the termination of our interest rate swap hedging agreements.

#### *Gain on sale of business*

Gain on sale of business was \$74.2 million for the year ended December 31, 2023, which was attributable to the sale of our travel health business to Bavarian Nordic on May 15, 2023.

#### *Other, net*

Other, net decreased \$20.6 million, or 176%, to an income of \$8.9 million in 2023. The decrease in expense was primarily attributable to a write-off of a tax indemnity receivable in the prior period that did not reoccur in the current period, favorable foreign exchange revaluations, higher interest income from rising interest rates during the year, income from the Transition Services Agreement with Bavarian Nordic and a gain on extinguishment of debt.

#### *Income taxes*

Income tax benefit of \$7.4 million for the year ended December 31, 2022 decreased \$36.7 million to a provision of \$29.3 million for the year ended December 31, 2023. The effective tax rate was (4)% for the year ended December 31, 2023 as compared to 3% in 2022. 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, goodwill impairment charge, GILTI, and other permanent items. This is partially offset by tax credits and favorable rates in foreign jurisdictions.

SEGMENT RESULTS

COMMERCIAL PRODUCTS

<i>(dollars in millions)</i>	Commercial Products				
	Year Ended December 31,			% Change	
	2023	2022			
<b>Revenues</b>	\$	497.3	\$	386.6	29 %
<b>Cost of sales</b>		210.3		160.3	31 %
<b>Gross margin <sup>(1)</sup></b>	\$	287.0	\$	226.3	27 %
<b>Gross margin % <sup>(1)</sup></b>		58 %		59 %	
<b>Segment adjusted gross margin <sup>(2)</sup></b>	\$	287.0	\$	226.3	27 %
<b>Segment adjusted gross margin % <sup>(2)</sup></b>		58 %		59 %	

<sup>(1)</sup> Gross margin is calculated as revenues less cost of sales. Gross margin % is calculated as gross margin divided by revenues.

<sup>(2)</sup> Segment adjusted gross margin, which is a non-GAAP financial measure, is calculated as gross margin plus restructuring costs and non-cash items related to changes in fair value of contingent consideration and inventory step-up provision. Segment adjusted gross margin %, which is a non-GAAP financial measure, is calculated as segment adjusted gross margin divided by revenues. The Company's management utilizes segment adjusted gross margin and segment adjusted gross margin % for purposes of evaluating our ongoing operations and for internal planning and forecasting purposes. We believe that these non-GAAP operating measures, when reviewed collectively with our GAAP financial information, provide useful supplemental information to investors in assessing our operating performance.

Year Ended December 31, 2023 Compared with Year Ended December 31, 2022

NARCAN<sup>®</sup>

NARCAN<sup>®</sup> sales increased \$113.8 million, or 30%, to \$487.5 million in 2023. The increase was primarily driven by higher sales of NARCAN<sup>®</sup> OTC and branded NARCAN<sup>®</sup> to U.S. public interest channels and Canadian retail, partially offset by the cessation of authorized generic NARCAN<sup>®</sup> sales related to the termination of the Company's relationship with Sandoz and a reduction in commercial retail sales in the U.S.

Other Commercial Products

Other Commercial Products sales decreased \$3.1 million, or 24%, to \$9.8 million. The decrease was driven by lower sales of Vivotif<sup>®</sup>, partially offset by higher sales of Vaxchora<sup>®</sup>. During the second quarter of 2023, we sold Vivotif<sup>®</sup> and Vaxchora<sup>®</sup> to Bavarian Nordic as part of our travel health business.

### Cost of Sales and Gross Margin

Cost of Commercial product sales increased \$50.0 million, or 31%, to \$210.3 million in 2023. The increase was primarily driven by higher sales of NARCAN<sup>®</sup> OTC and higher branded NARCAN<sup>®</sup> sales.

Commercial Products gross margin increased \$60.7 million, or 27%, to \$287.0 million in 2023. Commercial Products gross margin percentage decreased 1 percentage point to 58% in 2023. The decrease was largely due to a decrease in the per unit selling price in response to increased competition for generic NARCAN<sup>®</sup>, partially offset by a decrease in royalty expense. Commercial Products Segment Adjusted Gross Margin is consistent with gross margin.

### **MCM PRODUCTS**

<i>(dollars in millions)</i>	MCM Products				
	Year Ended December 31,				% Change
	2023	2022			
<b>Revenues</b>	\$	447.2	\$	579.6	(23)%
<b>Cost of sales</b>		305.6		264.3	16 %
<b>Gross margin <sup>(1)</sup></b>	\$	141.6	\$	315.3	(55)%
<b>Gross margin % <sup>(1)</sup></b>		32 %		54 %	
<b>Add back:</b>					
Changes in fair value of contingent consideration		0.2		2.6	(92)%
Restructuring costs		5.6		—	NM
Inventory step-up provision		3.9		51.4	(92)%
<b>Segment adjusted gross margin <sup>(2)</sup></b>	\$	151.3	\$	369.3	(59)%
<b>Segment adjusted gross margin % <sup>(2)</sup></b>		34 %		64 %	

<sup>(1)</sup> Gross margin is calculated as revenues less cost of sales. Gross margin % is calculated as gross margin divided by revenues.

<sup>(2)</sup> Segment adjusted gross margin, which is a non-GAAP financial measure, is calculated as gross margin plus restructuring costs and non-cash items related to changes in fair value of contingent consideration and inventory step-up provision. Segment adjusted gross margin %, which is a non-GAAP financial measure, is calculated as segment adjusted gross margin divided by revenues. The Company's management utilizes segment adjusted gross margin and segment adjusted gross margin % for purposes of evaluating our ongoing operations and for internal planning and forecasting purposes. We believe that these non-GAAP operating measures, when reviewed collectively with our GAAP financial information, provide useful supplemental information to investors in assessing our operating performance.

NM - Not meaningful

### **Year Ended December 31, 2023 Compared with Year Ended December 31, 2022**

#### Anthrax MCM

Anthrax MCM sales decreased \$102.5 million, or 35%, to \$187.6 million in 2023. The decrease reflects the impact of timing of sales related to CYFENDUS<sup>®</sup> and BioThrax, partially offset by an increase in Anthrasil<sup>®</sup> sales. 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, the timing and amount of USG purchases, the availability of governmental funding and timing of Company delivery of orders that follow.

#### Smallpox MCM

Smallpox MCM sales decreased \$67.0 million, or 29%, to \$167.4 million in 2023. The decrease was primarily due to lower sales of TEMBEXA<sup>®</sup>, partially offset by an increase related the exercise and full delivery in the current period of a \$120 million option by the USG to purchase ACAM2000<sup>®</sup>. Fluctuations in revenues result from the timing of the exercise of annual purchase options in existing procurement contracts, the timing of USG purchases, the availability of governmental funding and timing of Company delivery of orders that follow.

#### Other Product Sales

Other Product sales increased \$37.1 million, or 67%, to \$92.2 million in 2023. The increase was primarily due to higher BAT<sup>®</sup> product sales, partially offset by lower RSDL<sup>®</sup> and Trobigard<sup>®</sup> product sales due to timing.

### Cost of Sales and Gross Margin

Cost of MCM Product sales increased \$41.3 million, or 16%, to \$305.6 million in 2023. The increase was primarily due to higher sales of ACAM2000<sup>®</sup>, BAT<sup>®</sup> and AIG, partially offset by lower sales of CYFENDUS<sup>®</sup>, coupled with higher allocations to MCM Product COGS at our Bayview facility, shutdown costs and inventory write-offs.

MCM Products gross margin decreased \$173.7 million, or 55%, to \$141.6 million in 2023. MCM Products gross margin percentage decreased 22 percentage points to 32% in 2023. The decrease was largely due to lower sales volumes and higher shutdown related costs and inventory write-offs, coupled with an unfavorable product revenue mix which was weighted more heavily to lower margin products compared with the prior year. The 2023 MCM Product Segment Adjusted Gross Margin excludes the impact of restructuring costs of \$5.6 million, non-cash items related to the changes in the fair value of contingent consideration of \$0.2 million and the inventory step-up provision of \$3.9 million.

### SERVICES

(in millions)	Services			
	Year Ended December 31,		% Change	
	2023	2022		
Revenues	\$ 78.5	\$ 109.9		(29)%
Cost of services	189.5	268.5		(29)%
Gross margin <sup>(1)</sup>	<u>\$ (111.0)</u>	<u>\$ (158.6)</u>		30 %
Gross margin % <sup>(1)</sup>	(141)%	(144)%		
Add back:				
Restructuring costs	\$ 8.4	—		NM
Segment adjusted gross margin <sup>(2)</sup>	<u>\$ (102.6)</u>	<u>\$ (158.6)</u>		35 %
Segment adjusted gross margin % <sup>(2)</sup>	(131)%	(144)%		

<sup>(1)</sup> Gross margin is calculated as revenues less cost of sales. Gross margin % is calculated as gross margin divided by revenues.

<sup>(2)</sup> Segment adjusted gross margin, which is a non-GAAP financial measure, is calculated as gross margin plus restructuring costs and non-cash items related to changes in fair value of contingent consideration and inventory step-up provision. Segment adjusted gross margin %, which is a non-GAAP financial measure, is calculated as segment adjusted gross margin divided by revenues. The Company's management utilizes segment adjusted gross margin and segment adjusted gross margin % for purposes of evaluating our ongoing operations and for internal planning and forecasting purposes. We believe that these non-GAAP operating measures, when reviewed collectively with our GAAP financial information, provide useful supplemental information to investors in assessing our operating performance.

NM - Not meaningful

### Year Ended December 31, 2023 Compared with Year Ended December 31, 2022

#### Services Revenues

Bioservices revenue decreased \$32.2 million, or 31%, to \$72.8 million in 2023. The decrease was driven by reduced production activities at the Company's Winnipeg and Camden facilities. The decreases were partially offset by an increase in production at our Canton facility for a Bioservices customer.

Bioservices lease revenue increased \$0.8 million, or 16%, to \$5.7 million in 2023. The increase was related to a Bioservices customer at our Canton facility.

#### Cost of Services and Gross Margin

Cost of Services decreased \$79.0 million, or 29%, to \$189.5 million in 2023. The decrease was primarily due to reduced production activities related to the halt in manufacturing under the Janssen Agreement coupled with higher allocations to MCM Product cost of sales at our Bayview facility and lower production activities at our Winnipeg facility, partially offset by increased costs at our Camden facility for additional investments in quality enhancement and improvement initiatives and increased costs associated with production activities at our Canton facility for a Bioservices customer.

Services gross margin increased \$47.6 million, or 30%, to \$(111.0) million in 2023. Services gross margin percentage increased 3 percentage points to (141)% in 2023. The increase was primarily driven by one-time costs and reserves related to the Janssen

Agreement in the prior year. The 2023 Services Segment Adjusted Gross Margin excludes the impact of restructuring costs of \$8.4 million.

#### **OTHER REVENUE**

**Year Ended December 31, 2023 Compared with Year Ended December 31, 2022**

##### Contracts and Grants

Contract and grants revenue decreased \$15.1 million, or 36%, to \$26.3 million in 2023. The decrease was primarily attributable to one-time indirect rate adjustments in the prior period, the conclusion of COVID-19 related studies in the fourth quarter of 2022, and decreases in development activities associated with various externally funded research and development projects. These decreases were partially offset by increases in revenue on the BARDA contract for the procurement of Ebanga™, which was awarded in the current period, and TEMBEXA®.

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

RESULTS OF OPERATIONS

Consolidated and Segment Operating Results:

(in millions, except %)	Year Ended December 31,		\$ Change	% Change
	2022	2021		
<b>Revenues:</b>				
<b>Commercial Product sales, net:</b>				
NARCAN®	\$ 373.7	\$ 434.4	\$ (60.7)	(14)%
Other Commercial Products	12.9	3.6	9.3	NM
<b>Total Commercial Product sales, net</b>	<b>386.6</b>	<b>438.0</b>	<b>(51.4)</b>	<b>(12)%</b>
<b>MCM Product sales, net:</b>				
Anthrax MCM	\$ 290.1	\$ 262.6	\$ 27.5	10 %
Smallpox MCM	234.4	266.7	(32.3)	(12)%
Other Products	55.1	56.6	(1.5)	(3)%
<b>Total MCM product sales, net</b>	<b>579.6</b>	<b>585.9</b>	<b>(6.3)</b>	<b>(1)%</b>
<b>Services:</b>				
Bioservices - Services	105.0	310.3	(205.3)	(66)%
Bioservices - Leases	4.9	305.2	(300.3)	(98)%
<b>Total Services revenues</b>	<b>109.9</b>	<b>615.5</b>	<b>(505.6)</b>	<b>(82)%</b>
<b>Contracts and grants</b>	<b>41.4</b>	<b>134.2</b>	<b>(92.8)</b>	<b>(69)%</b>
<b>Total revenues</b>	<b>\$ 1,117.5</b>	<b>\$ 1,773.6</b>	<b>\$ (656.1)</b>	<b>(37)%</b>
<b>Operating expenses:</b>				
Cost of Commercial product sales	160.3	187.2	(26.9)	(14)%
Cost of MCM product sales	264.3	195.4	68.9	35 %
Cost of Bioservices	268.5	365.5	(97.0)	(27)%
Research and development	188.3	235.2	(46.9)	(20)%
Selling, general and administrative	339.5	348.7	(9.2)	(3)%
Goodwill impairment	6.7	41.7	(35.0)	(84)%
Amortization of intangible assets	59.9	58.5	1.4	2 %
<b>Total operating expenses</b>	<b>1,287.5</b>	<b>1,432.2</b>	<b>(144.7)</b>	<b>(10)%</b>
<b>Income (loss) from operations</b>	<b>(170.0)</b>	<b>341.4</b>	<b>(511.4)</b>	<b>NM</b>
<b>Other income (expense):</b>				
Interest expense	(37.3)	(34.5)	(2.8)	8 %
Other, net	(11.7)	(3.7)	(8.0)	NM
<b>Total other income (expense), net</b>	<b>(49.0)</b>	<b>(38.2)</b>	<b>(10.8)</b>	<b>28 %</b>
Income (loss) before income taxes	(219.0)	303.2	(522.2)	NM
Income tax provision (benefit)	(7.4)	83.7	(91.1)	NM
<b>Net income (loss)</b>	<b>\$ (211.6)</b>	<b>\$ 219.5</b>	<b>\$ (431.1)</b>	<b>NM</b>

NM - Not meaningful

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

Revenues and gross margin

(dollars in millions)	Year Ended December 31,			% Change
	2022	2021	2021	
<b>Total revenues</b>	\$ 1,117.5	\$ 1,773.6		(37)%
Contracts and grants	41.4	134.2		(69)%
<b>Total segment revenues <sup>(1)</sup></b>	\$ 1,076.1	\$ 1,639.4		(34)%
Cost of Commercial Product sales	160.3	187.2		(14)%
Cost of MCM Product sales	264.3	195.4		35 %
Cost of Bioservices	268.5	365.5		(27)%
<b>Total cost of sales or services</b>	693.1	748.1		(7)%
<b>Total segment gross margin <sup>(1)</sup></b>	\$ 383.0	\$ 891.3		(57)%
<b>Total segment gross margin % <sup>(1)</sup></b>	36 %	54 %		

<sup>(1)</sup> We define total segment revenues, which is a non-GAAP financial measure, as our total revenues, less contracts and grants revenue, which is also equal to the sum of the revenues of our operating segments. We define total segment gross margin, which is a non-GAAP financial measure, as total segment revenues less our aggregate cost of sales or services. We define total segment gross margin %, which is a non-GAAP financial measure, as total segment gross margin as a percentage of total segment revenues.

Total revenues decreased \$656.1 million, or 37%, to \$1.1 billion in 2022. The decrease was primarily due to a decrease in Bioservices revenue of \$505.6 million, coupled with decreases in Contracts and grants revenue of \$92.8 million, Commercial Products revenue of \$51.4 million and MCM Products revenue of \$6.3 million.

Total segment gross margin decreased \$508.3 million, or 57%, to \$383.0 million in 2022. Total segment gross margin percentage decreased 19 percentage points to 36%. The decrease was primarily due to a decrease in the Bioservices segment gross margin of \$408.6 million, coupled with decreases in MCM Products segment gross margin and Commercial Products segment gross margin of \$75.2 million and \$24.5 million, respectively. Total segment 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 operating expenses*

R&D Expenses

R&D expenses decreased \$46.9 million, or 20%, to \$188.3 million in 2022. The decrease was primarily 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 (as defined below), 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 \$9.2 million, or 3%, to \$339.5 million in 2022. The decrease was primarily 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 11 percentage points to 30% 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.

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 Bioservices 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.

#### Amortization of Intangible Assets

Amortization of intangible assets increased \$1.4 million, or 2%, 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.

#### *Interest expense*

Interest expense increased \$2.8 million, or 8%, to \$37.3 million in 2022. The increase was primarily due to higher interest costs related to our syndicated borrowings, partially offset by a decrease in interest expense related to our interest rate swap hedging agreements.

#### *Other, net*

Other, net increased \$8.0 million to an expense of \$11.7 million in 2022. The increase was primarily due to a write-off of a tax indemnity receivable, which was offset in income tax provision, and unrealized foreign currency losses recorded related to the remeasurement of certain intercompany balances. The increases in expense were partially offset by an increase in interest income due to higher interest rates in 2022.

### Income tax provision

Income tax provision decreased \$91.1 million to an income tax benefit of \$7.4 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 3% for the year ended December 31, 2022 as compared to 28% in 2021. The effective annual tax rate decreased largely due to the impact of a valuation allowance charge in the U.S., state and foreign jurisdictions, a charge due to 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

#### COMMERCIAL PRODUCTS

(dollars in millions)	Commercial Products				
	Year Ended December 31,		2021	% Change	
	2022	2021			
Revenues	\$	386.6	\$	438.0	(12)%
Cost of sales		160.3		187.2	(14)%
Gross margin <sup>(1)</sup>	\$	226.3	\$	250.8	(10)%
Gross margin % <sup>(1)</sup>		59 %		57 %	
Segment adjusted gross margin <sup>(2)</sup>	\$	226.3	\$	250.8	(10)%
Segment adjusted gross margin % <sup>(2)</sup>		59 %		57 %	

<sup>(1)</sup> Gross margin is calculated as revenues less cost of sales. Gross margin % is calculated as gross margin divided by revenues.

<sup>(2)</sup> Segment adjusted gross margin, which is a non-GAAP financial measure, is calculated as gross margin plus restructuring costs and non-cash items related to changes in fair value of contingent consideration and inventory step-up provision. Segment adjusted gross margin %, which is a non-GAAP financial measure, is calculated as segment adjusted gross margin divided by revenues. The Company's management utilizes segment adjusted gross margin and segment adjusted gross margin % for purposes of evaluating our ongoing operations and for internal planning and forecasting purposes. We believe that these non-GAAP operating measures, when reviewed collectively with our GAAP financial information, provide useful supplemental information to investors in assessing our operating performance.

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

##### NARCAN<sup>®</sup>

NARCAN<sup>®</sup> sales decreased \$60.7 million, or 14%, 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<sup>®</sup> Nasal Spray 4mg in December 2021, partially offset by an increase in U.S. public interest and Canadian sales.

##### Other Commercial Products

Other Commercial Products sales increased \$9.3 million to \$12.9 million in 2022. The increase was primarily driven by higher sales of Vivotif<sup>®</sup> and Vaxchora<sup>®</sup> in 2022.

##### Cost of Sales and Gross Margin

Cost of Commercial product sales decreased \$26.9 million, or 14%, to \$160.3 million in 2022. The decrease was primarily driven by a decrease in royalties paid for NARCAN<sup>®</sup> sales due to the royalty settlement in 2022.

Commercial Products gross margin decreased \$24.5 million, or 10%, to \$226.3 million in 2022. Commercial Products gross margin percentage increased 2 percentage points to 59% in 2022. The increase was largely due to a decrease in royalties paid for NARCAN<sup>®</sup> sales due to the royalty settlement in 2022.

## MCM PRODUCTS

(dollars in millions)	MCM Products		
	Year Ended December 31,		% Change
	2022	2021	
<b>Revenues</b>	\$ 579.6	\$ 585.9	(1)%
<b>Cost of sales</b>	264.3	195.4	35 %
<b>Gross margin <sup>(1)</sup></b>	<u>\$ 315.3</u>	<u>\$ 390.5</u>	(19)%
<b>Gross margin % <sup>(1)</sup></b>	54 %	67 %	
Add back:			
Changes in fair value of contingent consideration	2.6	2.9	(10)%
Inventory step-up provision	51.4	—	NM
<b>Segment adjusted gross margin <sup>(2)</sup></b>	<u>\$ 369.3</u>	<u>\$ 393.4</u>	(6)%
<b>Segment adjusted gross margin % <sup>(2)</sup></b>	64 %	67 %	

<sup>(1)</sup> Gross margin is calculated as revenues less cost of sales. Gross margin % is calculated as gross margin divided by revenues.

<sup>(2)</sup> Segment adjusted gross margin, which is a non-GAAP financial measure, is calculated as gross margin plus restructuring costs and non-cash items related to changes in fair value of contingent consideration and inventory step-up provision. Segment adjusted gross margin %, which is a non-GAAP financial measure, is calculated as segment adjusted gross margin divided by revenues. The Company's management utilizes segment adjusted gross margin and segment adjusted gross margin % for purposes of evaluating our ongoing operations and for internal planning and forecasting purposes. We believe that these non-GAAP operating measures, when reviewed collectively with our GAAP financial information, provide useful supplemental information to investors in assessing our operating performance.

NM - Not meaningful

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

Anthrax MCM

Anthrax MCM sales increased \$27.5 million, or 10%, to \$290.1 million in 2022. The increase 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.

Smallpox MCM

Smallpox MCM sales decreased \$32.3 million, or 12%, to \$234.4 million in 2022. The decrease was primarily due to lower sales of ACAM2000<sup>®</sup>, partially offset by TEMBEXA<sup>®</sup> sales following the 2022 acquisition of worldwide rights for TEMBEXA<sup>®</sup>. Fluctuations in revenues result from the timing of the exercise of annual purchase options in existing procurement contracts, the timing of USG purchases, the availability of governmental funding and timing of Company delivery of orders that follow.

Other Product Sales

Other Product sales decreased \$1.5 million, or 3%, to \$55.1 million in 2022. The decrease was primarily due to lower BAT<sup>®</sup> product sales, partially offset by higher RSDL<sup>®</sup> and Trobigard<sup>®</sup> product sales.

Cost of Sales and Gross Margin

Cost of MCM Product sales increased \$68.9 million, or 35%, to \$264.3 million in 2022. The increase was primarily due to cost of sales for TEMBEXA<sup>®</sup> following our 2022 acquisition of the worldwide rights for TEMBEXA<sup>®</sup>. Excluding the acquisition related product costs, cost of MCM product sales increased \$8.7 million, primarily due to inventory write-offs, primarily related to CYFENDUS<sup>®</sup> and ACAM2000<sup>®</sup> and higher costs due to under-utilized capacity at our facilities. These increases were partially offset by decreases in ACAM2000<sup>®</sup> 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.

MCM Products gross margin decreased \$75.2 million, or 19%, to \$315.3 million in 2022. MCM Products gross margin percentage decreased 13 percentage points to 54% in 2022. The decrease was largely due to lower sales volumes and higher shutdown related costs and inventory write-offs, coupled with an unfavorable product revenue mix which was weighted more heavily to lower

margin products compared with the prior year. The 2022 MCM Product Segment 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 of \$51.4 million.

## SERVICES

(in millions)	Services				
	Year Ended December 31,		2021	% Change	
	2022	2021			
<b>Revenues</b>	\$	109.9	\$	615.5	(82)%
<b>Cost of services</b>		268.5		365.5	(27)%
<b>Gross margin <sup>(1)</sup></b>	\$	(158.6)	\$	250.0	NM
<b>Gross margin % <sup>(1)</sup></b>		(144)%		41 %	
<b>Segment adjusted gross margin <sup>(2)</sup></b>	\$	(158.6)	\$	250.0	NM
<b>Segment adjusted gross margin % <sup>(2)</sup></b>		(144)%		41 %	

<sup>(1)</sup> Gross margin is calculated as revenues less cost of services. Gross margin % is calculated as gross margin divided by revenues.

<sup>(2)</sup> Segment adjusted gross margin, which is a non-GAAP financial measure, is calculated as gross margin plus restructuring costs and non-cash items related to changes in fair value of contingent consideration and inventory step-up provision. Segment adjusted gross margin %, which is a non-GAAP financial measure, is calculated as segment adjusted gross margin divided by revenues. The Company's management utilizes segment adjusted gross margin and segment adjusted gross margin % for purposes of evaluating our ongoing operations and for internal planning and forecasting purposes. We believe that these non-GAAP operating measures, when reviewed collectively with our GAAP financial information, provide useful supplemental information to investors in assessing our operating performance.

NM - Not meaningful

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

#### Services Revenues

Bioservices revenue decreased \$205.3 million, or 66%, to \$105.0 million in 2022. The decrease was primarily due to \$170.9 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.

Bioservices lease revenue decreased \$300.3 million, or 98%, to \$4.9 million in 2022. The decrease was primarily due to a reduction of \$243.1 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 \$97.0 million, or 27%, to \$268.5 million in 2022. The decrease was primarily due to reduced production activities across our Bioservices 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 decreased \$408.6 million to \$(158.6) million in 2022. Services gross margin percentage decreased 185 percentage points to (144)% in 2022. The decrease was primarily driven by reduced production activities across our Bioservices 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 CYFENDUS<sup>®</sup>. Decreases were partially offset by revenue increases relating to indirect rate adjustments during the period.

## Financial Condition, Liquidity and Capital Resources

Our financial condition is summarized as follows:

(in millions, except percentages)	December 31,		Change %
	2023	2022	
<b>Financial assets:</b>			
Cash and cash equivalents	\$ 111.7	\$ 642.6	(83)%
<b>Borrowings:</b>			
Debt, current portion	\$ 413.7	\$ 957.3	(57)%
Debt, net of current portion	446.5	448.5	— %
Total borrowings	\$ 860.2	\$ 1,405.8	(39)%
<b>Working capital:</b>			
Current assets	\$ 679.5	\$ 1,210.4	(44)%
Current liabilities	651.3	1,228.9	(47)%
Total working capital	\$ 28.2	\$ (18.5)	252 %

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 ("Revolving Credit Facility"), our senior term loan facility ("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 and participation in an at-the market equity offering program that we entered into on May 18, 2023 (the "ATM Program"). As of December 31, 2023, we had unrestricted cash and cash equivalents of \$111.7 million and remaining capacity under our Revolving Credit Facility of \$80.3 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, 2023, there was \$219.2 million outstanding on our Revolving Credit Facility and \$198.2 million on our Term Loan Facility that mature in May 2025. 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. The evaluation considered the potential mitigating effects of management's plans that have not been fully implemented. Management has evaluated the mitigating effects 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. Management's plans include (A) amending the Senior Secured Credit Facilities, and (B) improving operating performance, reducing working capital and the potential sale of assets to pay down the Senior Secured Credit Facilities before they become due. As neither plan is in the complete control of Management, neither is probable of occurring. In this regard, management may not be able to find a buyer for the assets it is willing to divest and may not be able to close on any asset sales for which management is able to reach an agreement with a buyer, and as a result the Company may be unable to meet its obligations as they become due. In addition, any asset sales that are completed could have potential negative impacts on the Company's future operating cash flows and profitability.

### Debt Covenants

The Senior Secured Credit Facilities mature in May 2025 which provide for (1) revolving credit commitments, (2) a term loan, and (3) the issuance of commercial letters of credit. As of December 31, 2023, we had \$417.4 million outstanding under the Senior Secured Credit Facilities. Under the Senior Secured Credit Facilities, the Company is subject to a monthly minimum consolidated EBITDA covenant through February 29, 2024, and is also required to raise at least \$75.0 million through the issuance of equity and/or unsecured indebtedness by April 30, 2024. Beginning with the quarter ended March 31, 2024, the Company is subject to a minimum

consolidated debt service coverage ratio and a maximum consolidated leverage ratio covenant. As of December 31, 2023, the Company was not in compliance with the minimum consolidated EBITDA covenant under the Senior Secured Credit Facilities and did not expect to be able to raise the remaining of the \$75.0 million through the issuance of equity under the at-the-market equity offering program (the "ATM Program") that we entered into on May 18, 2023, by April 30, 2024, as required by the requisite lenders. In addition, the Company is required to deliver audited annual financial statements without a "going concern" explanatory paragraph with respect to its financial statements for the year ended December 31, 2023, within 90-days of year end, while the financial statements included in this Annual Report contain an explanatory paragraph related to Going Concern. On February 29, 2024, the requisite lenders agreed to enter into the Forbearance Agreement, which includes 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, 2023 and the fiscal quarter ending March 31, 2024 and (b) the going concern explanatory paragraph contained in the audited financial statements for the fiscal year ended December 31, 2023. This forbearance period will expire on the earlier to occur of (i) any other event of default and (ii) April 30, 2024. 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 Senior Secured Credit Facilities. The Senior Secured Credit Facilities and the Company's other debt facilities are described in more detail in Note 10, "Debt" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report.

Further, acceleration of the repayment of the Senior Secured Credit Facilities would result in a cross-default of the Company's obligations under the 3.875% Senior Unsecured Notes due in 2028. If the Company would be unable to obtain additional waivers or forbearance of such covenants or defaults, to successfully renegotiate the terms of the Senior Secured Credit Facilities, or to cure the potential covenant breach or default, and the lenders enforced one or more of their rights upon default and/or the default resulted in a cross-default under the 3.875% Senior Unsecured Notes due in 2028, the Company would be unable to meet its obligations under those agreements and could be forced into insolvency proceedings.

Based on the facts and circumstances described above, there can be no assurance that the Forbearance Period will continue to remain in place, and that the Company would be able to comply with covenants in the future. As a result, the Company continues to evaluate a number of factors related to its ability to continue as a going concern, including its ability to comply with the terms and operating and financial covenants required by the Senior Secured Credit Facilities, its ability to satisfy the capital raise requirement, other market conditions, economic conditions, particularly in the pharmaceutical and biotechnology industry, and disruptions or volatility caused by factors such as regional conflicts, inflation, and supply chain disruptions. The Company has engaged legal and financial advisors to assist with a comprehensive review of alternatives to enhance its capital structure, which may include taking steps to cure any potential defaults or seeking forbearance, waivers, further cost reductions, asset sales or other alternatives to avoid an event of default.

The Company had \$111.7 million of cash on hand at December 31, 2023. On January 9, 2023, the Company announced the January 2023 Plan, intended to reduce operating costs, improve operating margins, and continue advancing the Company's ongoing commitment to profitable growth. The January 2023 Plan included a reduction of the Company's current workforce by approximately 125 employees. Additionally, on August 8, 2023, the Company announced the August 2023 Plan, intended to strengthen its core business and financial position by reducing investment in and de-emphasizing focus on its Bioservices business for future growth. The August 2023 Plan included a reduction of the Company's current workforce by approximately 400 employees. These actions, in combination with other cost reduction initiatives, are expected to result in annualized savings of over \$160 million when fully implemented.

#### At-the-Market Equity Offering Facility

We may, from time to time, sell up to \$150.0 million aggregate gross sales price of shares of our common stock through Evercore Group L.L.C. and RBC Capital Markets, LLC, as sales agents, under the ATM Program that we entered into on May 18, 2023. Between the adoption of the ATM Program and December 31, 2023, we sold 1.1 million shares of our common stock under the ATM Program for gross proceeds of \$9.1 million, representing an average price of \$8.22 per share. As of December 31, 2023, \$140.9 million aggregate gross sales price of shares of our common stock remains available for issuance under the ATM Program. We intend to use proceeds obtained from the sale of shares under the ATM Program for general corporate purposes.

## Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2023 and 2022.

<i>(in millions)</i>	Year Ended December 31,	
	2023	2022
Net cash provided by (used in):		
Operating activities	\$ (206.3)	\$ (34.1)
Investing activities	212.3	(381.3)
Financing activities	(535.7)	481.2
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(1.2)	0.5
Net change in cash, cash equivalents and restricted cash	<u>\$ (530.9)</u>	<u>\$ 66.3</u>

### Operating Activities:

Net cash used in operating activities increased \$172.2 million in 2023. The increase in net cash used in operating activities was primarily due to negative working capital changes of \$68.2 million, driven by lower cash collections on accounts receivable, and an increase in cash payments for accrued compensation and income taxes, partially offset by lower cash payments for inventories, prepaid expenses and other assets, accrued expenses and other liabilities, and accounts payable.

### Investing Activities:

Net cash provided by investing activities increased \$593.6 million in 2023. The increase in net cash provided by investing activities was primarily due to the proceeds received from the sale of the travel health business during the second quarter of 2023 of \$270.2 million, a decrease in payments for the acquisition of businesses of \$243.7 million and a decrease of \$64.2 million in capital expenditures, partially offset by an increase in milestone payments of \$6.3 million for prior asset acquisitions.

### Financing Activities:

Net cash used in financing activities increased \$1.0 billion in 2023. The increase in cash used in financing activities was primarily due to increased principal payments on our Revolving Credit Facility and Term Loan Facility of \$398.8 million and \$130.8 million, respectively, coupled with a reduction in proceeds of \$578.0 million under our Revolving Credit Facility, partially offset by a decrease in purchases of treasury stock of \$82.1 million in the current year and an increase of \$8.4 million in proceeds from the sale of stock under our ATM program.

## Debt

As of December 31, 2023, the Company has \$868.4 million of fixed and variable rate debt with varying maturities, with \$418.4 million payable within 12 months (see Note 10, "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 short-term and long-term 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 bioservices;
- development contracts and grant funding;
- proceeds from the sale of our common stock through the ATM Program; 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 bioservices;
- 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, including through the ATM Program, 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, 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, 2023 and December 31, 2022 was:

<i>(in millions)</i>	December 31,	
	2023	2022
Total Capacity	\$ 300.0	\$ 600.0
Less:		
Outstanding Letters of Credit	0.5	1.3
Outstanding Indebtedness	219.2	598.0
Unused Capacity	<u>\$ 80.3</u>	<u>\$ 0.7</u>

#### Contractual Obligations

As of December 31, 2023, 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, 2023, the Company had fixed lease payment obligations of \$20.4 million, with \$4.3 million due within 12 months. The Company has non-cancelable purchase commitments of \$526.9 million, with an estimated \$117.0 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 Bioservices 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.

MCM product 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 MCM 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.

The Company's NARCAN<sup>®</sup> OTC customer contracts are fixed price contracts. For that majority of the Company's NARCAN<sup>®</sup> OTC contract, the Company invoices and records revenue when the pharmacies and wholesalers receive product from the third-party logistics warehouse used by the Company, which is the point at which control is transferred to the customer. Revenues for these NARCAN<sup>®</sup> OTC arrangements are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Estimates of variable consideration includes allowance for returns, specialty distributor fees, wholesaler fees and prompt payment discounts. NARCAN<sup>®</sup> OTC may also be sold on consignment through third-party online retailers where revenues are recognized point in time when sold to the end customer. The Company pays these third-party online retailers selling commissions and fulfillment fees which are recorded as selling general & administrative expenses and cost of commercial product sales, respectively, in the Consolidated Statement of Operations. Revenues from NARCAN<sup>®</sup> OTC are 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. The Company considers several factors in the estimation process for the allowance for returns of NARCAN<sup>®</sup> OTC, including inventory levels within the distribution channel and historical return activity, including activity for product sold for which the return period has passed, as well as other relevant factors. Because returned product cannot be resold, there is no corresponding asset for product returns.

For additional information on our revenues, refer to Note 13, "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 8, "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 15, "Income taxes" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K.

#### Goodwill and long-lived assets

We evaluate our goodwill for impairment annually as of the first day of the fourth quarter and whenever events or changes in circumstances indicate that the carrying value of goodwill may not be recoverable. We assess our goodwill for impairment at the reporting unit level.

As part of the evaluation of goodwill for potential impairment, we exercise judgment to:

- Perform a qualitative assessment to determine whether it is "more likely than not" that the fair value of a reporting unit is less than its carrying value. Factors we consider when making the determination include assessing macroeconomic conditions, industry and market considerations, cost factors, overall financial performance, and other relevant reporting unit specific events;
- Decide whether to bypass the qualitative assessment and perform a quantitative assessment. Factors we consider when making this determination include changes in the Company or general economic conditions since the previous quantitative assessment was performed, the amount by which the fair value exceeded the carrying value at that time and the period of time that has passed since such quantitative assessment; and
- Perform a quantitative assessment by comparing the estimated fair value of the reporting unit with the carrying amount of that reporting unit. We estimate fair value using a combination of an income approach (based on discounted cash flows) and market approach, using appropriate weighting factors.

The cash flows employed in the income approach are based on our most recent forecasts, budgets and business plans, as well as various growth rate assumptions for years beyond the current business plan period, discounted using an estimated weighted average cost of capital, which reflects an assessment of the risk inherent in the future revenue streams and cash flows. In the market approach, we utilize market multiples derived from comparable guideline companies and comparable market transactions to the extent available. These valuations are based on estimates and assumptions, including projected future cash flows, determination of appropriate comparable guideline companies and the determination of whether a premium or discount should be applied to such comparable guideline companies.

The process of evaluating the potential impairment of goodwill requires significant judgment and estimates. In 2023, due to triggering events in the respective quarters, we performed interim impairment tests during the second and third quarter for the MCM reporting unit. The results of the test performed during the second quarter, which yielded no impairment of goodwill. The results of the test performed during the third quarter indicated that for our MCM reporting unit, an impairment existed. As a result, the Company recorded a \$218.2 million non-cash goodwill impairment charge for the MCM reporting unit within the Products segment, reducing the goodwill balance to zero across all reporting units.

Long-lived assets such as finite lived intangible assets and property, plant and equipment are not required to be tested for impairment annually, instead they are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. These events or changes in circumstances may include a significant deterioration of operating results, changes in business plans or changes in anticipated future cash flows. If an impairment indicator is present, we evaluate recoverability of assets to be held and used by a comparison of the carrying value of the assets with future undiscounted net

cash flows expected to be generated by the assets. We group assets at the lowest level for which there are identifiable cash flows that are largely independent of the cash flows generated by other asset groups. If the total of the expected undiscounted future cash flows is less than the carrying amount of the asset group, we estimate the fair value of the asset group to determine whether an impairment loss should be recognized. 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. 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.

During the second quarter of 2023, due to deterioration in performance and resulting downward revisions to our internal Bioservices forecast made during the second quarter, including future expected cash flows, the Company determined there were sufficient indicators of impairment on certain asset groups within the Bioservices reporting unit to require an impairment analysis. As a result, the Company performed recoverability tests on certain asset groups within the Bioservices reporting unit and concluded that the impacted asset groups were not recoverable as the undiscounted expected cash flows did not exceed their carrying values. Based on this analysis, the Company recorded a non-cash impairment charge of \$306.7 million during 2023.

#### **Significant New Accounting Pronouncements**

See Note 2, "Summary of significant accounting policies" 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 2023 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. We terminated our interest rate swaps in June 2023, and we are satisfied with the current fix-float mix of the Company's debt portfolio. Floating rate debt carries interest based generally on the eurocurrency rate, as defined in our senior secured credit agreement, as amended by the Credit Agreement Amendment, plus an applicable margin. Increases in interest rates could result in an increase in interest payments for our floating rate debt. See Note 10, “Debt” in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K.

From time to time, we may use derivative instruments to manage our interest rate risk and market risk exposure.

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, 2023 would increase our interest expense by approximately \$4.2 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.

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## 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, 2023 and 2022, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, 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, 2023, 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 8, 2024 expressed an unqualified 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 Senior Secured Credit Facilities 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 Matter

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

*Revenue recognition - Allowance for product returns*

*Description of the Matter*

As described in Notes 2 and 13 to the consolidated financial statements, the Company recognized revenues of \$487.5 million for the year ended December 31, 2023 related to the sale of NARCAN<sup>®</sup> products. For these product sales, revenue is recognized at a point in time, net of estimates of allowances, including allowances for product returns.

Auditing the Company's measurement of allowances for returns of NARCAN<sup>®</sup> product sales involved significant auditor judgment because the calculation involves subjective assumptions and estimates made by management, including historical return activity used to forecast expected returns and estimates of inventory levels within the distribution channel.

*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 process to measure the allowance for returns on NARCAN<sup>®</sup> product sales. For example, we tested controls over management's review of the assumptions used in the calculation of the product returns allowance. We also tested management's controls over the completeness and accuracy of the data used in the underlying calculations.

To test the calculation of the product returns allowance, our audit procedures included the following procedures, amongst others. We independently estimated the allowance for product returns using the Company's historical data and compared the result to the Company's estimated returns allowance, inspected contracts and related modifications with the Company's customers to evaluate the Company's standard returns policy, performed revenue cutoff testing to assess whether there were relevant factors at period end not considered in the Company's analysis of product returns, and examined credit memos issued after year end for relevant factors or trends not consistent with the Company's analysis of product returns. We also tested the Company's retrospective review of the accuracy of the allowance for returns on product revenue and compared the results of the retrospective review to the current year assumptions.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2004.  
Tysons, Virginia  
March 8, 2024



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

	December 31,	
	2023	2022
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 111.7	\$ 642.6
Accounts receivable, net	191.0	159.2
Inventories, net	328.9	350.7
Prepaid expenses and other current assets	47.9	57.9
Total current assets	<u>679.5</u>	<u>1,210.4</u>
Property, plant and equipment, net	382.8	817.6
Intangible assets, net	566.6	728.8
Goodwill	—	218.2
Other assets	194.3	191.3
Total assets	<u>\$ 1,823.2</u>	<u>\$ 3,166.3</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 112.2	\$ 103.5
Accrued expenses	18.6	34.9
Accrued compensation	74.1	87.3
Debt, current portion	413.7	957.3
Other current liabilities	32.7	45.9
Total current liabilities	<u>651.3</u>	<u>1,228.9</u>
Debt, net of current portion	446.5	448.5
Deferred tax liability	47.2	59.7
Other liabilities	28.9	41.5
Total liabilities	<u>1,173.9</u>	<u>1,778.6</u>
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, 57.8 and 55.7 shares issued; 52.2 and 50.1 shares outstanding, respectively.	0.1	0.1
Treasury stock, at cost, 5.6 and 5.6 common shares, respectively	(227.7)	(227.7)
Additional paid-in capital	904.4	873.5
Accumulated other comprehensive income (loss), net	(5.7)	3.1
Retained earnings (accumulated deficit)	(21.8)	738.7
Total stockholders' equity	<u>649.3</u>	<u>1,387.7</u>
Total liabilities and stockholders' equity	<u>\$ 1,823.2</u>	<u>\$ 3,166.3</u>

*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,		
	2023	2022	2021
<b>Revenues:</b>			
Commercial Product sales	\$ 497.3	\$ 386.6	\$ 438.0
MCM Product sales	447.2	579.6	585.9
Total Product sales, net	944.5	966.2	1,023.9
<b>Bioservices:</b>			
Services	72.8	105.0	310.3
Leases	5.7	4.9	305.2
Total Bioservices revenues	78.5	109.9	615.5
Contracts and grants	26.3	41.4	134.2
Total revenues	1,049.3	1,117.5	1,773.6
<b>Operating expenses:</b>			
Cost of Commercial Product sales	210.3	160.3	187.2
Cost of MCM Product sales	305.6	264.3	195.4
Cost of Bioservices	189.5	268.5	365.5
Goodwill impairment	218.2	6.7	41.7
Impairment of long-lived assets	306.7	—	—
Research and development	111.4	188.3	235.2
Selling, general and administrative	368.4	339.5	348.7
Amortization of intangible assets	65.6	59.9	58.5
Total operating expenses	1,775.7	1,287.5	1,432.2
<b>Income (loss) from operations</b>	<b>(726.4)</b>	<b>(170.0)</b>	<b>341.4</b>
<b>Other income (expense):</b>			
Interest expense	(87.9)	(37.3)	(34.5)
Gain on sale of business	74.2	—	—
Other, net	8.9	(11.7)	(3.7)
Total other income (expense), net	(4.8)	(49.0)	(38.2)
<b>Income (loss) before income taxes</b>	<b>(731.2)</b>	<b>(219.0)</b>	<b>303.2</b>
<b>Income tax provision (benefit)</b>	<b>29.3</b>	<b>(7.4)</b>	<b>83.7</b>
<b>Net income (loss)</b>	<b>\$ (760.5)</b>	<b>\$ (211.6)</b>	<b>\$ 219.5</b>
<b>Net income (loss) per common share</b>			
Basic	\$ (14.85)	\$ (4.22)	\$ 4.10
Diluted	\$ (14.85)	\$ (4.22)	\$ 4.06
<b>Weighted average shares outstanding</b>			
Basic	51.2	50.1	53.5
Diluted	51.2	50.1	54.1

*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,		
	2023	2022	2021
<b>Net income (loss)</b>	\$ (760.5)	\$ (211.6)	\$ 219.5
<b>Other comprehensive income (loss), net of tax:</b>			
Foreign currency translation adjustments, net	0.9	1.0	(1.0)
Unrealized gains (losses) on hedging activities	2.7	10.8	12.3
Reclassification adjustment for losses (gains) on hedging activities	(8.9)	(0.1)	(5.8)
Reclassification adjustment for gains on pension benefit obligation	(3.5)	7.5	3.7
Total other comprehensive income (loss), net of tax	(8.8)	19.2	9.2
<b>Comprehensive income (loss), net of tax</b>	<u>\$ (769.3)</u>	<u>\$ (192.4)</u>	<u>\$ 228.7</u>

*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,		
	2023	2022	2021
<b>Operating Activities</b>			
Net income (loss)	\$ (760.5)	\$ (211.6)	\$ 219.5
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Share-based compensation expense	23.1	45.1	42.4
Depreciation and amortization	125.1	143.3	123.8
Change in fair value of contingent obligations, net	0.2	2.6	2.9
Amortization of deferred financing costs	21.3	4.1	4.1
Deferred income taxes	(8.9)	(28.6)	46.0
Gain on sale of travel health business	(74.2)	—	—
Goodwill impairment	218.2	6.7	41.7
Impairment of long-lived assets	306.7	—	—
Write off of contract asset and liability	—	—	(17.2)
Other	13.0	6.4	2.0
Changes in operating assets and liabilities:			
Accounts receivable	(21.6)	118.1	(16.2)
Inventories	0.6	(57.1)	(66.6)
Prepaid expenses and other assets	11.7	(19.9)	7.7
Accounts payable	10.6	(14.0)	(1.6)
Accrued expenses and other liabilities	(55.7)	(66.7)	(9.2)
Long-term incentive plan accrual	4.8	—	—
Accrued compensation	(10.4)	(0.8)	4.0
Income taxes receivable and payable, net	(16.2)	28.7	(31.3)
Contract liabilities	5.9	9.6	(31.8)
<b>Net cash provided by (used in) operating activities</b>	<b>(206.3)</b>	<b>(34.1)</b>	<b>320.2</b>
<b>Investing Activities</b>			
Purchases of property, plant and equipment	(51.6)	(115.8)	(224.1)
Royalty settlement payment	—	(21.8)	—
Milestone payment from prior asset acquisition	(6.3)	—	—
Asset acquisitions	—	(243.7)	—
Proceeds from sale of travel health business, net	270.2	—	—
<b>Net cash provided by (used in) investing activities</b>	<b>212.3</b>	<b>(381.3)</b>	<b>(224.1)</b>
<b>Financing Activities</b>			
Purchases of treasury stock	—	(82.1)	(106.0)
Principal payments on convertible senior notes	—	—	(10.6)
Proceeds from revolving credit facility	20.0	598.0	—
Principal payments on revolving credit facility	(398.8)	—	—
Principal payments on term loan facility	(164.6)	(33.8)	(25.3)
Proceeds from stock-based compensation activity	1.8	5.0	15.9
Taxes paid for stock-based compensation activity	(2.5)	(5.9)	(13.8)
Proceeds from at-the-market sale of stock, net of commissions and expenses	8.4	—	—
Contingent consideration payments	—	—	(1.2)
<b>Net cash provided by (used in) financing activities:</b>	<b>(535.7)</b>	<b>481.2</b>	<b>(141.0)</b>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(1.2)	0.5	(0.3)
Net change in cash, cash equivalents and restricted cash	(530.9)	66.3	(45.2)
Cash, cash equivalents and restricted cash, beginning of period	642.6	576.3	621.5
Cash, cash equivalents and restricted cash, end of period	<b>\$ 111.7</b>	<b>\$ 642.6</b>	<b>\$ 576.3</b>
<b>Supplemental cash flow disclosures:</b>			
Cash paid for interest	\$ 68.3	\$ 33.0	\$ 30.4
Cash paid for income taxes	\$ 52.8	\$ 6.2	\$ 71.6
<b>Non-cash investing and financing activities:</b>			
Purchases of property, plant and equipment unpaid at period end	\$ 5.7	\$ 9.4	\$ 20.0
Purchases of treasury stock unpaid at period end	\$ —	\$ —	\$ 6.6
Gain on extinguishment of debt	\$ 2.5	\$ —	\$ —

*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)*

	S0.001 Par Value Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount		Shares	Amount			
<b>Balance at December 31, 2020</b>	54.3	\$ 0.1	\$ 784.9	(1.2)	\$ (39.6)	\$ (25.3)	\$ 730.8	\$ 1,450.9
Net income	—	—	—	—	—	—	219.5	219.5
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)
<b>Balance at December 31, 2021</b>	55.1	\$ 0.1	\$ 829.4	(3.8)	\$ (152.2)	\$ (16.1)	\$ 950.3	\$ 1,611.5
Net loss	—	—	—	—	—	—	(211.6)	(211.6)
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)
<b>Balance at December 31, 2022</b>	55.7	\$ 0.1	\$ 873.5	(5.6)	\$ (227.7)	\$ 3.1	\$ 738.7	\$ 1,387.7
Net loss	—	—	—	—	—	—	(760.5)	(760.5)
Other comprehensive loss, net of tax	—	—	—	—	—	(8.8)	—	(8.8)
Share-based compensation activity	1.0	—	22.5	—	—	—	—	22.5
At-the-market sale of stock, net of commissions and expenses	1.1	—	8.4	—	—	—	—	8.4
<b>Balance at December 31, 2023</b>	57.8	\$ 0.1	\$ 904.4	(5.6)	\$ (227.7)	\$ (5.7)	\$ (21.8)	\$ 649.3

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

**Emergent BioSolutions Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements**  
*(dollar and share amounts in tables expressed in millions, except per share data)*

**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 four PHT categories: chemical, biological, radiological, nuclear and explosives ("CBRNE"); emerging infectious diseases ("EID"); emerging health crises; and acute, emergency and community care. The Company has a product portfolio of 12 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 structures the business with a focus on markets and customers. As such, the key components of the business structure include the following four product and service categories: Anthrax - Medical Countermeasures ("MCM") Products, NARCAN® commercial product, Smallpox - MCM products and Emergent Bioservices (CDMO) ("Bioservices").

Beginning in the fourth quarter of 2023, the Company manages our business with a focus on three operating segments: (1) a Commercial Products segment consisting of NARCAN® Nasal Spray and other commercial products which were sold as part of our travel health business in the second quarter of 2023 (see Note 3, "Divestiture" for more information on the sale of the travel health business); (2) a MCM Products segment consisting of our Anthrax - MCM, Smallpox - MCM and Other Products, described below and (3) a Services segment consisting of our Bioservices offerings (See Note 18, "Segment information" for more information on our reportable segments).

**The Company's products and services include:**

**Commercial Products Segment:**

NARCAN®

- NARCAN® (naloxone HCl) Nasal Spray, an intranasal formulation of naloxone approved by the FDA (including in over-the-counter form) and Health Canada for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression;

Sale of Travel Health Business

On May 15, 2023, the Company completed the sale of its Commercial Products segment's travel health business, including rights to Vivoti®, the licensed typhoid vaccine; Vaxchora®, the licensed cholera vaccine; the development-stage chikungunya vaccine candidate CHIKV VLP; the Company's manufacturing site in Bern, Switzerland; and certain of its development facilities in San Diego, California. For additional information, refer to Note 3, "Divestiture".

**MCM Products Segment**

Anthrax - MCM Products

- Anthrasil® (Anthrax Immune Globulin Intravenous (human)), the only polyclonal antibody therapeutic licensed by the United States Food and Drug Administration ("FDA") and Health Canada for the treatment of inhalational anthrax in combination with appropriate antibacterial drugs;
- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the FDA for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- CYFENDUS® (Anthrax vaccine adsorbed (AVA), adjuvanted), previously known as AV7909, which was recently approved by the FDA 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. CYFENDUS® is procured by certain authorized government buyers for their use; and

- Raxibacumab injection, the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax;

#### Smallpox - MCM Products

- ACAM2000<sup>®</sup>, (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;
- CNJ-016<sup>®</sup> (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; and
- TEMBEXA<sup>®</sup>, 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.

#### Other Products

- BAT<sup>®</sup> (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;
- Ebanga<sup>™</sup> (ansuvimab-zykl), 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<sup>™</sup> in the U.S. and Canada, and Ridgeback will serve as the global access partner for Ebanga<sup>™</sup>;
- RSDL<sup>®</sup> (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; and
- Trobigard<sup>®</sup> atropine sulfate, obidoxime chloride auto-injector, a combination drug-device auto-injector procured product candidate that contains atropine sulfate and obidoxime chloride. Trobigard<sup>®</sup> was approved in Belgium in 2021 but has not been approved by the FDA. Trobigard<sup>®</sup> is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure outside of the U.S.

#### **Services Segment:**

#### Bioservices - CDMO

Our services revenue consists of distinct but interrelated bioservices: 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 Bioservices. 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. In August 2023, the Company initiated an organizational restructuring plan (the "August 2023 Plan") which included actions to reduce investment in and de-emphasize focus on its Bioservices business.

## 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.

### 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, 2023, there was \$219.2 million outstanding on our senior revolving credit facility ("Revolving Credit Facility") and \$198.2 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 May 2025. As of December 31, 2023, the Company had \$111.7 million in cash and cash equivalents. 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. The evaluation considered the potential mitigating effects of management's plans that have not been fully implemented. Management has evaluated the mitigating effects 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. Management's plans include (A) amending the Senior Secured Credit Facilities, and (B) improving operating performance, reducing working capital and the potential of the sale of assets to pay down the Senior Secured Credit Facilities before they become due. As neither plan is in the complete control of Management, neither is probable of occurring. In this regard, management may not be able to find a buyer for the assets it is willing to divest and may not be able to close on any asset sale for which management is able to reach an agreement with a buyer, and as a result the Company may be unable to meet its obligations as they become due. In addition, any asset sales that are completed could have potential negative impacts on the Company's future operating cash flows and profitability.

### Debt Covenants

The Senior Secured Credit Facilities mature in May 2025, which provide for (1) revolving credit commitments, (2) a term loan, and (3) the issuance of commercial letters of credit. As of December 31, 2023, we had \$417.4 million outstanding under the Senior Secured Credit Facilities. Under the Senior Secured Credit Facilities, the Company is subject to a monthly minimum consolidated EBITDA covenant through February 29, 2024, and is also required to raise at least \$75.0 million through the issuance of equity and/or unsecured indebtedness by April 30, 2024. Beginning with the quarter ended March 31, 2024, the Company is subject to a minimum consolidated debt service coverage ratio and a maximum consolidated leverage ratio covenant. As of December 31, 2023, the Company was not in compliance with the minimum consolidated EBITDA covenant under the Senior Secured Credit Facilities and did not expect to be able to raise the remaining of the \$75.0 million through the issuance of equity under the at-the-market equity offering program (the "ATM Program") that we entered into on May 18, 2023, by April 30, 2024, as required by the requisite lenders. In addition, the Company is required to deliver audited annual financial statements without a "going concern" explanatory paragraph with respect to its financial statements for the year ended December 31, 2023, within 90-days of year end, while the financial statements included in this Annual Report contain an explanatory paragraph related to Going Concern. On February 29, 2024, the requisite lenders agreed to enter into a Forbearance Agreement and Sixth Amendment to Amended and Restated Credit Agreement (the "Forbearance Agreement and Amendment"), which includes 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, 2023 and the fiscal quarter ending March 31, 2024 and (b) the going concern explanatory paragraph contained in the audited financial statements for the fiscal year ended December 31, 2023. This forbearance period will expire on the earlier of (i) any other event of default and (ii) April 30, 2024. 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 Senior Secured Credit Facilities. The Senior Secured Credit Facilities and the Company's other debt facilities are described in more detail below in Note 10, "Debt".

Further, acceleration of the repayment of the Senior Secured Credit Facilities would result in a cross-default of the Company's obligations under the 3.875% Senior Unsecured Notes due in 2028. If the Company would be unable to obtain additional waivers or forbearance of such covenants or defaults, to successfully renegotiate the terms of the Senior Secured Credit Facilities, or to cure the potential covenant breach or default, and the lenders enforced one or more of their rights upon default and/or the default resulted in a cross-default under the 3.875% Senior Unsecured Notes due in 2028, the Company would be unable to meet its obligations under those agreements and could be forced into insolvency proceedings.



Based on the facts and circumstances described above, there can be no assurance that the Forbearance Period will continue to remain in place, and that the Company would be able to comply with covenants in the future. As a result, the Company continues to evaluate a number of factors related to its ability to continue as a going concern, including its ability to comply with the terms and operating and financial covenants required by the Senior Secured Credit Facilities, its ability to satisfy the capital raise requirement, other market conditions, economic conditions, particularly in the pharmaceutical and biotechnology industry, and disruptions or volatility caused by factors such as regional conflicts, inflation, and supply chain disruptions. The Company has engaged legal and financial advisors to assist with a comprehensive review of alternatives to enhance its capital structure, which may include taking steps to cure any potential defaults or seeking forbearance, waivers, further cost reductions, asset sales or other alternatives to avoid an event of default.

#### **Use of estimates**

The preparation of financial statements requires management to make estimates, judgments and assumptions that affect reported amounts and disclosures in the consolidated financial statements and accompanying notes. Due to the inherent uncertainty involved in making those estimates, judgments and assumptions, actual results could differ from those estimates. Our most significant estimates relate to revenue recognitions and the assessment of the recoverability of goodwill, definite lived intangible assets and other long-lived assets. Other estimates include allowances for expected credit losses, inventory, depreciation and amortization, business combinations, contingent consideration, share-based compensation, income taxes, and other contingencies. Management continually re-evaluates its estimates, judgments and assumptions and basis its estimates on historical trends, projections, current experience and other assumptions that it believes are reasonable. These estimates are sometimes complex, sensitive to changes in assumptions and require fair value determinations using Level 3 fair value measurements.

#### **Cash and cash equivalents**

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions. Also, the Company maintains cash balances with financial institutions in excess of insured limits.

#### **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 and Bioservices 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, NARCAN<sup>®</sup> Nasal Spray, is sold commercially over-the-counter at retail pharmacies and digital commerce websites as well as through physician-directed or standing order prescriptions at retail pharmacies, health departments, local law enforcement agencies, community-based organizations, substance abuse centers and other federal agencies.

We maintain an allowance for expected credit losses, which represents the estimated aggregate amount of credit risk arising from the inability or unwillingness of specific customers to pay our fees or disputes that may affect our ability to fully collect our billed accounts receivable. We estimate the current-period provision for expected credit losses on a specific identification basis and we consider factors such as the age of the receivables balance, knowledge of the specific customers' circumstances and historical collection experience for similar customers. Amounts determined to be uncollectible are charged or written-off against the reserve. Accounts receivable, net of the allowance for expected credit losses, represents the amount we expect to collect. Our actual experience may vary from our estimates. At each reporting date, we adjust the allowance for expected credit losses to reflect our current estimate. 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 2024 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<sup>®</sup> 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<sup>®</sup> and Anthrax Vaccines to customers in addition to the USG, which would harm their growth opportunities. The Company's commercial product sales, largely NARCAN<sup>®</sup> Nasal Spray, are sold commercially over-the-counter at retail pharmacies and digital commerce websites as well as through physician-directed or standing order prescriptions at retail pharmacies, health departments, local law enforcement agencies, community-based organizations, substance abuse centers and other federal agencies. Refer to Note 13, "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 38%, 43% and 51% of total revenues for 2023, 2022 and 2021, respectively. The Company's accounts receivable as of December 31, 2023 and 2022, consist primarily of amounts due from the USG or other large multi-national highly reputable customers for product sales, Bioservices or from government agencies under government grants.

##### 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, 2023, 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 actual cost. Actual 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 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. The Company determines normal capacity for each production facility and allocates fixed production-overhead costs on that basis. 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. Inventory reserves for write-downs are relieved when the inventory is disposed of through scrap or sale.

### Pre-launch inventory

Within the Company's Commercial Products and MCM Products segments costs relating to raw materials and production of inventory in preparation for product launch prior to regulatory approval are capitalized when the review process has progressed to a point where objective and persuasive evidence exists that regulatory approval is probable, the future economic benefit is expected to be realized, and the Company believes that material uncertainties related to the ultimate regulatory approval have been significantly reduced. Pre-launch inventory is recorded to research and development expense unless these criteria are met. For pre-launch inventory that is capitalized, the Company considers a number of specific facts and circumstances, including the product candidate's current status in the drug development and regulatory approval process, results from related clinical trials, results from meetings with relevant regulatory agencies prior to the filing of regulatory applications, potential obstacles to the approval process, historical experience, viability of commercialization and market trends. This policy is not applicable to pre-launch inventory purchased to satisfy a performance obligation related to a Bioservices contract as Bioservices pre-launch inventory may be capitalized if it has future economic benefit based on the terms of the contract.

## 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 7, "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 NARCAN® Nasal Spray, 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, 2023.

##### 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.

MCM product 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 MCM 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.

The Company's NARCAN<sup>®</sup> over-the-counter ("OTC") customer contracts are fixed price contracts. For that majority of the Company's NARCAN<sup>®</sup> OTC contract, the Company invoices and records revenue when the pharmacies and wholesalers receive product from the third-party logistics warehouse used by the Company, which is the point at which control is transferred to the customer. Revenues for these NARCAN<sup>®</sup> OTC arrangements are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Estimates of variable consideration includes allowance for returns, specialty distributor fees, wholesaler fees and prompt payment discounts. NARCAN<sup>®</sup> OTC may also be sold on consignment through third-party online retailers where revenues are recognized point in time when sold to the end customer. The Company pays these third-party online retailers selling commissions and fulfillment fees which are recorded as selling general & administrative expenses and cost of commercial product sales, respectively, in the Consolidated Statement of Operations. Revenues from NARCAN<sup>®</sup> OTC are 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. The Company considers several factors in the estimation process for the allowance for returns of NARCAN<sup>®</sup> OTC, including inventory levels within the distribution channel and historical return activity, including activity for product sold for which the return period has passed, as well as other relevant factors. Because returned product cannot be resold, there is no corresponding asset for product returns.

#### Bioservices

The Company performs its Bioservices offerings 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 Bioservices 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 Bioservices 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 share-based compensation

The Company has two share-based employee compensation plans, the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "Emergent Plan") and the Emergent BioSolutions, Inc. Inducement Plan (the "Inducement 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.

On September 28, 2023, the Company's Board of Directors adopted and approved the Emergent BioSolutions, Inc. Inducement Plan, pursuant to which the Company may from time to time make equity grants to individuals not previously an employee or director of the Company or any of its subsidiaries (or following a bona fide period of interruption of employment) as a material inducement to their employment by the Company. The Inducement Plan was adopted by the board of directors without stockholder approval pursuant to New York Stock Exchange Listing Rule 303A.08. The board of directors reserved 5.0 million shares of the Company's common stock for issuance under the Inducement Plan. The terms and conditions of the Inducement Plan are substantially similar to the Company's stockholder-approved Emergent Plan as discussed below.

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 historically maintained a defined benefit plan for employees in certain countries outside the U.S., including retirement benefit plans required by applicable local law. The Company's defined benefit plan was included in the sale of the travel health business on May 15, 2023. See Note 3, "Divestiture" for more information. The plan was 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 reviewed its actuarial assumptions on an annual basis and made modifications to the assumptions based on current rates and trends. Actuarial gains and losses were deferred in accumulated other comprehensive income (loss), net of tax and were 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 were 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. From time to time, the Company enters 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 objective and strategy with respect to these interest rate swaps is to protect the Company against adverse fluctuations in interest rates.

During the second quarter of 2023, the Company terminated its designated interest rate swap transactions with a total notional value of \$350.0 million. Hedge accounting was also discontinued at that time. As of December 31, 2023, all accumulated other comprehensive income associated with the terminated interest rate swaps was amortized to earnings over the remaining term of the interest rate swaps prior to termination.

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. See Note 9, "Derivative instruments and hedging activities" for further details on the interest rate swaps.

### New Accounting Standards

#### Accounting Standards Not Yet Adopted

In November 2023, the Financial Accounting Standards board ("FASB") issued Accounting Standards Update ("ASU") 2023-07 ("ASU 2023-07"), *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which improves reportable segment disclosure requirements, on an annual and interim basis, primarily through enhanced disclosures about significant segment expenses. Additionally, it requires a public entity to disclose the title and position of the Chief Operating Decision Maker ("CODM"). The ASU does not change how a public entity identifies its operating segments, aggregates them, or applies the quantitative thresholds to determine its reportable segments. The amendments in the ASU are effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, although early adoption is permitted. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, requires a public business entity ("PBE") to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. The amendments in the ASU are effective for public business entities for annual periods beginning after December 15, 2024, although early adoption is permitted. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements.

### 3. Divestiture

On May 15, 2023, pursuant to the Purchase and Sale Agreement (the "Purchase and Sale Agreement"), by and between the Company, through its wholly owned subsidiaries Emergent International Inc. and Emergent Travel Health Inc., and Bavarian Nordic ("Bavarian Nordic"), the Company completed the previously announced sale of the Company's travel health business, including rights to Vivotif<sup>®</sup>, the licensed typhoid vaccine; Vaxchora<sup>®</sup>, the licensed cholera vaccine; the development-stage chikungunya vaccine candidate CHIKV VLP; the Company's manufacturing site in Bern, Switzerland; and certain of its development facilities in San Diego, California.

At the closing, Bavarian Nordic paid a cash purchase price of \$270.2 million, exclusive of customary closing adjustments for cash, indebtedness, working capital and transaction expenses of the business at closing. Bavarian Nordic may also be required to pay

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 earn-out payments of up to \$30.0 million based on aggregate net sales of Vaxchora® and Vivotif® in calendar year 2026.

As a result of the divestiture, during the year ended December 31, 2023, the Company recognized a pre-tax gain of \$74.2 million, net of transaction costs of \$4.0 million recorded within "Gain on sale of business" on the Consolidated Statements of Operations.

The Company determined that the disposal of the travel health business does not qualify for reporting as a discontinued operation since it does not represent a strategic shift that has or will have a major effect on our operations and financial results. No adjustments were made to prior period results as a result of the disposal.

In connection with the divestiture, the Company entered into a Transition Services Agreement ("TSA") with Bavarian Nordic to help support its ongoing operations. Under the TSA, the Company provides certain transition services to Bavarian Nordic, including information technology, finance and enterprise resource planning, research and development, human resources, employee benefits and other limited services. Income from performing services under the TSA was recorded within "Other, net" on the Consolidated Statements of Operations and was \$3.2 million for the year ended December 31, 2023.

#### 4. Long-lived asset impairment and restructuring charges

##### Impairment of long-lived assets

The Company tests its long-lived assets that are held and used for recoverability whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable.

During the second quarter of 2023, due to deterioration in performance and resulting downward revisions to our internal Bioservices forecast made during the second quarter, including future expected cash flows, the Company determined there were sufficient indicators of impairment on certain asset groups within the Bioservices reporting unit to require an impairment analysis. As a result, the Company performed recoverability tests on certain asset groups within the Bioservices reporting unit and concluded that the impacted asset groups were not recoverable as the undiscounted expected cash flows did not exceed their carrying values.

Asset groups are written down only to the extent that their carrying value is higher than their respective fair value. The Company, with the assistance of a third-party valuation firm, applied valuation methods to estimate the fair values for each of the assets within the different asset classes. An orderly liquidation value was applied to estimate the fair value of the personal property assets and market and cost based approaches were applied to estimate the fair value of the real property assets. All of the valuation approaches applied represented Level 3 non-recurring fair value measurements. Based on this analysis, the Company allocated and recognized a non-cash impairment charge of \$306.7 million during the year ended December 31, 2023.

The table below presents the total impairment charge by asset class for the year ended December 31, 2023:

	Year Ended December 31, 2023
Buildings, building improvements and leasehold improvements	\$ 81.5
Furniture and equipment	117.5
Software	0.3
Construction-in-progress	107.4
<b>Total impairment of long-lived assets</b>	<b>\$ 306.7</b>

##### January 2023 Organizational Restructuring Plan

In January 2023, the Company initiated an organizational restructuring plan (the "January 2023 Plan") intended to reduce operating costs, improve operating margins, and continue advancing the Company's ongoing commitment to profitable growth. As part of the January 2023 Plan, the Company reduced its workforce by approximately 125 employees. The Company incurred \$9.3 million in charges during the year ended December 31, 2023. These charges consist primarily of charges related to employee transition, severance payments and employee benefits. All activities related to the January 2023 Plan were substantially completed during the first quarter of 2023. Restructuring costs are recognized as an operating expense within the Consolidated Statement of Operations and are classified based on the Company's classification policy for each category of operating expense.

August 2023 Organizational Restructuring Plan

In August 2023, the Company initiated the August 2023 Plan intended to strengthen its core business and financial position by reducing investment in and de-emphasizing focus on its Bioservices business for future growth. As part of the August 2023 Plan, the Company reduced its workforce by approximately 400 employees. The Company incurred \$20.0 million in charges in connection with the August 2023 Plan during the year ended December 31, 2023. These charges consist primarily of charges related to severance payments, transition services, and employee benefits. All activities related to the August 2023 Plan were substantially completed during the third quarter of 2023. Restructuring costs are recognized as an operating expense within the Consolidated Statement of Operations and are classified based on the Company's classification policy for each category of operating expense.

The following table presents the total restructuring costs associated with the Company's segments as well as unallocated corporate and research and development ("R&D") charges for the year ended December 31, 2023:

	Year Ended December 31, 2023
Commercial Products	\$ —
MCM Products	5.6
Services	8.4
Total restructuring costs by segment	14.0
Corporate	11.7
R&D	3.6
Total restructuring costs	\$ 29.3

The following table presents the total restructuring costs, by function, for the year ended December 31, 2023:

	Year Ended December 31, 2023
Employee transition	\$ 0.6
Severance payments	27.0
Employee benefits	1.7
Total restructuring costs	\$ 29.3

The following table provides the components of and changes in the Company's restructuring accrual for the January 2023 Plan during the year ended December 31, 2023:

	Employee Transition	Severance Payments	Employee Benefits	Total
Balance at December 31, 2022	\$ —	\$ —	\$ —	\$ —
Accruals	0.3	8.7	0.3	9.3
Cash payments	(0.3)	(7.3)	(0.3)	(7.9)
Balance at December 31, 2023	\$ —	\$ 1.4	\$ —	\$ 1.4

The following table provides the components of and changes in the Company's restructuring accrual for the August 2023 Plan during the year ended December 31, 2023:

	Employee Transition	Severance Payments	Employee Benefits	Total
Balance at December 31, 2022	\$ —	\$ —	\$ —	\$ —
Accruals	0.3	18.3	1.4	20.0
Cash payments	(0.3)	(13.0)	(1.3)	(14.6)
Balance at December 31, 2023	\$ —	\$ 5.3	\$ 0.1	\$ 5.4

## 5. Inventories, net

Inventories, net consist of the following:

	December 31,	
	2023	2022
Raw materials and supplies	\$ 128.7	\$ 142.3
Work-in-process	113.3	116.2
Finished goods	86.9	92.2
Total inventories, net	<u>\$ 328.9</u>	<u>\$ 350.7</u>

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

## 6. Property, plant and equipment, net

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

	December 31,	
	2023 <sup>(1)</sup>	2022
Land and improvements	\$ 30.0	\$ 54.9
Buildings, building improvements and leasehold improvements	229.9	327.9
Furniture and equipment	433.6	567.5
Software	64.0	65.6
Construction-in-progress	36.7	185.5
Property, plant and equipment, gross	\$ 794.2	\$ 1,201.4
Less: Accumulated depreciation and amortization	(411.4)	(383.8)
Total property, plant and equipment, net	<u>\$ 382.8</u>	<u>\$ 817.6</u>

<sup>(1)</sup> During the year ended December 31, 2023, the Company recorded a non-cash impairment charge of \$306.7 million related to certain Bioservices long-lived assets. See Note 4, "Long-lived asset impairment and restructuring charges" for more details regarding the impairment charge.

For the year ended December 31, 2023, construction-in-progress primarily included costs incurred to advance the Company's MCM Product capabilities. For the year ended December 31, 2022, construction-in-progress primarily included costs incurred related to construction to advance the Company's Bioservices capabilities.

Property, plant and equipment, net is stated at cost, less accumulated depreciation and amortization. Depreciation and amortization expense associated with property, plant and equipment was \$59.5 million, \$83.4 million and \$62.2 million for the years ended December 31, 2023, 2022, and 2021, respectively. 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 manufacturing services agreement (the "Janssen Agreement") with Janssen Pharmaceuticals, Inc. ("Janssen"). For additional information related to the termination of the Janssen Agreement, refer to Note 13 "Revenue recognition".

## 7. Intangible assets and goodwill

### Intangible Assets

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

	Weighted Average Useful Life in Years	December 31, 2023			December 31, 2022		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Products <sup>(1)(2)</sup>	13.6	\$ 855.4	\$ 288.8	\$ 566.6	\$ 982.1	\$ 253.3	\$ 728.8
Customer relationships	0.0	28.6	28.6	—	28.6	28.6	—
Bioservices	0.0	5.5	5.5	—	5.5	5.5	—
Total intangible assets	13.5	\$ 889.5	\$ 322.9	\$ 566.6	\$ 1,016.2	\$ 287.4	\$ 728.8

<sup>(1)</sup> During the year ended December 31, 2023, the Company sold \$102.9 million of intangible assets, net as part of the sale of its travel health business to Bavarian Nordic. See Note 3, "Divestiture" for more information on the sale of the travel health business.

<sup>(2)</sup> During the year ended December 31, 2023, the Company recorded a \$6.3 million intangible asset addition related to the contingent consideration payment to Ridgeback for the award of a 10-year contract by the Biomedical Advanced Research and Development Authority for advanced development, manufacturing scale-up, and procurement of Ebanga™ treatment for Ebola. The related intangible asset was acquired through an asset acquisition that was completed in 2022.

Amortization expense associated with the Company's intangible assets was recorded as follows:

	Year Ended December 31,		
	2023	2022	2021
Amortization expense	65.6	59.9	58.5

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

Year	As of December 31, 2023
2024	\$ 65.1
2025	65.1
2026	63.9
2027	60.6
2028	51.7
Thereafter	260.2
Total remaining amortization	\$ 566.6

## Goodwill

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

	Commercial Products <sup>(1)</sup>	MCM Products <sup>(2)</sup>	Services <sup>(3)</sup>	Total
<b>Balance at December 31, 2021</b>	\$ —	\$ 218.2	\$ 6.7	\$ 224.9
Goodwill impairment	—	—	(6.7)	(6.7)
<b>Balance at December 31, 2022</b>	\$ —	\$ 218.2	\$ —	\$ 218.2
Goodwill impairment	—	(218.2)	—	(218.2)
<b>Balance at December 31, 2023</b>	\$ —	\$ —	\$ —	\$ —

<sup>(1)</sup> Amounts for the Company's Commercial Products segment include gross carrying values of \$41.7 million as of December 31, 2023, 2022 and 2021, and accumulated impairment losses of \$41.7 million as of December 31, 2023, 2022 and 2021.

<sup>(2)</sup> Amounts for the Company's MCM Products segment include gross carrying values of \$218.2 million as of December 31, 2023, 2022 and 2021, and accumulated impairment losses of \$218.2 million as of December 31, 2023.

<sup>(3)</sup> Amounts for the Company's Services segment include gross carrying values of \$6.7 million as of December 31, 2023, 2022, and 2021, and accumulated impairment losses of \$6.7 million as of December 31, 2023 and 2022.

The Company performs its goodwill impairment evaluation annually, during the fourth quarter, or sooner if triggering events are identified. During the third quarter of 2023, the Company observed continued market volatility including significant declines in its market capitalization and revised its financial outlook during the third quarter of 2023, which was identified as a triggering event. As a result of the quantitative assessments performed in connection with the preparation of the financial statements as of and for the quarter ended September 30, 2023, the Company recorded a \$218.2 million non-cash goodwill impairment charge for the MCM Products reporting unit, which is included in "Goodwill impairment" on the Consolidated Statement of Operations for the year ended December 31, 2023. The MCM Products reporting unit and segment had no remaining goodwill as of December 31, 2023. The goodwill impairment charge resulted from a reduction in the estimated fair value of the MCM reporting unit due to changes in the risk profile of the Company as well as revisions to the long-term operating plan that reflected lower expectations for growth and profitability than previous expectations. The Company used a quantitative assessment, utilizing an income-based (discounted cash flows) approach, Level 3 non-recurring fair value measurement, for its goodwill impairment testing.

## 8. 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, 2023				December 31, 2022			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
<b>Assets:</b>								
Money market accounts	\$ 40.5	\$ 40.5	\$ —	\$ —	\$ 320.8	\$ 320.8	\$ —	\$ —
Time deposits	—	—	—	—	170.7	—	170.7	—
Derivative instruments	—	—	—	—	8.5	—	8.5	—
<b>Total</b>	<b>\$ 40.5</b>	<b>\$ 40.5</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 500.0</b>	<b>\$ 320.8</b>	<b>\$ 179.2</b>	<b>\$ —</b>
<b>Liabilities:</b>								
Contingent consideration	\$ 5.6	\$ —	\$ —	\$ 5.6	\$ 8.0	\$ —	\$ —	\$ 8.0
<b>Total</b>	<b>\$ 5.6</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 5.6</b>	<b>\$ 8.0</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 8.0</b>

## 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 Consolidated 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, 2023, 2022 and 2021:

	Contingent Consideration
<b>Balance at December 31, 2020</b>	\$ 59.3
Change in fair value	2.9
Settlements	(23.8)
<b>Balance at December 31, 2021</b>	\$ 38.4
Change in fair value	2.6
Settlements	(33.0)
<b>Balance at December 31, 2022</b>	\$ 8.0
Change in fair value	0.2
Settlements	(2.6)
<b>Balance at December 31, 2023</b>	\$ 5.6

As of December 31, 2023 and 2022, the current portion of the contingent consideration liability was \$2.7 million and \$3.4 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, 2023	Valuation Technique	Unobservable Input	Range
Royalty based	\$5.6 million	Discounted cash flow	Discount rate	9.5%
			Probability of payment	0.0% - 75.0%
			Projected year of payment	2023 - 2028

#### Non-Variable Rate Debt

As of December 31, 2023 and 2022, the fair value of the Company's 3.875% Senior Unsecured Notes was \$184.3 million and \$225.1 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 10, "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, 2023 and December 31, 2022, other than those liabilities mentioned above and those assets outlined in Note 7 "Intangible assets and goodwill", there were no material assets or liabilities measured at fair value on a non-recurring basis.

### 9. 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. From time to time, the Company enters into interest rate swap transactions to manage exposures that arise from payments of variable interest rate debt associated with the Company's senior secured credit agreements. The objective and strategy with respect to these interest rate swaps is to protect the Company against adverse fluctuations in interest rates.

During the second quarter of 2023, the Company terminated its designated interest rate swap transactions with a total notional value of \$350.0 million. Hedge accounting was also discontinued at that time. As of December 31, 2023, there was no remaining accumulated other comprehensive income associated with the terminated interest rate swaps.



The table below presents the fair value of the Company's derivative financial instruments designated as hedges as well as their classification on the Consolidated Balance Sheets:

	Classification	Fair Value of Asset Derivatives		
		December 31,		
		2023	2022	
Interest Rate Swaps	Other Current Assets	\$ —	\$ 8.5	8.5

Prior to their termination, the valuation of the interest rate swaps was determined using widely accepted valuation techniques, including discounted cash flow analysis on the expected cash flows of each interest rate swap. This analysis reflected 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 were 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) were based on an expectation of future interest rates (forward curves) derived from observable market interest rate curves. We incorporated 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 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 following table summarizes the amount of gains or losses reclassified from "Accumulated other comprehensive income (loss), net" into "Interest expense" on the Consolidated Statement of Operations during the years ended December 31, 2023 and 2022:

	Classification	Year Ended December 31,		
		2023	2022	
Interest rate swaps gain (loss)	Interest expense	\$ 8.9	\$ (0.1)	(0.1)

#### 10. Debt

The table below present the components of the Company's debt:

		December 31,	
		2023	2022
Senior secured credit agreement - Term loan due 2025	\$	198.2	\$ 362.8
Senior secured credit agreement - Revolver loan due 2025		219.2	598.0
3.875% Senior Unsecured Notes due 2028		450.0	450.0
Other		1.0	3.0
Total debt	\$	868.4	\$ 1,413.8
Current portion of long-term debt, net of debt issuance costs		(413.7)	(957.3)
Unamortized debt issuance costs		(8.2)	(8.0)
Non-current portion of debt	\$	446.5	\$ 448.5

During the years ended December 31, 2023 and 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, 2023 and 2022, the Company had \$5.3 million and \$1.3 million of debt issuance costs associated with the revolver loan, 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 "2028 Notes"). Interest on the 2028 Notes is payable on February 15th and August 15th of each year until maturity, beginning on February 15, 2021. The 2028 Notes will mature on August 15, 2028.

As of August 15, 2023, the Company may redeem the 2028 Notes, in whole or in part, at the redemption prices set forth in the related indenture, plus accrued and unpaid interest. As of August 15, 2023, the Company may redeem all or a portion of the 2028 Notes at a redemption price equal to 100% of the principal amount of the 2028 Notes plus a "make-whole" premium and accrued and unpaid interest as set forth in the related indenture. Upon the occurrence of a change of control, the Company must offer to repurchase the 2028 Notes at a purchase price of 101% of the principal amount of such 2028 Notes plus accrued and unpaid interest.

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

### Senior Secured Credit Facilities

On May 15, 2023, the Company entered into the Fourth Amendment to Amended and Restated Credit Agreement, Waiver and First Amendment to Amended and Restated Collateral Agreement (the "Credit Agreement Amendment"). The Credit Agreement Amendment amended the existing Amended and Restated Credit Agreement to, among other things, (a) extend the maturity date of the Senior Secured Credit Facilities from October 13, 2023 to May 15, 2025, (b) reduce the available commitments under the Revolving Credit Facility from \$600.0 million to \$300.0 million, (c) remove the Company's ability to incur incremental loans and (d) amend certain mandatory prepayment triggers, affirmative covenants, negative covenants and events of default thereunder. In connection with the Credit Agreement Amendment, the Company used the approximately \$270.2 million of proceeds from the sale of its travel health business to Bavarian Nordic, which closed on May 15, 2023, together with approximately \$217.2 million of cash on hand, to repay approximately \$144.4 million in outstanding principal amount of loans under the Term Loan Facility and \$342.8 million outstanding principal amount of loans under the Revolving Credit Facility. The Credit Agreement Amendment also requires that the Company make quarterly principal payments on the Term Loan Facility of approximately \$3.9 million, which commenced on June 30, 2023 and will extend through March 31, 2025.

The Credit Agreement Amendment also (i) amended the consolidated debt service coverage ratio financial covenant to require the minimum level to be 2.25 to 1.00 for the fiscal quarters ending March 31, 2024, June 30, 2024, September 30, 2024 and December 31, 2024, and then 2.50 to 1.00 for each fiscal quarter ending thereafter, (ii) amended the consolidated leverage ratio to require the maximum level to be 4.50 to 1.00 for the fiscal quarter ending March 31, 2024 and each fiscal quarter ending thereafter, (iii) added minimum Consolidated EBITDA requirements and maximum capital expenditure requirements for each of the months ending April 30, 2023 through February 29, 2024 and a minimum liquidity requirement as of the end of each calendar month and (iv) requires the Company to increase its liquidity by April 30, 2024 by raising at least \$75.0 million of equity or unsecured indebtedness. See Note 2, "Summary of significant accounting policies" for additional information related to the Company's compliance with the debt covenants described above.

In addition, the Credit Agreement Amendment replaced the interest rate benchmark such that borrowings under the Revolving Credit Facility and the outstanding principal amount of the Term Loan Facility shall bear interest at a rate per annum equal to (a) a rate based on SOFR, EURIBOR or CDOR plus a margin of 6.00% until March 31, 2024 and thereafter, a margin ranging from 2.75% to 4.00% depending on the Company's consolidated leverage ratio, or (b) a base rate (which is the highest of the prime rate, the federal funds rate plus 0.50%, and a SOFR rate for an interest period of one month plus 1.00%) plus a margin of 5.00% until March 31, 2024 and thereafter, a margin ranging from 1.75% to 3.00% depending on the Company's consolidated leverage ratio. In addition, the commitment fee the Company is required to pay in respect of the annual daily unused commitments under the Revolving Credit Facility shall be 0.15% to 0.40% per annum, depending on the Company's consolidated leverage ratio.

Under the Credit Agreement Amendment, the Company and the other guarantors also agreed to provide a lien over certain assets as additional collateral for the benefit of the lenders, including owned real property, equity interests of foreign subsidiaries and certain deposit accounts.

On February 29, 2024, the Company entered into the Forbearance Agreement and Amendment to, among other things, (a) provide that the Administrative Agent and the Lenders forbear from exercising all rights and remedies under the Senior Secured Credit Facilities and the other related loan documents arising from the occurrence and continuation of certain specified events of default during the Forbearance Period and (b) provide consent by the required revolving credit lenders to make further loans to the Company or other extensions of credit to the credit parties during the Forbearance Period, notwithstanding the occurrence of the specified events of default, subject to certain conditions set forth in the Forbearance Agreement and Amendment, including a limit on Revolving Credit Facility indebtedness of \$270 million. The Forbearance Agreement and Amendment also amends, among other things, (x)(A) the

interest rate benchmark to provide that borrowings shall bear interest at a rate per annum equal to 5.00% with respect to Base Rate Loans, (B) the interest rate benchmark from 6.00% per annum to 6.50% per annum with respect to SOFR Loans, Daily Simple SONIA Loans and Eurocurrency Rate Loans, and (C) 0.40% with respect to Commitment Fees, (y) the mandatory prepayment threshold amount for unrestricted cash and cash equivalents from \$125,000,000 to \$100,000,000, and (z) the mandatory principal prepayment amount from 75% of all milestone payments received by the Company and its subsidiaries from certain project milestone payments to 100%. Under the Forbearance Agreement and Amendment, the Company and the other guarantors have also agreed to cause Emergent BioSolutions Canada Inc. to (i) become a guarantor under the Senior Secured Credit Facilities and (ii) grant a security lien in all collateral owned by Emergent BioSolutions Canada Inc. (subject to the exclusions and exceptions specified in the Collateral Agreement) to the Administrative Agent. In addition, in connection with the entry into the Forbearance Agreement and Amendment, the Company paid a forbearance fee of approximately \$1.2 million. Refer to Note 2, "Summary of significant accounting policies" for further discussion of the Forbearance Agreement and Amendment.

Debt Maturity

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

Year	As of December 31, 2023
2024	\$ 418.4
2025	—
2026	—
2027	—
2028	450.0
Thereafter	—
<b>Total debt</b>	<b>\$ 868.4</b>

**11. Share-based compensation and stockholders' equity**

**Share-based compensation**

The Company has two share-based employee compensation plans, the Emergent Plan and the Inducement Plan, which include stock options and performance and restricted stock units.

As of December 31, 2023, an aggregate of 29.1 million shares of common stock were authorized for issuance under the Emergent Plan, of which a total of approximately 5.9 million shares of common stock remain available for future awards to be made to plan participants. As of December 31, 2023, an aggregate of 5.0 million shares of common stock were authorized for issuance under the Inducement Plan and no shares had been issued under the Inducement Plan. 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 and the Inducement Plan have a contractual life of seven years.

Stock Options

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,		
	2023	2022	2021
Expected dividend yield	0 %	0 %	0 %
Expected volatility	63%-69%	54%-62%	47%-48%
Risk-free interest rate	4.00%-4.46%	1.54%-4.31%	0.43%-0.94%
Expected average life of options	4.5 years	4.5 years	4.5 years

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, 2022	1.7	\$ 51.74		
Stock options granted	0.7	\$ 9.66		
Stock options exercised	—	\$ —		
Stock options forfeited	(1.3)	\$ 42.82		
Stock options outstanding at December 31, 2023	1.1	\$ 34.44	5.1	\$ —
Stock options exercisable at December 31, 2023	0.4	\$ 56.60	3.4	\$ —

There was no cash received from option exercises for the year ended December 31, 2023. Cash received from option exercises for the years ended December 31, 2022 and 2021 was \$0.5 million and \$10.4 million, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2023, 2022 and 2021 was \$5.35, \$17.85 and \$35.16 per share, respectively. The intrinsic value of stock options exercised is the amount by which the market value of our common stock on the exercise date exceeds the exercise price. There was no intrinsic value of options exercised during the year ended December 31, 2023. The total intrinsic value of options exercised during the years ended December 31, 2022 and 2021 was \$0.3 million and \$15.7 million, respectively.

As of December 31, 2023, there was \$4.4 million of unrecognized compensation cost related to stock options.

Performance stock units and restricted stock units

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, 2022	2.2	\$ 42.30	\$ 25.8
Stock awards granted <sup>(1)</sup>	2.4	\$ 8.51	
Stock awards released	(0.7)	\$ 46.73	
Stock awards forfeited <sup>(1)</sup>	(1.3)	\$ 26.92	
Stock awards outstanding at December 31, 2023	2.6	\$ 16.57	\$ 6.20

<sup>(1)</sup> Performance stock units granted and forfeited during the year ended December 31, 2023 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, 2023, 2022 and 2021 was \$31.8 million, \$30.9 million and \$26.9 million, respectively. As of December 31, 2023, there was \$22.6 million of unrecognized compensation cost related to unvested restricted stock units. That cost is expected to be recognized straight-line over a weighted average period of 1.8 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 200% 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, 2023, 2022 and 2021 was \$2.4 million, \$2.5 million and \$3.8 million, respectively. As of December 31, 2023, there was \$2.2 million of unrecognized compensation cost related to unvested performance stock units. That cost is expected to be recognized straight-line over a weighted average period of 1.8 years.

Share-based compensation expense

Share-based compensation expense, net of forfeitures was recorded in the following financial statement line items:

	Year Ended December 31,		
	2023	2022	2021
Cost of Commercial Product sales	\$ 0.1	\$ 0.8	\$ 1.0
Cost of MCM Product sales	3.8	6.5	5.4
Cost of Bioservices	1.0	1.8	1.1
R&D	2.0	5.4	5.0
Selling, general and administrative	16.2	30.6	29.9
Total share-based compensation expense	<u>\$ 23.1</u>	<u>\$ 45.1</u>	<u>\$ 42.4</u>

**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.

At-the-Market Equity Offering Facility

We may, from time to time, sell up to \$150.0 million aggregate gross sales price of shares of our common stock through Evercore Group L.L.C. and RBC Capital Markets, LLC, as sales agents, under an ATM Program that we entered into on May 18, 2023. Between the entry into the ATM Program and December 31, 2023, we sold 1.1 million shares of our common stock under the ATM Program for gross proceeds of \$9.1 million, representing an average share price of \$8.22 per share. As of December 31, 2023, \$140.9 million aggregate gross sales price of shares of our common stock remains available for issuance under the ATM Program. We intend to use proceeds obtained from the sale of shares under the ATM Program for general corporate purposes.

2021 Share 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 "2021 Share Repurchase Program"), of which \$187.9 million was utilized to purchase approximately 4.4 million. The 2021 Share Repurchase Program expired on November 11, 2022. During the year ended December 31, 2022, the Company utilized \$75.5 million to purchase approximately 1.8 million shares. The 2021 Share Repurchase Program did not obligate the Company to acquire any specific number of shares. Repurchased shares are available for use in connection with the Company's stock plans and for other corporate purposes.

*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
<b>Balance at December 31, 2021</b>	\$ (4.0)	\$ (4.5)	\$ (7.6)	\$ (16.1)
Other comprehensive income (loss) 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 (loss)	7.5	10.7	1.0	19.2
<b>Balance at December 31, 2022</b>	\$ 3.5	\$ 6.2	\$ (6.6)	\$ 3.1
Other comprehensive income before reclassifications	—	2.7	0.9	3.6
Amounts reclassified from accumulated other comprehensive income (loss)	(3.5)	(8.9)	—	(12.4)
Net current period other comprehensive income (loss)	(3.5)	(6.2)	0.9	(8.8)
<b>Balance at December 31, 2023</b>	\$ —	\$ —	\$ (5.7)	\$ (5.7)

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

	December 31, 2023			December 31, 2022			December 31, 2021		
	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	\$ (4.1)	\$ 0.6	\$ (3.5)	\$ 8.7	\$ (1.2)	\$ 7.5	\$ 4.3	\$ (0.6)	\$ 3.7
Derivative instruments	(8.5)	2.3	(6.2)	14.6	(3.9)	10.7	8.9	(2.4)	6.5
Foreign currency translation adjustments	1.6	(0.7)	0.9	0.6	0.4	1.0	(1.2)	0.2	(1.0)
Total adjustments	\$ (11.0)	\$ 2.2	\$ (8.8)	\$ 23.9	\$ (4.7)	\$ 19.2	\$ 12.0	\$ (2.8)	\$ 9.2

## 12. 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 common shares outstanding during the period. Diluted net income (loss) per common share adjusts basic loss per common share for the effects of potentially dilutive common shares and is calculated using the treasury stock method. Potentially dilutive common shares include the dilutive effect of shares issuable under our equity compensation plans, including stock options, restricted stock units and performance stock units. Diluted net income (loss) per share excludes anti-dilutive securities, which represent the number of potential common shares related to shares issuable under our equity compensation plans that were excluded from diluted net income (loss) per common share because their effect would have been antidilutive. No adjustment for the potential dilutive effect of dilutive securities is reported for the years ended December 31, 2023 and 2022 as the effect would have been anti-dilutive due to the Company's net loss.

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

	Year Ended December 31,		
	2023	2022	2021
<b>Numerator:</b>			
Net income (loss)	\$ (760.5)	\$ (211.6)	\$ 219.5
<b>Denominator:</b>			
Weighted-average number of shares-basic	51.2	50.1	53.5
Dilutive effect of employee incentive plans	—	—	0.6
Weighted-average number of shares-diluted	51.2	50.1	54.1
Net income (loss) per common share - basic	\$ (14.85)	\$ (4.22)	\$ 4.10
Net income (loss) per common share - diluted	\$ (14.85)	\$ (4.22)	\$ 4.06

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, 2023, 2022 and 2021. 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,		
	2023	2022	2021
Anti-dilutive stock awards	3.6	2.8	1.0

### 13. Revenue recognition

The Company operates in three business segments (see Note 18, "Segment information"). The Company's revenues disaggregated by the major sources were as follows:

	Year Ended December 31,								
	2023			2022			2021		
	USG	Non-USG	Total	USG	Non-USG	Total	USG	Non-USG	Total
Commercial Product sales	\$ 0.8	\$ 496.5	\$ 497.3	\$ 0.8	\$ 385.8	\$ 386.6	\$ 2.2	\$ 435.8	\$ 438.0
MCM Product sales	373.5	73.7	447.2	444.6	135.0	579.6	527.8	58.1	585.9
<b>Bioservices:</b>									
Services	—	72.8	72.8	—	105.0	105.0	—	310.3	310.3
Leases	—	5.7	5.7	—	4.9	4.9	243.1	62.1	305.2
Total Bioservices	\$ —	\$ 78.5	\$ 78.5	\$ —	\$ 109.9	\$ 109.9	\$ 243.1	\$ 372.4	\$ 615.5
Contracts and grants	20.4	5.9	26.3	37.2	4.2	41.4	130.2	4.0	134.2
Total revenues	\$ 394.7	\$ 654.6	\$ 1,049.3	\$ 482.6	\$ 634.9	\$ 1,117.5	\$ 903.3	\$ 870.3	\$ 1,773.6

For the years ended December 31, 2023, 2022 and 2021, the Company's product sales from NARCAN®, Other commercial products, Anthrax MCM, Smallpox MCM and Other products as a percentage of total product sales were as follows:

	Year Ended December 31,		
	2023	2022	2021
% of product sales:			
Commercial Products:			
NARCAN®	51 %	39 %	42 %
Other Commercial products	1 %	1 %	— %
MCM Products:			
Anthrax MCM	20 %	30 %	26 %
Smallpox MCM	18 %	24 %	26 %
Other Products	10 %	6 %	6 %

For the years ended December 31, 2023 and 2021, aside from sales to the USG, there were no sales to an individual customer in excess of 10% of total revenues. 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's revenue accounted for 10% and was primarily attributable to the MCM Products segment. For the years ended December 31, 2023, 2022, and 2021, the Company's revenues from customers within the United States comprised 58%, 79% and 92%, 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 Janssen 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 Janssen 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 Janssen Agreement and (ii) to confirm Janssen's intent to not purchase the requisite minimum quantity of the Product pursuant to the Janssen Agreement and instead, wind-down the Janssen 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 Janssen Agreement for asserted material breaches of the Janssen 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 Janssen 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 Janssen 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, 2023 there were no impacts on previously recognized revenue or depreciation related to the conclusion of the Agreement. As of December 31, 2023, the Company has no billed or unbilled net accounts receivable related to the Agreement.

Beginning in the fourth quarter of 2022, because the arbitration process is expected to extend longer than one year, the Company reclassified amounts related to the Janssen Agreement from "Inventories, net" and from "Prepaid expenses and other current assets" to "Other assets", resulting in \$152.7 million in long-term assets related to the Janssen Agreement on the Consolidated Balance Sheet as of December 31, 2022. The long-term asset balance within "Other Assets" related to the Janssen Agreement as of December 31, 2023 was \$158.8 million. These assets include termination penalties, certain inventory related items and raw materials inventory representing materials purchased for the Janssen Agreement which Janssen has not reimbursed. The Company evaluated the net realizable value of the inventory as of December 31, 2023, concluding that because the Janssen 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. As of December 31, 2023, all non-cancelable orders have been received by Janssen and are included in the long-term asset balance within "Other Assets".

*BARDA Centers of Innovation and Advanced Development and Manufacturing Agreement ("CIADM")*

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 years ended December 31, 2023 and December 31, 2022. Revenue associated with the base arrangement was \$71.3 million during the year ended December 31, 2021 and is reflected as a component of contracts and grants revenue on the Consolidated Statements of Operations. Revenue associated with the BARDA COVID-19 Development Public-Private Partnership was \$243.1 million during the year ended December 31, 2021 and is recorded as Bioservices "Leases" on the Consolidated Statements of Operations.

**Bioservices Operating Leases**

Certain multi-year Bioservices 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 5.0 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, 2023, the Company's non-USG lease revenues were \$5.7 million, which is included within Bioservices "Leases" on the Consolidated Statement of Operations. Excluding future amounts related to the Agreement as discussed above, the Company estimates future operating lease revenues to be \$0.8 million in 2024, \$0.9 million in 2025, \$0.9 million in 2026, \$0.9 million in 2027, \$0.9 million in 2028 and no lease revenue in 2029 and beyond.

**Transaction price allocated to remaining performance obligations**

As of December 31, 2023, the Company has future contract value on unsatisfied performance obligations of approximately \$379.5 million associated with all arrangements entered into by the Company. The Company expects to recognize \$372.3 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, 2023 and December 31, 2022, the Company had \$21.9 million and \$34.8 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 amounts 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, 2022	\$	31.7
Balance at December 31, 2023	\$	29.9
Revenue recognized in the period from amounts included in contract liability at the beginning of the period:	\$	20.2

As of December 31, 2023 and 2022, the current portion of contract liabilities was \$27.2 million and \$26.4 million, respectively, and was included in "Other current liabilities" on the Consolidated Balance Sheet.

#### Accounts Receivable and Allowance for Expected Credit Losses

The following table summarizes the components of "Accounts receivable, net" as presented on the Consolidated Balance Sheets:

	December 31,	
	2023	2022
Accounts receivable:		
Billed	\$ 141.8	\$ 102.7
Unbilled	51.4	57.2
Allowance for expected credit losses	(2.2)	(0.7)
<b>Accounts receivable, net</b>	<b>\$ 191.0</b>	<b>\$ 159.2</b>

The Company's provisions for expected credit losses for the year's ended years ended December 31, 2023, 2022 and 2021 was \$2.1 million, \$0.3 million, and \$(0.1) million, respectively.

#### 14. Leases

The Company is the lessee for operating leases for offices, R&D facilities and manufacturing facilities, which may include renewal or termination options. The Company determines if an arrangement is a lease at inception. Operating leases are included in ROU assets and liabilities. The Company's leases have remaining lease terms of less than one year to approximately 10 years. Most leases included one or more options to renew, with renewal terms that can extend the lease term up to five years. For a discussion of lessor activities, refer to Note 13, "Revenue recognition".

The components of lease expense were as follows:

	Year Ended December 31,		
	2023	2022	2021
Operating lease cost:			
Amortization of right-of-use assets	\$ 4.0	\$ 5.6	\$ 5.6
Interest on lease liabilities	0.8	1.1	1.3
<b>Total operating lease cost</b>	<b>\$ 4.8</b>	<b>\$ 6.7</b>	<b>\$ 6.9</b>

Operating lease costs are reflected as components of "Cost of Commercial Product sales", "Cost of MCM Product sales", "Cost of Bioservices", "R&D" expense and "Selling, general and administrative" expense on the Company's Consolidated Statements of Operations.

Supplemental balance sheet information related to leases was as follows:

Leases	Classification	December 31,	
		2023	2022
Operating lease right-of-use assets	Other assets	\$ 16.2	\$ 19.4
Operating lease liabilities, current portion	Other current liabilities	\$ 3.5	\$ 5.8
Operating lease liabilities	Other liabilities	13.8	14.8
<b>Total operating lease liabilities</b>		<b>\$ 17.3</b>	<b>\$ 20.6</b>

Operating leases:		
Weighted average remaining lease term (years)		6.2
Weighted average discount rate		5.3 %

The maturity analysis below summarizes future undiscounted cash flows for our operating leases as of December 31, 2023:

Year	As of December 31, 2023
2024	\$ 4.3
2025	3.7
2026	2.9
2027	2.3
2028	2.0
Thereafter	5.2
<b>Total undiscounted lease liabilities</b>	<b>20.4</b>
Less: Imputed interest	3.1
<b>Total lease liabilities</b>	<b>\$ 17.3</b>

## 15. 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, 2023, 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 an additional valuation allowance of \$192.7 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 years ended December 31, 2023, 2022 and 2021. BEAT provisions do not have material impact on the consolidated financial statements.

For the year ended December 31, 2023, 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 \$5.5 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,		
	2023	2022	2021
Current			
Federal	\$ (0.6)	\$ (9.4)	\$ (3.1)
State	0.5	1.9	14.9
International	36.7	33.8	28.9
Total current	36.6	26.3	40.7
Deferred			
Federal	(2.0)	(37.7)	37.1
State	(1.2)	(3.2)	4.2
International	(4.1)	7.2	1.6
Total deferred	(7.3)	(33.7)	43.0
Income tax (benefit) provision	\$ 29.3	\$ (7.4)	\$ 83.7

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

	December 31,	
	2023	2022
<b>Deferred tax assets</b>		
Federal losses carryforward	\$ 58.7	\$ 14.8
State losses carryforward	38.9	13.0
R&D carryforward	21.9	18.4
Stock compensation	6.8	10.4
Foreign losses carryforward	13.9	9.1
Deferred revenue	—	2.0
Inventory reserves	12.6	10.9
Lease liability	4.3	4.7
IRC 263A capitalized costs	2.8	5.2
Capitalized R&D	35.3	27.3
IRC 163(j) Interest Limitation	26.2	7.9
Fixed assets	26.7	0.1
Intangible assets	13.8	—
Accrued compensation	2.8	0.5
Other	4.8	6.5
Gross deferred tax assets	269.5	130.8
Valuation allowance	(257.8)	(65.1)
<b>Total deferred tax assets</b>	<b>11.7</b>	<b>65.7</b>
<b>Deferred tax liabilities</b>		
Fixed assets	(2.6)	(63.7)
Intangible assets	(40.4)	(46.1)
Right-of-use asset	(4.0)	(4.5)
Foreign Withholding Tax	(5.5)	(4.7)
Prepaid expenses	(4.2)	(3.9)
Other	(2.2)	(2.5)
<b>Total deferred tax liabilities</b>	<b>(58.9)</b>	<b>(125.4)</b>
<b>Net deferred tax liabilities</b>	<b>\$ (47.2)</b>	<b>\$ (59.7)</b>

As of December 31, 2023, the Company has approximately \$279.3 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 \$243.3 million which will carryforward indefinitely, although, limited to eighty percent of taxable income annually. The Company has U.S. federal tax credit carryforwards of \$16.9 million which will expire in 2027 through 2042.

As of December 31, 2023, the Company had post-apportionment NOLs totaling approximately \$667.6 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 \$55.7 million in net operating losses from foreign jurisdictions as of December 31, 2023, which will carryforward indefinitely.

The Company's valuation allowance increased by \$192.7 million due to the Company's generation of significant losses in 2023.

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,		
	2023	2022	2021
U.S.	\$ (805.1)	\$ (442.6)	\$ 100.1
International	73.9	224.0	203.3
Earnings (losses) before taxes on income	<u>(731.2)</u>	<u>(218.6)</u>	<u>303.4</u>
Federal tax at statutory rates	\$ (153.6)	\$ (46.0)	\$ 63.5
State taxes, net of federal benefit	(52.7)	(13.5)	14.1
Impact of foreign operations	(8.5)	(7.2)	(18.7)
Change in valuation allowance	193.6	37.8	8.2
Tax credits	(0.9)	(3.5)	(4.7)
Stock compensation	6.8	4.7	(3.9)
Goodwill Impairments	23.3	1.8	8.3
Adjustment of prior year taxes	1.3	(1.8)	0.8
Transaction costs	—	—	0.1
Compensation limitation	0.3	0.7	2.9
Unrecognized tax benefit	(0.6)	(9.0)	1.2
GILTI, net	17.8	20.7	13.0
Foreign withholding tax	0.8	4.7	—
Permanent differences	1.7	3.2	(1.2)
Income tax (benefit) provision	<u>\$ 29.3</u>	<u>\$ (7.4)</u>	<u>\$ 83.7</u>

The effective annual tax rate for the years ended December 31, 2023, 2022, and 2021 was (4)%, 3% and 28%, respectively.

The effective annual tax rate of (4)% in 2023 is lower than the statutory rate primarily due to the impact of a valuation allowance charge in the U.S., state and certain Foreign Jurisdictions, goodwill impairment, GILTI, and other permanent items. This is partially offset by tax credits and favorable rates in foreign jurisdictions.

The effective annual tax rate of 3% in 2022 is lower than the statutory rate primarily due to the impact of a valuation allowance charge in the U.S., state and certain 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 28% 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. Bioservices margins, the termination of the CIADM arrangement in the U.S. and an increase in sales of NARCAN<sup>®</sup> in which a portion of the profit is attributable to a foreign subsidiary.

The total unrecognized tax benefits recorded at December 31, 2023 and 2022 of \$6.6 million and \$6.8 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, 2023, 2022 and 2021:

	Year Ended December 31,		
	2023	2022	2021
Gross unrecognized tax benefits, beginning of period	\$ 6.8	\$ 12.7	\$ 12.2
Increases (decreases) for tax positions for prior years	0.4	(1.5)	0.3
Increases for tax positions for current year	0.1	0.7	0.2
Settlements	—	—	—
Lapse of statute of limitations	(0.7)	(5.1)	—
Gross unrecognized tax benefits, end of period	\$ 6.6	\$ 6.8	\$ 12.7

The total gross unrecognized tax benefit of \$6.6 million, includes the release of \$0.7 million of liability that related to the 2019 R&D and other reserves due to a lapse of the statute of limitations during the year.

The Company includes interest and potential penalties related to unrecognized tax benefits in income tax expense. As of December 31, 2023 and 2022, the total amount of interest and penalties accrued was \$1.6 million, respectively, in each of the years. The Company recognized interest and penalty expense (benefit) in 2023, 2022 and 2021 of \$0.2 million, \$(2.1) million and \$1.1 million, respectively.

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, 2023 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 2020 and onwards remain open to examination. The Company's tax returns for Canada remain open to examination for the tax years 2015 through 2022. The Company's Irish tax returns remain open to examination for the tax years 2017 through 2022.

As of December 31, 2023, the Company's 2018 and 2020 Canadian Scientific Research and Experimental Development Claims are subject to proceedings with the Tax Court of Canada and the Company's 2021 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 through 2022 Michigan state income tax returns are under audit.

## 16. Defined benefit and 401(k) savings plan

### Define benefit pension plan

The Company historically sponsored a defined benefit pension plan covering eligible employees in Switzerland (the "Swiss Plan"), which was sold as part of our travel health business to Bavarian Nordic, as described further in Note 3, "Divestiture". Under the Swiss Plan, the Company and certain of its employees with annual earnings in excess of government determined amounts were 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 were comprised of an insurance contract that had a fair value consistent with its contract value based on the practicability exception using Level 3 inputs. The entire liability was listed as non-current because plan assets were greater than the expected benefit payments over the next year. The Company recognized pension expense related to the Swiss Plan of \$0.6 million, \$0.8 million and \$2.0 million, reflected as a component of selling, general and administrative expenses, for the years ended December 31, 2023, 2022 and 2021, respectively.

The funded status of the Swiss Plan for the years ended December 31, 2022 is as follows:

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



Components of net periodic pension cost incurred during the years ended December 31, 2023, 2022 and 2021 are as follows:

	Year Ended December 31,		
	2023 <sup>(1)</sup>	2022	2021
Service cost	\$ 0.7	\$ 1.9	\$ 2.4
Interest cost	0.3	0.1	—
Expected return on plan assets	(0.4)	(0.8)	(0.8)
Amortization of loss	—	0.1	0.6
Amortization of prior service credit	—	(0.1)	(0.2)
Settlements	—	(0.4)	—
Net periodic benefit cost	<u>\$ 0.6</u>	<u>\$ 0.8</u>	<u>\$ 2.0</u>

<sup>(1)</sup> The Swiss Plan was sold as part of our travel health business to Bavarian Nordic, as described further in Note 3, "Divestiture".

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

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

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.

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:

	December 31, 2022
Net actuarial gain	\$ 9.0
Prior service cost	(0.3)
Total recognized in other comprehensive income (loss)	<u>\$ 8.7</u>

There were no future benefits expected to be paid as of December 31, 2023.

#### 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, 2023, 2022 and 2021, the Company made matching contributions of approximately \$8.3 million, \$8.8 million and \$8.9 million, respectively.

#### 17. Purchase commitments

We enter into agreements in the normal course of business with vendors for raw materials and other goods or services. 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. Purchase commitments exclude agreements that are cancellable without penalty.

As of December 31, 2023, the Company has approximately \$526.9 million of purchase commitments associated with raw materials and Bioservices that will be purchased in the next five years, of which the Company estimates that approximately \$117.0 million will be purchased within the next year. For the years ended December 31, 2023, 2022, and 2021, the Company purchased \$107.8 million, \$199.6 million and \$110.7 million, respectively, of materials and services under these commitments.

## 18. Segment information

In the fourth quarter of 2023, we realigned our reportable operating segments to reflect recent changes in our internal operating and reporting process. The revised reporting structure reflects the internal reporting and review process used by our CODM for making decisions and assessing performance and is consistent with how we currently manage the business. We now manage our business with a focus on three reportable segments. Our Commercial Products segment, which includes NARCAN<sup>®</sup> products and other commercial products which were sold as part of our travel health business in the second quarter of 2023 (see Note 3, "Divestiture" for more information on the sale of the travel health business), our MCM Products segment, which includes the Anthrax - MCM products, Smallpox - MCM products and Other Products, and our Services segment consisting of our Bioservices offerings.

The Company evaluates the performance of these reportable segments based on revenue and segment adjusted gross margin, which is a non-GAAP financial measure. Segment revenue includes external customer sales, but it does not include inter-segment services. We define segment adjusted gross margin, as segment gross margin excluding the impact of restructuring costs and non-cash items related to changes in fair value of contingent consideration and inventory step-up provision. We define total segment adjusted gross margin, which is a non-GAAP financial measure, as total segment gross margin, excluding the impact of restructuring costs, inventory step-up provision and the 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 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.

For all tables presented below, the prior period disclosures have been recast to conform to the current period segment presentation.

The following table presents segment revenues, segment cost of sales or services, segment gross margin, segment gross margin % and total segment adjusted gross margin for each of our reportable segments for the years ended December 31, 2023, 2022, and 2021:

	Year Ended December 31,		
	2023	2022	2021
<b>Revenues:</b>			
Commercial Products	\$ 497.3	\$ 386.6	\$ 438.0
MCM Products	447.2	579.6	585.9
Services <sup>(1)</sup>	78.5	109.9	615.5
<b>Segment revenues</b>	<b>1,023.0</b>	<b>1,076.1</b>	<b>1,639.4</b>
Contracts and grants revenue	26.3	41.4	134.2
<b>Total revenues</b>	<b>\$ 1,049.3</b>	<b>\$ 1,117.5</b>	<b>\$ 1,773.6</b>
<b>Cost of sales or services:</b>			
Cost of Commercial Products	\$ 210.3	\$ 160.3	\$ 187.2
Cost of MCM Products	305.6	264.3	195.4
Cost of Services	189.5	268.5	365.5
<b>Total cost of sales or services</b>	<b>\$ 705.4</b>	<b>\$ 693.1</b>	<b>\$ 748.1</b>
<b>Gross margin</b>			
Commercial Products	\$ 287.0	\$ 226.3	\$ 250.8
MCM Products	141.6	315.3	390.5
Services <sup>(1)</sup>	(111.0)	(158.6)	250.0
<b>Total segment gross margin <sup>(2)</sup></b>	<b>\$ 317.6</b>	<b>\$ 383.0</b>	<b>\$ 891.3</b>
<b>Gross margin %</b>			
Commercial Products	58 %	59 %	57 %
MCM Products	32 %	54 %	67 %
Services <sup>(1)</sup>	(141)%	(144)%	41 %
Total Segment	31 %	36 %	54 %
<b>Segment adjusted gross margin</b>			
Commercial Products	\$ 287.0	\$ 226.3	\$ 250.8
MCM Products	151.3	369.3	393.4
Services <sup>(1)</sup>	(102.6)	(158.6)	250.0
<b>Total segment adjusted gross margin</b>	<b>\$ 335.7</b>	<b>\$ 437.0</b>	<b>\$ 894.2</b>

<sup>(1)</sup> Services revenue, Services gross margin and Services segment adjusted gross margin for the year ended December 31, 2021 includes the impact of \$243.1 million of Bioservices leases revenues related to the BARDA COVID-19 Development Public Private Partnership which ended in November 2021.

<sup>(2)</sup> Segment revenues less total cost of sales or services.

The following table provides a reconciliation of the Company's total segment adjusted gross margin to the Consolidated Statement of Operations:

	Year Ended December 31,		
	2023	2022	2021
<b>Total segment adjusted gross margin</b>	\$ 335.7	\$ 437.0	\$ 894.2
<b>Reconciling items:</b>			
Contracts and grants revenue	\$ 26.3	\$ 41.4	\$ 134.2
Segment restructuring costs	(14.0)	—	—
Segment inventory step-up provision	(3.9)	(51.4)	—
Changes in fair value of contingent consideration	(0.2)	(2.6)	(2.9)
Impairment of long-lived assets	(306.7)	—	—
Research and development	(111.4)	(188.3)	(235.2)
Selling, general and administrative	(368.4)	(339.5)	(348.7)
Goodwill impairment	(218.2)	(6.7)	(41.7)
Amortization of intangible assets	(65.6)	(59.9)	(58.5)
Interest expense	(87.9)	(37.3)	(34.5)
Gain on sale of business	74.2	—	—
Other, net	8.9	(11.7)	(3.7)
<b>Income (loss) before income taxes</b>	\$ (731.2)	\$ (219.0)	\$ 303.2

The following table includes depreciation expense for each segment:

	Year Ended December 31,		
	2023	2022	2021
<b>Depreciation:</b>			
Commercial Products	\$ 0.3	\$ 3.2	\$ 3.1
MCM Products	22.8	29.7	24.7
Services	22.5	43.2	28.3
Other	13.9	7.3	6.1
<b>Total</b>	\$ 59.5	\$ 83.4	\$ 62.2

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

	Year Ended December 31,		
	2023	2022	2021
<b>Revenue:</b>			
United States	\$ 607.2	\$ 886.1	\$ 1,623.4
Canada	224.2	148.6	66.7
Other	217.9	82.8	83.5
<b>Total revenues</b>	\$ 1,049.3	\$ 1,117.5	\$ 1,773.6

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

	December 31,	
	2023	2022
<b>Long-lived assets, net:</b>		
United States	\$ 352.3	\$ 696.1
Switzerland	—	88.1
Canada	37.2	37.5
Other	2.9	5.0
<b>Total long-lived assets, net</b>	\$ 392.4	\$ 826.7

## 19. 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 (the "Lead Plaintiffs") 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 Plaintiffs filed an opposition to that motion on July 19, 2022. A hearing on the motion to dismiss was conducted on April 19, 2023 and an order was entered on September 1, 2023, granting in part and denying in part the motion to dismiss. The defendant's answer to the complaint was filed on October 30, 2023. 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, and on November 2, 2023, the Court approved the parties' joint stipulation to extend the stay of the proceedings and discovery until the close of fact discovery in the Federal Securities Class Action.

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.

## 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 interim chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. 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, 2023, our interim chief executive officer and chief financial officer concluded that, as of such date, that the disclosure controls and procedures were effective at the reasonable assurance level.

### Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. 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. Our system of 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. 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, 2023. 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, 2023, our internal control over financial reporting was effective based on those criteria.

Ernst & Young LLP, the independent registered public accounting firm that has audited our consolidated financial statements included herein, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2023, a copy of which is included in this Annual Report on Form 10-K.

### Changes in Internal Control Over Financial Reporting

During the quarter ended September 30, 2023, a material weakness was identified related to the design of our controls associated with the review of the calculation of our state deferred tax assets and liabilities and the operating effectiveness of the controls associated with the review of the valuation allowance calculation and included in Amendment No. 1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

To remediate the material weakness and as part of our commitment to strengthening our internal control over financial reporting, we enhanced and revised the design of existing controls and procedures to properly assess the state income taxes issue.

During the quarter ended December 31, 2023, we successfully completed the testing necessary to conclude that the material weakness has been remediated.

Except those 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, 2023 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, 2023, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Emergent BioSolutions Inc. and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, 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, 2023, and the related notes and financial statement schedule listed in the Index at Item 15 and our report dated March 8, 2024, expressed an unqualified opinion thereon 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 8, 2024



**ITEM 9B. OTHER INFORMATION**

During the three months ended December 31, 2023, none of the Company's directors or Section 16 reporting officers adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

**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](http://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 nor 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 2024 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 2024 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 2024 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 2024 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 2024 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, 2023 and 2022
- Consolidated Statements of Operations for the years ended December 31, 2023, 2022 and 2021
- Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2023, 2022 and 2021
- Consolidated Statements of Cash Flows for the years ended December 31, 2023, 2022 and 2021
- Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2023, 2022 and 2021
- Notes to Consolidated Financial Statements

Financial Statement Schedules

Schedule II - Valuation and Qualifying Accounts for the years ended December 31, 2023, 2022 and 2021 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

<i>(in millions)</i>	Beginning Balance	Charged to Costs and Expenses	Deductions	Ending Balance
<b>Year Ended December 31, 2023</b>				
Prepaid expenses and other current assets allowance	\$ 7.1	0.8	(0.4)	\$ 7.5
<b>Year Ended December 31, 2022</b>				
Prepaid expenses and other current assets allowance	\$ 3.7	3.9	(0.5)	\$ 7.1
<b>Year Ended December 31, 2021</b>				
Prepaid expenses and other current assets allowance	\$ 3.9	0.2	(0.4)	\$ 3.7

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	<a href="#">Third Restated Certificate of Incorporation of the Company</a> (incorporated by reference to Exhibit 3 to the Company's Quarterly Report on Form 10-Q filed on August 5, 2016).
3.2	<a href="#">Amended and Restated By-laws of the Company</a> (incorporated by reference to Exhibit 3 to the Company's Current Report on Form 8-K filed on August 16, 2012).
4.1	<a href="#">Specimen Common Stock Certificate</a> (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	<a href="#">Registration Rights Agreement, dated as of September 22, 2006, among the Company and the stockholders listed on Schedule 1 thereto</a> (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	<a href="#">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.</a> (incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
4.4	<a href="#">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</a> (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 29, 2014).
4.5	<a href="#">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.)</a> (incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
4.6	<a href="#">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.)</a> (incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
4.7	<a href="#">Description of the Company's Securities</a> (incorporated by reference to Exhibit 4.6 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.1	<a href="#">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</a> (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K, filed on October 15, 2018).
10.2	<a href="#">First Amendment to Amended and Restated Credit Agreement, dated June 27, 2019</a> (incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.3	<a href="#">Second Amendment to Amended and Restated Credit Agreement, dated August 7, 2020</a> (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on August 7, 2020).
10.4	* <a href="#">Consent, Limited Waiver, and Third Amendment to the Amended and Restated Credit Agreement, dated February 14, 2023</a> (incorporated by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K, filed on March 1, 2023).
10.5	†† <a href="#">Fourth Amendment to Amended and Restated Credit Agreement, Waiver and First Amendment to Amended and Restated Collateral Agreement, dated May 15, 2023</a> (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on May 18, 2023).
10.6	# <a href="#">Fifth Amendment to Amended and Restated Credit Agreement, dated July 14, 2023</a>
10.7	†† <a href="#">Forbearance Agreement and Sixth Amendment to Amended and Restated Credit Agreement, dated February 29, 2024</a> (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed March 6, 2024)
10.8	* <a href="#">Emergent BioSolutions Inc. 2006 Stock Incentive Plan</a> (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).
10.9	* <a href="#">Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan</a> (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 7, 2009).
10.10	* <a href="#">Second Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan</a> (incorporated by reference to Appendix A to the Company's definitive proxy statement on Schedule 14A filed on April 6, 2012).
10.11	* <a href="#">Third Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan</a> (incorporated by reference to Appendix A to the Company's definitive proxy statement on Schedule 14A filed on April 7, 2014).

Exhibit Number	Exhibit Description
10.12	* <a href="#">Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan</a> (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 5, 2016).
10.13	* <a href="#">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</a> (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K filed on March 1, 2023).
10.14	* <a href="#">Emergent BioSolutions Inc. Stock Incentive Plan</a> (incorporated by reference to Exhibit 99 to Registration Statement on Form S-8, filed on May 30, 2018).
10.15	* <a href="#">Emergent BioSolutions Inc. Amended and Restated Stock Incentive Plan</a> (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-8, filed on June 5, 2023).
10.16	* <a href="#">Emergent BioSolutions Inc. Amended Employee Stock Purchase Plan</a> (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form S-8, filed on June 5, 2023).
10.17	* <a href="#">Equity Distribution Agreement, dated May 17, 2023</a> (incorporated by reference to Exhibit 10.2 to the 8-K filed on May 18, 2023).
10.18	* <a href="#">Consulting Agreement, dated as of July 7, 2023 and effective as of July 7, 2023, by and between Emergent BioSolutions Inc. and Haywood Miller</a> (incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q filed on August 8, 2023).
10.19	** <a href="#">Executive Agreement, dated February 19, 2024 between Emergent BioSolutions Inc. and Joseph Papa</a> (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 21, 2024).
10.20	* <a href="#">Form of Letter Agreement, dated July 26, 2023</a> (incorporated by reference to Exhibit 99.1 to the 8-K filed on July 27, 2023).
10.21	* <a href="#">Form of Director Nonstatutory Stock Option Agreement</a> (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.22	* <a href="#">Form of Director Restricted Stock Unit Agreement</a> (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.23	* <a href="#">Global Form of Restricted Stock Unit Award Agreement</a> (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.24	* <a href="#">Global Form of Non-Qualified Stock Option Agreement</a> (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.25	* <a href="#">Form of 2019-2021 Performance-Based Stock Unit Award Agreement</a> (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 12, 2019).
10.26	* <a href="#">Form of 2020-2022 Performance-Based Stock Unit Award Agreement</a> (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 18, 2020).
10.27	* <a href="#">Form of 2021-2023 Performance-Based Stock Unit Award Agreement</a> (incorporated by reference to Exhibit 99 to the Company's Current Report on Form 8-K filed on February 16, 2021).
10.28	††* <a href="#">Form of 2022-2024 Performance-Based Stock Unit Award Agreement</a> (incorporated by reference to Exhibit 10 to Current Report on Form 8-K filed on February 22, 2022).
10.29	††* <a href="#">Form of 2023-2025 Performance Based Stock Unit Award Agreement</a> (incorporated by reference to Exhibit 10 to Current Report on Form 8-K filed on March 23, 2023).
10.30	* <a href="#">Emergent BioSolutions Inc. Inducement Plan</a> (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed on December 11, 2023).
10.31	* <a href="#">Form of Indemnity Agreement for Directors and Senior Officers</a> (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on January 18, 2013).
10.32	* <a href="#">Annual Bonus Plan for Executive Officers</a> (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on March 5, 2010).
10.33	* <a href="#">Amended and Restated Senior Management Severance Plan</a> (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 22, 2011).
10.34	* <a href="#">Second Amended and Restated Senior Management Severance Plan</a> (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on July 16, 2015).
10.35	† <a href="#">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</a> (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K, filed on February 28, 2017).
10.36	<a href="#">Modification No. 1, effective January 27, 2017, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.37	† <a href="#">Modification No. 2, effective February 23, 2017, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K filed on February 23, 2018).

Exhibit Number	Exhibit Description
10.38	<a href="#">Modification No. 3, effective March 22, 2017, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.39	† <a href="#">Modification No. 4, effective April 5, 2017, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.40	† <a href="#">Modification No. 5, effective September 8, 2017, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 3, 2017).
10.41	† <a href="#">Modification No. 6, effective September 21, 2017, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.42	† <a href="#">Modification No. 7, effective February 26, 2018, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 4, 2018).
10.43	<a href="#">Modification No. 8, effective March 6, 2018, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.44	† <a href="#">Modification No. 9, effective June 6, 2018, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.45	† <a href="#">Modification No. 10, effective June 18, 2018, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.46	† <a href="#">Modification No. 11, effective June 20, 2018, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.47	† <a href="#">Modification No. 12, effective June 21, 2018, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.48	† <a href="#">Modification No. 13, effective September 21, 2018 to the CDC BioThrax Procurement</a> (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 2, 2018).
10.49	† <a href="#">Modification No. 14, effective October 1, 2018, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.50	† <a href="#">Modification No. 15, effective December 7, 2018, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.46 to the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.51	† <a href="#">Modification No. 16, effective January 14, 2019, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.47 to the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.52	†† <a href="#">Modification No. 17, effective June 13, 2019, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 2, 2019).
10.53	†† <a href="#">Modification No. 18, effective September 11, 2019, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.54	†† <a href="#">Modification No. 19, effective January 6, 2020, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.40 to the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.55	†† <a href="#">Modification No. 20, effective January 7, 2020, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.41 to the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.56	†† <a href="#">Modification No. 21, effective January 7, 2020, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.57	†† <a href="#">Modification No. 22 to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.46 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.58	†† <a href="#">Modification No. 23, effective September 30, 2020, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.47 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.59	†† <a href="#">Modification No. 24, effective February 2, 2021, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021).
10.60	†† <a href="#">Modification No. 25, effective September 29, 2021, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021).
10.61	†† <a href="#">Modification No. 26, effective November 1, 2021, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.48 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.62	† <a href="#">Modification No. 27, effective March 31, 2022, to the CDC BioThrax Procurement Contract</a> (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
10.63	†	<a href="#">Modification No. 28, effective April 14, 2022, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 2, 2022).
10.64	†	<a href="#">Modification No. 29, effective June 16, 2022, to the CDC BioThrax Procurement Contract</a> (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 2, 2022).
10.65	†	<a href="#">Award/Contract (the BARDA AV7909 Contract), effective September 30, 2016, from the BioMedical Advanced Research and Development Authority to Emergent Product Development Gaithersburg Inc.</a> (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2016).
10.66	†	<a href="#">Modification No. 1, effective March 16, 2017, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021).
10.67	†	<a href="#">Modification No. 2, effective August 29, 2018, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021).
10.68	††	<a href="#">Modification No. 3, effective July 30, 2019, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2019).
10.69	††	<a href="#">Modification No. 4, effective March 3, 2020, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 1, 2020).
10.70	††	<a href="#">Modification No. 5, effective April 10, 2020, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 1, 2020).
10.71	††	<a href="#">Modification No. 6, effective July 13, 2020, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.72	††	<a href="#">Modification No. 7, effective December 2, 2020, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.73	††	<a href="#">Modification No. 8, effective March 22, 2021, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.74	††	<a href="#">Modification No. 9, effective April 21, 2021, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.75	††	<a href="#">Modification No. 10, effective June 10, 2021 to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.76	††	<a href="#">Modification No. 11, effective September 30, 2021, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021).
10.77	††	<a href="#">Modification No. 12, effective December 2, 2021, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.61 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.78	††	<a href="#">Modification No. 13, effective March 30, 2023, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2023).
10.79	††	<a href="#">Modification No. 14, effective March 30, 2023, to the BARDA AV7909 Contract</a> (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2023).
10.80	# †	<a href="#">Modification No. 15, effective October 6, 2023, to the BARDA AV7909 Contract.</a>
10.81	# †	<a href="#">Modification No. 16, effective November 21, 2023, to the BARDA AV7909 Contract.</a>
10.82	†	<a href="#">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</a> (incorporated by reference to Exhibit 10.51 the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.83	†	<a href="#">Amendment No. 1 to License Agreement, dated as of December 13, 2016, by and between Opiant Pharmaceuticals, Inc. and Adapt Pharma Operations Limited</a> (incorporated by reference to Exhibit 10.52 the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.84		<a href="#">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</a> (incorporated by reference to Exhibit 10.1 the Company's Quarterly Report on Form 10-Q filed on May 8, 2019).
10.85	††	<a href="#">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.</a> (incorporated by reference to Exhibit 10.48 the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.86	††	<a href="#">Modification No. 1, effective May 28, 2020 to the ACAM2000 Contract</a> (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).
10.87	††	<a href="#">Modification No. 2, effective October 28, 2020 to the ACAM2000 Contract</a> (incorporated by reference to Exhibit 10.60 the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.88	††	<a href="#">Modification No. 3, effective April 1, 2021 to the ACAM2000 Contract</a> (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).

Exhibit Number	Exhibit Description
10.89	†† <a href="#">Modification No. 4, effective July 13, 2021 to the ACAM2000 Contract</a> (incorporated by reference to Exhibit 10.69 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.90	†† <a href="#">Modification No. 5, effective September 29, 2021 to the ACAM2000 Contract</a> (incorporated by reference to Exhibit 10.70 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.91	†† <a href="#">Modification No. 6, effective November 1, 2021 to the ACAM2000 Contract</a> (incorporated by reference to Exhibit 10.71 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.92	# <a href="#">Modification No. 7, effective October 6, 2022, to the ACAM2000 Contract.</a>
10.93	# † <a href="#">Modification No. 8, effective November 21, 2022, to the ACAM2000 Contract.</a>
10.94	† <a href="#">Modification No. 9, effective May 24, 2023, to the ACAM2000 Contract</a> (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2023).
10.95	† <a href="#">Modification No. 10, effective May 26, 2023, to the ACAM2000 Contract</a> (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2023).
10.96	† <a href="#">Award/Contract, effective June 15, 2012 (BARDA ADM Contract), from the BioMedical Advance Research and Development Authority to Emergent Manufacturing Operations Baltimore LLC</a> (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).
10.97	†† <a href="#">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)</a> (incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.98	†† <a href="#">Modification No. 1, effective April 12, 2021, to Task Order 75A50120F33006</a> (incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.99	†† <a href="#">Modification No. 3, effective October 1, 2021, to Task Order 75A50120F33006</a> (incorporated by reference to Exhibit 10.75 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.100	†† <a href="#">Modification No. 4, effective November 1, 2021, to Task Order 75A50120F33006</a> (incorporated by reference to Exhibit 10.76 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.101	†† <a href="#">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)</a> (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).
10.102	†† <a href="#">Modification No. 1, effective August 24, 2020, to Task Order 75A50120F33007</a> (incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.103	†† <a href="#">Modification No. 2, effective September 18, 2020, to Task Order 75A50120F33007</a> (incorporated by reference to Exhibit 10.64 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.104	†† <a href="#">Modification No. 3, effective October 7, 2020, to Task Order 75A50120F33007</a> (incorporated by reference to Exhibit 10.65 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.105	†† <a href="#">Modification No. 4, effective January 29, 2021, to Task Order 75A50120F33007</a> (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.106	†† <a href="#">Modification No. 5, effective February 22, 2021, to Task Order 75A50120F33007</a> (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.107	†† <a href="#">Modification No. 6, effective March 24, 2021, to Task Order 75A50120F33007</a> (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.108	†† <a href="#">Modification No. 7, effective May 24, 2021, to Task Order 75A50120F33007</a> (incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.109	†† <a href="#">Modification No. 8, effective November 1, 2021, to Task Order 75A50120F33007</a> (incorporated by reference to Exhibit 10.85 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.110	†† <a href="#">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)</a> (incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.111	†† <a href="#">Modification No. 1, effective August 24, 2020, to Task Order 75A50120F33008</a> (incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.112	†† <a href="#">Modification No. 2, effective November 17, 2020, to Task Order 75A50120F33008</a> (incorporated by reference to Exhibit 10.68 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.113	†† <a href="#">Modification No. 19, effective May 25, 2020, to the BARDA ADM Contract</a> (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).
10.114	†† <a href="#">Modification No. 20, effective May 26, 2020, to the BARDA ADM Contract</a> (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).

Exhibit Number	Exhibit Description
10.115	†† <a href="#">Modification No. 21, effective June 12, 2020 to the BARDA ADM Contract</a> (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.116	†† <a href="#">Modification No. 22, effective June 12, 2020 to the BARDA ADM Contract</a> (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.117	†† <a href="#">Modification No. 23, effective July 22, 2020 to the BARDA ADM Contract</a> (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.118	†† <a href="#">Modification No. 24, effective August 28, 2020 to the BARDA ADM Contract</a> (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.119	†† <a href="#">Modification No. 25, effective September 23, 2020 to the BARDA ADM Contract</a> (incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.200	†† <a href="#">Modification No. 26, effective November 2, 2020 to the BARDA ADM Contract</a> (incorporated by reference to Exhibit 10.77 the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.201	†† <a href="#">Modification No. 27, effective May 6, 2021, to the BARDA ADM Contract</a> (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.202	†† <a href="#">Modification No. 28, effective May 27, 2021, to the BARDA ADM Contract</a> (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.203	†† <a href="#">Modification No. 30, effective September 30, 2021, to the BARDA ADM Contract</a> (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021).
10.204	†† <a href="#">Modification No. 31, effective October 20, 2021, to the BARDA ADM Contract</a> (incorporated by reference to Exhibit 10.100 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.205	†† <a href="#">Modification No. 32, effective November 1, 2021, to the BARDA ADM Contract</a> , (incorporated by reference to Exhibit 10.101 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.206	†† <a href="#">Master Services Agreement, dated July 24, 2020, by and between Emergent Manufacturing Operations Baltimore, LLC and AstraZeneca Pharmaceuticals LP</a> , (AZ MSA) (incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.207	†† <a href="#">Manufacturing Product Schedule, dated July 26, 2020 to AZ MSA</a> (incorporated by reference to Exhibit 10.13 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.208	†† <a href="#">Work Order to Manufacturing Services Agreement, dated June 10, 2020, between Emergent Manufacturing Operations Baltimore, LLC and AstraZeneca Pharmaceuticals LP</a> (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).
10.209	†† <a href="#">Amendment No. 1, effective September 30, 2020, to AZ MSA</a> (incorporated by reference to Exhibit 10.15 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.210	†† <a href="#">Amendment No. 2, effective October 30, 2020, to AZ MSA</a> (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.211	†† <a href="#">Amendment No. 3, effective November 25, 2020, to AZ MSA</a> (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.212	†† <a href="#">Amendment No. 4, effective January 21, 2021, to AZ MSA</a> (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.213	†† <a href="#">Change Order No. 1 to Work Order #5997-01, effective July 31, 2020, to AZ MSA</a> (incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.214	†† <a href="#">Change Order No. 2 to Work Order #5997-01, effective August 04, 2020, to AZ MSA</a> (incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.215	†† <a href="#">Change Order No. 4 to Work Order #5997-01, effective November 17, 2020, to AZ MSA</a> (incorporated by reference to Exhibit 10.13 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.216	†† <a href="#">Change Order No. 5 to Work Order #5997-01, effective September 16, 2020, to AZ MSA</a> (incorporated by reference to Exhibit 10.14 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.217	†† <a href="#">Change Order No. 6 to Work Order #5997-01, effective October 13, 2020, to AZ MSA</a> (incorporated by reference to Exhibit 10.15 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.218	†† <a href="#">Change Order No. 10 to Work Order #5997-01, effective March 10, 2021, to AZ MSA</a> (incorporated by reference to Exhibit 10.16 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.219	†† <a href="#">Change Order No. 13 to Work Order #5997-01, effective April 23, 2021, to AZ MSA</a> (incorporated by reference to Exhibit 10.17 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.220	†† <a href="#">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 &amp; Johnson</a> (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
10.221	†† <a href="#">Amendment No. 1, effective February 25, 2021, to INJ MSA</a> (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.222	† <a href="#">Asset Purchase Agreement, dated May 15, 2022, by and among Emergent BioSolutions Inc., the Sellers identified therein, Chimerix, Inc.</a> , (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on May 16, 2022).
10.223	†† <a href="#">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</a> (incorporated by reference to Exhibit 10.204 to the Company's Annual Report on Form 10-K filed on March 1, 2023).
10.224	# <a href="#">Emergent BioSolutions Compensation Recovery Policy, effective October 26, 2023.</a>
21	# <a href="#">Subsidiaries of the Company.</a>
23	# <a href="#">Consent of Independent Registered Public Accounting Firm.</a>
31.1	# <a href="#">Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).</a>
31.2	# <a href="#">Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).</a>
32.1	# <a href="#">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.</a>
32.2	# <a href="#">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.</a>
#	The following financial information related to the Company's Annual Report on Form 10-K for the year ended December 31, 2023, 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 (Loss), (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.
#	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 8, 2024

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
<u>/s/Joseph C. Papa</u> Joseph C. Papa	President, Chief Executive Officer and Director (Principal Executive Officer)	March 8, 2024
<u>/s/Richard S. Lindahl</u> Richard S. Lindahl	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 8, 2024
<u>/s/Zsolt Harsanyi, Ph.D.</u> Zsolt Harsanyi, Ph.D.	Director	March 8, 2024
<u>/s/Kathryn Zoon, Ph.D.</u> Kathryn Zoon, Ph.D.	Director	March 8, 2024
<u>/s/Ronald B. Richard</u> Ronald B. Richard	Director	March 8, 2024
<u>/s/Louis W. Sullivan, M.D.</u> Louis W. Sullivan, M.D.	Director	March 8, 2024
<u>/s/Don DeGolyer</u> Don DeGolyer	Director	March 8, 2024
<u>/s/Neal Fowler</u> Neal Fowler	Director	March 8, 2024
<u>/s/Marvin White</u> Marvin White	Director	March 8, 2024
<u>/s/Sujata Dayal</u> Sujata Dayal	Director	March 8, 2024
<u>/s/Keith Katkin</u> Keith Katkin	Director	March 8, 2024

**FIFTH AMENDMENT TO AMENDED AND RESTATED CREDIT AGREEMENT**

FIFTH AMENDMENT TO AMENDED AND RESTATED CREDIT AGREEMENT (this "Amendment"), dated as of July 14, 2023, among EMERGENT BIOSOLUTIONS INC., a Delaware corporation (the "Borrower") and WELLS FARGO BANK, NATIONAL ASSOCIATION, as administrative agent (the "Administrative Agent"). Unless otherwise indicated, all capitalized terms used herein and not otherwise defined herein shall have the respective meanings provided such terms in the Credit Agreement referred to below.

## WITNESSETH:

WHEREAS, the Borrower, the lenders party thereto from time to time (the "Lenders") and the Administrative Agent have entered into that certain Amended and Restated Credit Agreement, dated as of October 15, 2018 (as amended by the First Amendment to Amended and Restated Credit Agreement dated as of June 27, 2019, as further amended by the Second Amendment to Amended and Restated Credit Agreement dated as of August 7, 2020, as further amended by the Consent, Limited Waiver, Third Amendment to Amended and Restated Credit Agreement dated as of February 14, 2023, and as further amended by the Fourth Amendment to Amended and Restated Credit Agreement, Waiver and First Amendment to Amended and Restated Collateral Agreement dated as of May 15, 2023, and as may further be amended, restated, amended and restated, supplemented or otherwise modified prior to the date hereof, including as amended by this Amendment, the "Credit Agreement");

WHEREAS, pursuant to Section 12.2 of the Credit Agreement, the Administrative Agent and the Borrower are permitted to amend any provision of the Loan Documents (and such amendment shall become effective without any further action or consent of any other party to any Loan Document) if the Administrative Agent and the Borrower shall have jointly identified an obvious error or any error, ambiguity, defect or inconsistency or omission of a technical or immaterial nature in any such provisions;

WHEREAS, the Borrower and the Administrative Agent have jointly identified an obvious error resulting from an omission of a technical nature in the Credit Agreement; and

WHEREAS, the parties hereto have agreed to the amendments to the Credit Agreement set forth in Section 1 hereof.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration set forth herein, the parties hereto agree that the Credit Agreement is amended as follows:

SECTION 1. Amendment to Credit Agreement. Subject to and in accordance with the terms and conditions set forth herein, the parties hereto agree that the Credit Agreement is amended as follows:

(a) The definition of "Applicable Margin" in Section 1.1 of the Credit Agreement is hereby amended by amending and restating the introductory paragraph thereof in its entirety to read as follows:

*"Applicable Margin" means (a) from the Fourth Amendment Effective Date through the later of March 31, 2024 and the first Calculation Date occurring after December 31, 2023, (i) 5.00% per annum with respect to Base Rate Loans, (ii) 6.00% per annum with respect to SOFR Loans, Daily Simple SONIA Loans and Eurocurrency Rate Loans, and (iii) 0.40% with respect to Commitment Fees, and (b) thereafter, the corresponding percentages per annum as set forth below based on the Consolidated Leverage Ratio calculated as of the last day of the most recently ended fiscal quarter of the Borrower preceding the applicable Calculation Date:"*

(b) The definition of “Applicable Margin” in Section 1.1 of the Credit Agreement is hereby further amended by amending and restating the headers in the pricing grid set forth therein to read as follows:

<i>Pricing Level</i>	<i>Consolidated Leverage Ratio</i>	<i>Commitment Fee</i>	<i>Eurocurrency Rate, Adjusted Term SOFR or Adjusted Daily Simple SONIA +</i>	<i>Base Rate +</i>
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SECTION 2. Conditions of Effectiveness of Amendment. This Amendment, and the amendments set forth in Section 1 above, shall become effective on the date (such date, the “Amendment Effective Date”) when the Administrative Agent shall have received this Amendment, duly executed by a Responsible Officer of the Borrower and the Administrative Agent.

SECTION 3. Reference to and Effect on the Credit Agreement and the Loan Documents. Except as expressly provided herein, the Credit Agreement and the other Loan Documents shall remain unmodified and in full force and effect. This Amendment shall not be deemed (a) to be a waiver of, or consent to, or a modification or amendment of, any other term or condition of the Credit Agreement or any other Loan Document other than as expressly set forth herein, (b) to prejudice any right or rights which the Administrative Agent or the Lenders may now have or may have in the future under or in connection with the Credit Agreement or the other Loan Documents or any of the instruments or agreements referred to therein, as the same may be amended, restated, supplemented or modified from time to time, or (c) to be a commitment or any other undertaking or expression of any willingness to engage in any further discussion with the Borrower, any of its Subsidiaries or any other Person with respect to any other waiver, amendment, modification or any other change to the Credit Agreement or the Loan Documents or any rights or remedies arising in favor of the Lenders or the Administrative Agent, or any of them, under or with respect to any such documents. References in the Credit Agreement to “this Agreement” (and indirect references such as “hereunder”, “hereby”, “herein”, “hereof” or other words of like import) and in any Loan Document to the “Credit Agreement” shall be deemed to be references to the Credit Agreement as modified hereby.

SECTION 4. Costs and Expenses. The Borrower hereby reconfirms its obligations pursuant to Section 12.3(a) of the Credit Agreement to pay and reimburse the Administrative Agent in accordance with the terms thereof.

SECTION 5. Governing Law. THIS AMENDMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

SECTION 6. Counterparts. This Amendment may be executed in any number of counterparts and by the different parties hereto on separate counterparts, each of which counterparts when executed and delivered shall be an original, but all of which shall together constitute one and the same instrument. Delivery by facsimile or electronic transmission of an executed counterpart of a signature page to this Amendment shall be effective as delivery of an original executed counterpart of this Amendment.


SECTION 7. Entire Agreement. This Amendment is the entire agreement, and supersedes any prior agreements and contemporaneous oral agreements, of the parties concerning its subject matter. This Amendment is a Loan Document and is subject to the terms and conditions of the Credit Agreement.

SECTION 8. Successors and Assigns. This Amendment shall be binding on and inure to the benefit of the parties hereto and their successors and permitted assigns.


[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized officers to execute and deliver this Amendment as of the date first above written.

EMERGENT BIOSOLUTIONS INC., as Borrower

By:  \_\_\_\_\_  
Name: Richard S. Lindahl  
Title: Executive Vice President, Chief Financial  
Officer and Treasurer

WELLS FARGO BANK, NATIONAL ASSOCIATION, as  
Administrative Agent

By:   
Name: Troy Jefferson  
Title: Senior Vice President



Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>		1. CONTRACT ID CODE	PAGE OF PAGES 1 2
2. AMENDMENT/MODIFICATION NO. P00015	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (if applicable)
6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	CODE ASPR-BARDA	7. ADMINISTERED BY (if other than Item 6) ASPR-BARDA 200 Independence Ave., S.W. Room 638-G Washington DC 20201	CODE ASPR-BARDA
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR # 100 GAITHERSBURG MD 208793419		(x) 9A. AMENDMENT OF SOLICITATION NO.	
CODE 1365869 FACILITY CODE		9B. DATED (SEE ITEM 11)	
		X 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201600030C	
		10B. DATED (SEE ITEM 13) 09/30/2016	

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended.  is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning \_\_\_\_\_ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (if required)  
See Schedule

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR Part 43.103(a) - Bilateral Modifications
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor  is not  is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: [\*\*]

UEI: [\*\*]


The purpose of this modification is to modify ARTICLE C.1. STATEMENT OF WORK, ARTICLE G.3. KEY PERSONNEL, ARTICLE F.3 DELIVERABLES, and SECTION J- LIST OF ATTACHMENTS

All other terms and conditions remain unchanged.

OTA: N

Period of Performance: 09/30/2016 to 08/31/2025

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) Kelly Warfield SVP, S&D	15C. DATE SIGNED Oct 6, 2023	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Yifan Yang - Digitally signed by Yifan Yang - S YIFAN YANG	16C. DATE SIGNED Date: 2023.10.06 13:06:03 -04'00'
15B. CONTRACTOR/OFFEROR  Electronically signed by: Kelly Warfield Reason: I approve this document Date: Oct 6, 2023 12:50 EDT (Signature of person authorized to sign)		16B. UNITED STATES OF AMERICA S (Signature of Contracting Officer)	

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)  
Prescribed by GSA FAR (48 CFR) 53.243



The purpose of this modification is to modify ARTICLE C.1. STATEMENT OF WORK, ARTICLE G.3. KEY PERSONNEL, ARTICLE F.3 DELIVERABLES, and SECTION J- LIST OF ATTACHMENTS

**ARTICLE C.1. STATEMENT OF WORK is hereby modified as follows:**

Independently and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work dated September 30, 2023, set forth in SECTION J List of Attachments, attached hereto and incorporated into this Prime Contract.

**ARTICLE G.3. KEY PERSONNEL is hereby modified as follows:**

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individuals are considered to be essential to the work being performed hereunder:

Name	Position
[ * * ]	Principal Investigator
[ * * ]	Manufacturing Operations Lead
[ * * ]	Regulatory Affairs Lead
[ * * ]	Clinical Development Lead

**ARTICLE F.3 Deliverables – Item No. 14 Earned Value Management Requirements is updated as follows:**

Item No.	Description	Addresses	Deliverable Schedule
14	Earned Value Management Requirements	CO: (1) electronic copy COR: (1) electronic copy	As detailed in Section F.2 Reporting Requirements, subpart -F. No Longer Required from the period starting 10/01/2023 onward.

**SECTION J – LIST OF ATTACHMENTS is modified as follows:**

1. Statement of Work, dated Sep 30, 2023, 10 pages

All other terms and conditions of this contract remain unchanged.

**End of Modification #15**

## **ATTACHMENT 1: STATEMENT OF WORK**

### **NEXT GENERATION ANTHRAX VACCINE RFP 16-100-SOL-0015 AV7909 Anthrax Vaccine**

#### **1.0 Contractual Statement of Work**

##### **Preamble to the Statement of Work**

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work submitted in response to RFP 16-100-SOL-00015.

##### **1.1 Scope**

The scope of work for this contract includes AV7909 development activities through licensure that fall into the following areas: program management, nonclinical, clinical, regulatory, and chemistry, manufacturing, and controls (CMC). The scope of work also includes activities to support post-marketing requirements.

##### **1.2 Objective**

The objective of this Statement of Work (SOW) is to conduct all necessary activities to advance the development of AV7909 through Biologics License Application (BLA) submission and approval and post-marketing requirements. Activities to meet the objective of this SOW fall in the following eight (8) contract line item number (CLIN):

- CLIN 0001 – Approval of Emergency Use Authorization (EUA), licensure, approval, and clearance of product through the FDA (Base)
- CLIN 0001A – Conduct of a Phase 2 clinical potency study or other studies required by the FDA for the establishment of a potency specification (Option)
- CLIN 0012 – Include doxycycline arm in the conduct of the Phase 2 clinical drug-drug interaction study and qualify a redundant contract filler (Base)
- CLIN 0002 – Initial purchase, storage, and delivery of product (Base)
- CLIN 0004 - Surge Capacity – Additional procurement of product (EUA) (Option) – [\*\*] to [\*\*]
- CLIN 0006 – Surge Capacity – Additional procurement of product (EUA) (Option) – [\*\*] to [\*\*] doses
- CLIN 0010 – Surge Capacity - Additional procurement of product (EUA) (Option) – 1[\*\*] or more doses
- CLIN 0011 – Surge Capacity - Additional procurement of product (EUA and Licensed) (Option) – up to [\*\*] doses

##### **1.3 CLIN 0001 - Approval of Emergency Use Authorization (EUA), licensure, approval, and clearance of product through the FDA (Base)**

This section identifies representative tasks and sub-tasks for CLIN 0001 with associated WBS code for each task or subtask.

##### **[\*\*] Program Management**

Emergent shall provide program management activities. The activities shall include but are not limited to:

- Identification of and management to, distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Integrated Product Development Plan.
- Establishment of and tracking of milestones and timelines for the initiation, conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- Ongoing evaluation of qualitative and quantitative criteria and accompanying data used to assess the

- scientific merit and technical feasibility of proceeding to the next stage of product development.
- Maintaining and managing staff (in-house and contracted) to assure the necessary expertise and dedicated effort to perform the work.
- Directing and overseeing subcontractors and consultants to assure successful performance of planned activities within the cost and schedule constraints of the contract.
- Conducting performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both Emergent and subcontractors on a real time basis.
- Manage contract activities in accordance with Earned Value Management. In this regard, Emergent shall:
  - Provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support product approval. The Integrated Master Project Plan shall outline key, critical path milestones, with “Go/No-Go” decision criteria and a contract Work Breakdown Structure (due within 90 days of contract award with updates as requested by the Contracting Officer’s Representative (COR).
  - Submit an updated Integrated Master Schedule in an approved format.
  - Use principles of Earned Value Management System (EVMS) in the management of this contract.
  - Submit a plan for a Performance Measurement Baseline Review (PMBR) electronically via email to the Contracting Officer (CO) and COR for a PBMR to occur within 90 days of contract award.
- Develop and maintain a risk management plan.
- Participate in regular meetings to coordinate and oversee the contracting effort.

**[\*\*] Non-Clinical Toxicology**

Emergent shall conduct safety and toxicology of AV7909 using animal models following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations, 21CFR Part 58), as appropriate. The activities shall include but are not limited to:

- [\*\*]
- [\*\*]

**[\*\*] Non-Clinical Efficacy**

Emergent shall conduct efficacy, pharmacokinetics/pharmacodynamics, bioavailability, solubility, formulation, dose, route and schedule of the medical countermeasure using both in vitro and animal models following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations, 21 CFR Part 58), as appropriate. The activities shall include but are not limited to:

- [\*\*]
- [\*\*]

**[\*\*] Clinical Evaluation**

Emergent shall design and conduct Phase 2 and Phase 3 clinical studies in accordance with all Federal regulations and Good Clinical Practice (GCP) guidelines. The activities shall include but are not limited to:

- [\*\*]
- [\*\*]

**[\*\*][\*\*] Regulatory Activities**

Emergent shall conduct all required regulatory activities to support submission of BLA licensure for AV7909. The activities shall include but are not limited to:

- [\*\*]

**[\*\*] Chemistry and Manufacturing Controls (CMC)**

Emergent shall complete the manufacturing activities necessary to support BLA submission. The activities shall include but are not limited to:

- [\*\*]

**[\*\*] Phase 4 post-marketing requirement is modified as follows:**

[\*\*]

[\*\*]

[\*\*]

**1.4 CLIN 0001A - Conduct of a Phase 2 clinical [\*\*] study or other studies required by the FDA**



**for the establishment of a potency specification (Option)**

This section identifies representative tasks and sub-tasks for CLIN 0001A with associated WBS code for each task or subtask.

**[\* \*] Program Management**

Emergent shall provide program management activities. The activities shall include but are not limited to:

- Identification of and management to, distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Integrated Product Development Plan.
- Establishment of and tracking of milestones and timelines for the initiation conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- Ongoing evaluation of qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.
- Maintaining and managing staff (in-house and contracted) to assure the necessary expertise and dedicated effort to perform the work.
- Directing and overseeing subcontractors and consultants to assure successful performance of planned activities within the cost and schedule constraints of the contract.
- Conducting performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both Emergent and subcontractors on a real time basis.
- Manage contract activities in accordance with Earned Value Management. In this regard, Emergent shall:
  - Provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support product approval. The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/ No Go" decision criteria and a contract Work Breakdown Structure (due within 90 days of contract award with updates as requested by the Contracting Officer's Representative (COR).
  - Submit an updated Integrated Master Schedule in an approved format.
  - Use principles of Earned Value Management System (EVMS) in the management of this contract.
  - Submit a plan for a Performance Measurement Baseline Review (PMBR) electronically via email to the Contracting Officer (CO) and COR for a PBMR to occur within 90 days of contract award.
- Develop and maintain a risk management plan.
- Participate in regular meetings to coordinate and oversee the contracting effort.

**[\* \*] Clinical Evaluation**

Emergent shall design and conduct a Phase 2 clinical study in accordance with all Federal regulations and Good Clinical Practice (GCP) guidelines unless other studies are required by the FDA for the establishment of potency specification. The activities shall include, but are not limited to:

- [\*\*]

**[\*\*] Chemistry and Manufacturing Controls (CMC)**

Emergent shall complete the manufacturing activities necessary to support [\*\*] Study. The activities below are specific to conducting a Phase 2 [\*\*] study. If the FDA requires an alternate strategy for establishment of potency specification, the activities below may no longer be applicable.

Upon new guidance from the FDA, Emergent will update the SOW accordingly.

- [ \* \* ] CPG 7909 Manufacturing
- [ \* \* ] Manufacture of AV7909 for AVA.214 clinicaltrial WBS
- [ \* \* ] Stability Studies

**1.5 CLIN 0012 – Include doxycycline arm in the conduct of the Phase 2 clinical drug-drug interaction study and qualify a redundant contract filler (Base)**

This section identifies representative activities of CLIN 0012 associated with CLIN0001 subtask [ \* \* ] - AVA.210 Phase 2 [ \* \* ] and task [ \* \* ] Chemistry and Manufacturing Controls:

- [ \* \* ]
- [ \* \* ]

**1.6 CLIN 0002 - Initial purchase, storage, and delivery of product (Base)**

Under the Base Period funding Emergent shall manufacture, fill, and deliver [ \*\* ] doses procured in fiscal year 2019 as an initial procurement to the Strategic National Stockpile (SNS). Emergent is approved to use management reserve funding for shipping costs associated with these deliveries.

**1.7 CLIN 0003 - Phase 4 post marketing requirements (Option)**

Reclassified to CLIN 0001. See [ \* \* ] under CLIN 0001 for details.

**1.8 CLIN 0004 through 11 - Surge Capacity – Additional procurement of product (Option) -**

Emergent shall deliver up to [ \*\* ] dose regimens (equivalent to [ \*\* ] doses of AV7909). This option may be triggered after EUA pre-authorization approval by FDA, which is currently linked to release of PPQ lots, and deliveries will start within [ \* \* ] after trigger. [ \* \* ]

Under CLIN 0004, Emergent shall manufacture, fill, and deliver [ \*\* ] doses procured in fiscal year 2019 as an initial procurement to the Strategic National Stockpile (SNS). [ \* \* ]

Under CLIN 0006 Emergent shall manufacture, fill, and deliver [ \*\* ] doses procured from August 1, 2020 through July 31, 2021, as an additional procurement to the SNS. [ \* \* ]

For CLINs 0004 and 0006, BARDA may accept [ \*\* ] appropriate number of additional doses (“Additional Doses”). Additional Doses shall be calculated as [ \*\* ]% of the number of delivered [ \*\* ].

For CLIN 0011, BARDA agrees to accept [ \*\* ] at a discounted price. ≤

These anthrax vaccine doses will have [ \*\* ] prices depending on the [ \*\* ]. Vaccine doses delivered [ \*\* ] will be charged a dose price of [ \*\* ] per dose. Vaccines delivered with a [ \*\* ] but [ \*\* ] will be charged a unit dose price of [ \*\* ] per dose. BARDA will not accept any vaccine [ \*\* ].

≤

For delivery to the SNS, Emergent shall comply with the relevant associated activities and deliverables as outlined in the Quality Agreement (attached) as signed by Emergent, BARDA, and the SNS. Emergent shall provide appropriate documentation to BARDA for quality assurance of the final drug product delivered to the SNS and invoice appropriately.

#### **1.9 Reporting Requirements and Deliverables Reports**

As part of the work to be performed under this contract, Emergent will prepare and deliver the following reports throughout the period of performance.

##### **Monthly Technical Progress Reports**

On the fifteenth (15) day of each month for the previous calendar month, Emergent will submit to the COR and the CO a Technical Progress Report covering the previous calendar month. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period will consist of each calendar month. The frequency of Technical Progress Reporting will be determined by the CO and COR during negotiations of the contract. The format and type of Technical Progress Report and Executive Summary will be provided by the COR. The Technical Progress Reports will summarize progress for the reporting period, such as: management and administrative updates, technical progress, issues, proposed work, manufacturing and supply chain management, and a summary of invoices. A Technical Progress Report will not be required for the period when the same month Annual Progress Reports or a Final Report are due. Emergent will submit one copy of the Technical Progress Report electronically via e-mail to the CO and COR.

##### **Annual Progress Reports**

On the thirtieth (30th) calendar day following the last day of each reporting period, Emergent will submit to the COR and the CO an Annual Progress Report. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year. Annual Progress Reports will summarize progress for the reporting period, such as: management and administrative updates, technical progress, issues, proposed work, manufacturing and supply chain management, and a summary of invoices. An Annual Progress Report will not be required for the period when the Final Technical Progress Report is due.

##### **Draft Final Report and Final Report**

Emergent will submit the Draft Final Progress Report forty-five (45) calendar days prior to the expiration date of the contract and the Final Progress Report on or before the expiration date of the contract. These reports will include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report will be in sufficient detail to describe comprehensively the results achieved. An electronic copy of the Draft Final Report and Final Report will be submitted to the COR and CO.

##### **FDA Regulatory Agency Correspondence, Meeting Summaries, and Submissions**

With regard to interactions with the FDA, Emergent shall:

- Forward the initial draft minutes to BARDA within five business days of any formal meeting with the FDA or other regulatory agency, and forward the final minutes when available.
- Forward the initial draft minutes to BARDA within five business days of any informal meeting with the FDA or other regulatory agency, and forward the final minutes when available and if applicable.
- Forward the dates and times of any meeting with the FDA and other regulatory agencies to BARDA as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings.

- Provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. Emergent will provide BARDA with five (5) business days in which to review and provide comments prior to Emergent's submission to the FDA.

Emergent will notify the COR and CO within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency and provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). Emergent will provide the COR and CO copies of the plan for addressing areas of non-conformance to FDA regulations for Good Laboratory Practice (GLP) guidelines as identified in the audit report, status updates during the plan's execution, and a copy of all final responses to the FDA. Emergent will also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. Emergent will make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.



## **Key Deliverables**

A summary of Key Deliverables for this contract follow

<b>No.</b>	<b>Deliverable</b>	<b>Description</b>	<b>Due Date</b>
01	Monthly Progress Report	Shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.	Due on or before the 15th day of each month following the end of each reporting period. Monthly progress reports are not required in the same month Annual Progress reports or a Final Report are due.
02	Annual Progress Report	Shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.	Due on or before the 30 <sup>th</sup> calendar day following the end of each reporting period.
03	Draft Final Progress Report	To include a summation of the work performed and results obtained for execution of various studies or technical work packages during entire contract period of performance. Shall be in sufficient detail to describe comprehensively the results achieved.	Due 45 Calendar days prior to the expiration date of the contract.
04	Final Progress Report	To include a summation of the work performed and results obtained for execution of various studies or technical work packages during entire contract period of performance. Shall be in sufficient detail to describe comprehensively the results achieved.	Due on/before the expiration date of the contract.
05	FDA/Regulatory Agency Correspondence and Meeting Minutes	The Contractor shall forward initial draft minutes and final draft minutes of any formal or informal meeting with the FDA or other regulatory agency. The contractor shall forward the dates and times of any meeting with the FDA and other regulatory agencies as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings. The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. The Contractor shall forward SOPs upon request from the COR. The contractor shall notify the COR and CO within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency, and provide copies of any associated reports, documentation, or communication.	Due within 5 business days of each meeting for Contractor's minutes, upon receipt of minutes from FDA/regulatory agency, and upon request from the COR or Co-COR.
06	Integrated Master Project Plan (Critical Path Milestones, Work Breakdown Structure, Risk Mitigation Plan/ Matrix)	The contractor shall provide an Integrated Master Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to annual deliverables (key, critical path milestones, with "Go/No Go" decision criteria) and Work Breakdown Structure (WBS) elements that shall be discernable and consistent. The contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans.	Due within 90 days of contract award. Updates are due as requested by the COR or Co-COR.
07	Technology Packages	Technology packages developed under the contract that includes complete protocols must be submitted at the request of the BARDA COR.	Due upon request from the COR or Co-COR.

No.	Deliverable	Description	Due Date
08	Experimental Protocols	The Contractor shall submit to the COR all study/experiment/test plans, designs, and protocols prior to execution for BARDA approval or upon request by the COR or Co-COR when required.	Due upon request from the COR or Co-COR.
09	Annual/Final Invention Report	All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification. If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the CO.	Annual Invention Report Due on or before the 30th calendar day after the completion of each reporting period. Final Invention Report due on or before the expiration of the contract.
10	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission.	Due within 30 calendar days for manuscripts prior to publication and 15 calendar days for abstracts.
11	Press Releases	The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the CO has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.	Reports/Notices due for approval to the CO not less than five (5) business days prior to the issuance of any potential press release.
12	Security Report	The contractor shall report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products	Due within 24 hours after occurrence of an activity or incident.
13	Earned Value Management System Requirements	Subject to the requirements under FAR 52.234-4 Earned Value Management System, the Contract shall use principles of Earned Value Management System (EVMS) in the management of this contract (include this plan as part of the monthly, annual, and final reports). The Contractor shall also submit a Performance Measurement Baseline Review plan electronically via email to the CO and COR for a PMBR to occur within 90 days of contract award, and an Integrated Master Schedule electronically via email as outlined in a format agreed upon by BARDA to the COR and CO. The Offeror shall deliver an Earned Value Contract Performance Report on a monthly basis.	As detailed in Section F.3.2 Subpart F. [**]

Milestone #		WBS #	Milestone	Deliverables Summary (Details as specified in the Deliverables)		Quantity	Estimated Completion Date
CLIN 0001 & CLIN 0012	1	[**]	[**]	[**]	[**]	1 Electronic Copy to Contract Officer Representative (COR); 1 Electronic Copy to Contracting Officer (CO)	12/19/2017
	2	[**]	[**]	[**]	[**]	See Above	1/18/2018
	3	[**]	[**]	[**]	[**]	See Above	5/24/2018
	4	[**]	[**]	[**]	[**]	See Above	11/6/2018
	5	[**]	[**]	[**]	[**]	See Above	11/8/2018
	8	[**]	[**]	[**]	[**]	See Above	3/21/2021
	9	[**]	[**]	[**]	[**]	See Above	8/18/2020
	10	[**]	[**]	[**]	[**]	See Above	12/31/2021
	11	[**]	[**]	[**]	[**]	See Above	5/12/2021
	12	[**]	[**]	[**]	[**]	See Above	12/15/2021
	16	-	[**]	[**]	[**]	See Above	10/24/2019



Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>		1. CONTRACT ID CODE	PAGE OF PAGES
			1 4
2. AMENDMENT/MODIFICATION NO. P00016	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. ASP322481	5. PROJECT NO. (If applicable)
6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	CODE ASPR-BARDA	7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA 200 Independence Ave., S.W. Room 638-G Washington DC 20201	CODE ASPR-BARDA
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)  EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR # 100 GAITHERSBURG MD 208793419		(x)	9A. AMENDMENT OF SOLICITATION NO.
			9B. DATED (SEE ITEM 11)
		x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201600030C
			10B. DATED (SEE ITEM 13) 09/30/2016
CODE 1365869	FACILITY CODE		
<b>11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS</b>			
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.			
12. ACCOUNTING AND APPROPRIATION DATA (If required) 2024.Q990100.26088		Net Increase: [**]	
<b>13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.</b>			
CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.		
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).		
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR Part 43.103(a) - Bilateral Modifications		
	D. OTHER (Specify type of modification and authority)		
<b>E. IMPORTANT:</b> Contractor <input type="checkbox"/> is not <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> copies to the issuing office.			
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Tax ID Number: [**] UEI: [**] The purpose of this modification is to exercise CLIN 0011b and update ARTICLES B.3. OPTION PRICES, B.5 ADVANCE UNDERSTANDINGS, C.1. STATEMENT OF WORK, and SECTION J- LIST OF ATTACHMENTS.  Funds Obligated Prior to this Modification: [**] Funds Obligated with Mod #16: [**] Total Funds Obligated to Date: [**]  All other terms and conditions remain unchanged. Continued ... Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.			
15A. NAME AND TITLE OF SIGNER (Type or print) <b>Paul Williams</b> SVP, Products Business		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Jonathan Gonzalez	
15B. CONTRACTOR/OFFEROR <i>Paul Williams</i> <small>Electronically signed by: Paul Williams Reason: I approve this document Date: Nov 21, 2023 16:19 EST (Signature of person authorized to sign)</small>	15C. DATE SIGNED <b>Nov 21, 2023</b>	16B. UNITED STATES OF AMERICA Jonathan F. Gonzalez -S <small>Digitally signed by Jonathan F. Gonzalez-S Date: 2023.11.21 16:59:31 -0500 (Signature of Contracting Officer)</small>	16C. DATE SIGNED

**CONTINUATION SHEET**REFERENCE NO. OF DOCUMENT BEING CONTINUED  
HHSO100201600030C/P00016PAGE OF  
2 4NAME OF OFFEROR OR CONTRACTOR  
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. 1365869

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
12	OTA: N Appr. Yr.: 2024 CAN: Q990100 Object Class: 26088 Period of Performance: 09/30/2016 to 08/31/2025  Add Item 12 as follows:  CLIN 0011B Additional Surge Capacity (Licensure)				74,999,936.10

The purpose of this modification is to modify ARTICLES B.3 OPTION PRICES, B.5. ADVANCE UNDERSTANDINGS, ARTICLE C.1. STATEMENT OF WORK, and SECTION J- LIST OF ATTACHMENTS

**ARTICLE B.3. OPTION PRICES** – CLIN 0011B is added as follows:

CLIN	Period of Performance	Supplies/ Services	Doses*	Price per Dose	Total Not to Exceed Cost
0011B (Option Quantity)	Nov 21, 2023 through Mar 31, 2024	Additional Surge Capacity (Licensure)	[**]	[**]	\$74,999,936.10 (Funded)

\*Under CLIN 0011B a total of 2.8 million doses are expected to be procured at the unit prices stated above. There is no anticipated supply of material between [\*\*] from date of manufacture under CLIN0011B; this product would only be provided at the request of the USG at a price of \$18.00 per dose.

**ARTICLE B.5. ADVANCE UNDERSTANDINGS** – is modified as follows:

o. CLIN 0011B

- For CLIN 0011B receiving doses will be less than or equal to [\*\*] from the date of manufacture. The following table is provided to note doses to be delivered under CLIN 0011B.

Product	Dating	Price per Dose (USD)	Quantity for Delivery
Base Doses	[**]	[**]	2,822,730 doses

**ARTICLE C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT** is modified as follows:

**ARTICLE C.1. STATEMENT OF WORK**

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work set forth in SECTION J - List of Attachments, attached hereto and made a part of the contract.

**SECTION J – LIST OF ATTACHMENTS** is modified as follows:

1. Statement of Work, dated Nov 2, 2023, 10 pages

All other terms and conditions of this contract remain unchanged.

**End of Modification #16**

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**ATTACHMENT 1: STATEMENT OF WORK**

**NEXT GENERATION ANTHRAX VACCINE  
RFP 16-100-SOL-0015  
AV7909 Anthrax Vaccine**

**1.0 Contractual Statement of Work**

**Preamble to the Statement of Work**

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work submitted in response to RFP 16-100-SOL-00015.

**1.1 Scope**

The scope of work for this contract includes AV7909 development activities through licensure that fall into the following areas: program management, nonclinical, clinical, regulatory, and chemistry, manufacturing, and controls (CMC). The scope of work also includes activities to support post-marketing requirements.

**1.2 Objective**

The objective of this Statement of Work (SOW) is to conduct all necessary activities to advance the development of AV7909 through Biologics License Application (BLA) submission and approval and post-marketing requirements. Activities to meet the objective of this SOW fall in the following nine (9) contract line item number (CLIN):

- CLIN 0001 – Approval of Emergency Use Authorization (EUA), licensure, approval, and clearance of product through the FDA (Base)
- CLIN 0001A – Conduct of a Phase 2 clinical [\*\*] study or other studies required by the FDA [\*\*](Option)
- CLIN 0012 – Include doxycycline arm in the conduct of the Phase 2 clinical drug-drug interaction study and qualify a redundant contract filler (Base)
- CLIN 0002 – Initial purchase, storage, and delivery of product (Base)
- CLIN 0003 – Phase 4 post marketing requirements (Option)
- CLIN 0004 - Surge Capacity – Additional procurement of product (EUA) (Option) – [\*\*] to [\*\*]
- CLIN 0006 – Surge Capacity – Additional procurement of product (EUA) (Option) – [\*\*] to [\*\*]
- CLIN 0010 – Surge Capacity - Additional procurement of product (EUA) (Option) – [\*\*] or more doses
- CLIN 0011 – Surge Capacity - Additional procurement of product (EUA and Licensed) (Option) – up to [\*\*] doses
- **CLIN 0011B – Surge Capacity - Additional procurement of product (Licensed) (Option) – [\*\*] doses**

AV7909 Target Delivery Schedule (CLIN 0011)

Q2 2023	Q3 2023	Q4 2023
Apr – Jun	Jul – Sep	Oct
[**] doses		

**Cyfundus Target Delivery Schedule (CLIN 0011B)**

<b>Q4 2023 – Q1 2024</b>
<b>Nov - Mar</b>
<b>[**] doses</b>

**1.3 CLIN 0001 - Approval of Emergency Use Authorization (EUA), licensure, approval, and clearance of product through the FDA (Base)**

This section identifies representative tasks and sub-tasks for CLIN 0001 with associated WBS code for each task or subtask.

**\*\*] Program Management**

Emergent shall provide program management activities. The activities shall include but are not limited to:

- Identification of and management to, distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Integrated Product Development Plan.
- Establishment of and tracking of milestones and timelines for the initiation conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- Ongoing evaluation of qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.
- Maintaining and managing staff (in-house and contracted) to assure the necessary expertise and dedicated effort to perform the work.
- Directing and overseeing subcontractors and consultants to assure successful performance of planned activities within the cost and schedule constraints of the contract.
- Conducting performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both Emergent and subcontractors on a real time basis.
- Manage contract activities in accordance with Earned Value Management. In this regard, Emergent shall:
  - Provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support product approval. The Integrated Master Project Plan shall outline key, critical path milestones, with “Go/No-Go” decision criteria and a contract Work Breakdown Structure (due within 90 days of contract award with updates as requested by the Contracting Officer’s Representative (COR).
  - Submit an updated Integrated Master Schedule in an approved format.
  - Use principles of Earned Value Management System (EVMS) in the management of this contract.
  - Submit a plan for a Performance Measurement Baseline Review (PMBR) electronically via email to the Contracting Officer (CO) and COR for a PBMR to occur within 90 days of contract award.
- Develop and maintain a risk management plan.
- Participate in regular meetings to coordinate and oversee the contracting effort.

**\*\*] Non-Clinical Toxicology**

Emergent shall conduct safety and toxicology of AV7909 using animal models following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations, 21CFR Part 58), as appropriate. The activities shall include but are not limited to:

- [\*\*]
- [\*\*]

**\*\*] Non-Clinical Efficacy**

Emergent shall conduct efficacy, pharmacokinetics/pharmacodynamics, bioavailability, solubility, formulation, dose, route and schedule of the medical countermeasure using both in vitro and animal models

following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations, 21 CFR Part 58), as appropriate. The activities shall include but are not limited to:

- [\*\*]  
[\*\*]

**[\*\*] Clinical Evaluation**

Emergent shall design and conduct Phase 2 and Phase 3 clinical studies in accordance with all Federal regulations and Good Clinical Practice (GCP) guidelines. The activities shall include but are not limited to:

- [\*\*]  
[\*\*]

**[\*\*] Regulatory Activities**

Emergent shall conduct all required regulatory activities to support submission of BLA licensure for AV7909. The activities shall include but are not limited to:

- [\*\*]

**[\*\*] - Chemistry and Manufacturing Controls (CMC)**

Emergent shall complete the manufacturing activities necessary to support BLA submission. The activities shall include but are not limited to:

- [\*\*]

**[\*\*] - Phase 4 post-marketing requirement:**

Development of Post-Marketing Requirement (PMR) Program per FDA Request  
Phase 4 Retrospective Observational Study Protocol, ICF, Assent, Mock CRFs & CRF Completion  
Guidelines of AV7909 ([\*\*])

- [\*\*]

**1.4 CLIN 0001A - Conduct of a Phase 2 clinical potency study or other studies required by the FDA for the establishment of a [\*\*] specification (Option)**

This section identifies representative tasks and sub-tasks for CLIN 0001A with associated WBS code for each task or subtask.

**[\*\*] Program Management**

Emergent shall provide program management activities. The activities shall include but are not limited to:

- Identification of and management to, distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Integrated Product Development Plan.
- Establishment of and tracking of milestones and timelines for the initiation conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- Ongoing evaluation of qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.
- Maintaining and managing staff (in-house and contracted) to assure the necessary expertise and dedicated effort to perform the work.
- Directing and overseeing subcontractors and consultants to assure successful performance of planned activities within the cost and schedule constraints of the contract.



- Conducting performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both Emergent and subcontractors on a real time basis.
- Manage contract activities in accordance with Earned Value Management. In this regard, Emergent shall:
  - Provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support product approval. The Integrated Master Project Plan shall outline key, critical path milestones, with “Go/ No Go” decision criteria and a contract Work Breakdown Structure (due within 90 days of contract award with updates as requested by the Contracting Officer’s Representative (COR).
  - Submit an updated Integrated Master Schedule in an approved format.
  - Use principles of Earned Value Management System (EVMS) in the management of this contract.
  - Submit a plan for a Performance Measurement Baseline Review (PMBR) electronically via email to the Contracting Officer (CO) and COR for a PBMR to occur within 90 days of contract award.
- Develop and maintain a risk management plan.
- Participate in regular meetings to coordinate and oversee the contracting effort.

**\*\*] Clinical Evaluation**

Emergent shall design and conduct a Phase 2 clinical study in accordance with all Federal regulations and Good Clinical Practice (GCP) guidelines unless other studies are required by the FDA [\*\*]. The activities shall include, but are not limited to:

- [\*\*] - AVA.214 Phase 2 [\*\*] Study

**\*\*] - Chemistry and Manufacturing Controls (CMC)**

Emergent shall complete the manufacturing activities necessary to support AVA.214 Phase 2 [\*\*] Spec Study. The activities below are specific to conducting a Phase 2 [\*\*] clinical study. If the FDA requires an alternate strategy for [\*\*], the activities below may no longer be applicable. Upon new guidance from the FDA, Emergent will update the SOW accordingly.

- [\*\*]

**1.5 CLIN 0012 – Include doxycycline arm in the conduct of the Phase 2 clinical drug-drug interaction study and qualify a redundant contract filler (Base)**

This section identifies representative activities of CLIN 0012 associated with CLIN0001 subtask [\*\*] - AVA.210 Phase 2 [\*\*] and [\*\*] Chemistry and Manufacturing Controls:

- [\*\*]

**1.6 CLIN 0002 - Initial purchase, storage, and delivery of product (Base)**

Under the Base Period funding Emergent shall manufacture, fill, and deliver [\*\*] doses procured in fiscal year 2019 as an initial procurement to the Strategic National Stockpile (SNS). Emergent is approved to use management reserve funding for shipping costs associated with these deliveries.

**1.7 CLIN 0003 - Phase 4 post marketing requirements (Option)**

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**Program Management**

Emergent shall provide program management activities. The activities shall include but are not limited to:

- Identification of and management to, distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Integrated Product Development Plan.
- Establishment of and tracking of milestones and timelines for the initiation conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- Ongoing evaluation of qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.
- Maintaining and managing staff (in-house and contracted) to assure the necessary expertise and dedicated effort to perform the work.
- Directing and overseeing subcontractors and consultants to assure successful performance of planned activities within the cost and schedule constraints of the contract.
- Conducting performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both Emergent and subcontractors on a real time basis.
- Manage contract activities in accordance with Earned Value Management. In this regard, Emergent shall:
  - Provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support product approval. The Integrated Master Project Plan shall outline key, critical path milestones, with “Go/No Go” decision criteria and a contract Work Breakdown Structure (due within 90 days of contract award with updates as requested by the Contracting Officer’s Representative (COR).
  - Submit an updated Integrated Master Schedule in an approved format.
  - Use principles of Earned Value Management System (EVMS) in the management of this contract.
  - Submit a plan for a Performance Measurement Baseline Review (PMBR) electronically via email to the Contracting Officer (CO) and COR for a PBMR to occur within 90 days of contract award.
- Develop and maintain a risk management plan.
- Participate in regular meetings to coordinate and oversee the contracting effort.

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**1.8 CLIN 0004 through 11 - Surge Capacity – Additional procurement of product (Option)**

Emergent shall deliver up to [\*\*] (equivalent to [\*\*] doses of AV7909). This option may be triggered after EUA pre-authorization approval by FDA, which is currently linked to release

of PPQ lots, and deliveries will start within [\*\*] after trigger.

Under CLIN 0004, Emergent shall manufacture, fill, and deliver [\*\*] doses procured in fiscal year 2019 as an initial procurement to the Strategic National Stockpile (SNS). [\*\*]

Under CLIN 0006 Emergent shall manufacture, fill, and deliver [\*\*] doses procured from August 1, 2020 through July 31, 2021, as an additional procurement to the SNS. [\*\*]

For CLINs 0004 and 0006, BARDA may accept [\*\*] if such doses are delivered along with the appropriate number of additional doses (“Additional Doses”). Additional Doses shall be calculated as [\*\*]% of the number of delivered [\*\*]

For CLIN 0011, BARDA agrees to accept [\*\*] at a discounted price.

These anthrax vaccine doses will have two different [\*\*] depending on the [\*\*]. Vaccine doses delivered up to or equal to [\*\*] will be charged a dose price of [\*\*] per dose. Vaccines delivered with a [\*\*] will be charged a unit dose price of [\*\*]per dose. BARDA will not accept any vaccine [\*\*]

**For CLIN 0011B, Emergent shall provide [\*\*] doses, dated 1[\*\*] at [\*\*] per dose between November 21, 2023 through March 31, 2024.**

For delivery to the SNS, Emergent shall comply with the relevant associated activities and deliverables as outlined in the Quality Agreement (attached) as signed by Emergent, BARDA, and the SNS. Emergent shall provide appropriate documentation to BARDA for quality assurance of the final drug product delivered to the SNS and invoice appropriately.

#### **1.9 Reporting Requirements and Deliverables Reports**

As part of the work to be performed under this contract, Emergent will prepare and deliver the following reports throughout the period of performance.

##### **Monthly Technical Progress Reports**

On the fifteenth (15) day of each month for the previous calendar month, Emergent will submit to the COR and the CO a Technical Progress Report covering the previous calendar month. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period will consist of each calendar month. The frequency of Technical Progress Reporting will be determined by the CO and COR during negotiations of the contract. The format and type of Technical Progress Report and Executive Summary will be provided by the COR. The Technical Progress Reports will summarize progress for the reporting period, such as: management and administrative updates, technical progress, issues, proposed work, manufacturing and supply chain management, and a summary of invoices. A Technical Progress Report will not be required for the period when the same month Annual Progress Reports or a Final Report are due. Emergent will submit one copy



of the Technical Progress Report electronically via e-mail to the CO and COR.

**Annual Progress Reports**

On the thirtieth (30th) calendar day following the last day of each reporting period, Emergent will submit to the COR and the CO an Annual Progress Report. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year. Annual Progress Reports will summarize progress for the reporting period, such as: management and administrative updates, technical progress, issues, proposed work, manufacturing and supply chain management, and a summary of invoices. An Annual Progress Report will not be required for the period when the Final Technical Progress Report is due.

**Draft Final Report and Final Report**

Emergent will submit the Draft Final Progress Report forty-five (45) calendar days prior to the expiration date of the contract and the Final Progress Report on or before the expiration date of the contract. These reports will include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report will be in sufficient detail to describe comprehensively the results achieved. An electronic copy of the Draft Final Report and Final Report will be submitted to the COR and CO.

**FDA Regulatory Agency Correspondence, Meeting Summaries, and Submissions**

With regard to interactions with the FDA, Emergent shall:

- Forward the initial draft minutes to BARDA within five business days of any formal meeting with the FDA or other regulatory agency, and forward the final minutes when available.
- Forward the initial draft minutes to BARDA within five business days of any informal meeting with the FDA or other regulatory agency, and forward the final minutes when available and if applicable.
- Forward the dates and times of any meeting with the FDA and other regulatory agencies to BARDA as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings.
- Provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. Emergent will provide BARDA with five (5) business days in which to review and provide comments prior to Emergent's submission to the FDA.

Emergent will notify the COR and CO within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency and provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). Emergent will provide the COR and CO copies of the plan for addressing areas of non-conformance to FDA regulations for Good Laboratory Practice (GLP) guidelines as identified in the audit report, status updates during the plan's execution, and a copy of all final responses to the FDA. Emergent will also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. Emergent will make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.



**Key Deliverables**

A summary of Key Deliverables for this contract follow

No.	Deliverable	Description	Due Date
01	Monthly Progress Report	Shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.	Due on or before the 15th day of each month following the end of each reporting period. Monthly progress reports are not required in the same month Annual Progress reports or a Final Report are due.
02	Annual Progress Report	Shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.	Due on or before the 30 <sup>th</sup> calendar day following the end of each reporting period.
03	Draft Final Progress Report	To include a summation of the work performed and results obtained for execution of various studies or technical work packages during entire contract period of performance. Shall be in sufficient detail to describe comprehensively the results achieved.	Due 45 Calendar days prior to the expiration date of the contract.
04	Final Progress Report	To include a summation of the work performed and results obtained for execution of various studies or technical work packages during entire contract period of performance. Shall be in sufficient detail to describe comprehensively the results achieved.	Due on/before the expiration date of the contract.
05	FDA/Regulatory Agency Correspondence and Meeting Minutes	The Contractor shall forward initial draft minutes and final draft minutes of any formal or informal meeting with the FDA or other regulatory agency. The contractor shall forward the dates and times of any meeting with the FDA and other regulatory agencies as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings. The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. The Contractor shall forward SOPs upon request from the COR. The contractor shall notify the COR and CO within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency, and provide copies of any associated reports, documentation, or communication.	Due within 5 business days of each meeting for Contractor's minutes, upon receipt of minutes from FDA/regulatory agency, and upon request from the COR or Co-COR.
06	Integrated Master Project Plan (Critical Path Milestones, Work Breakdown Structure, Risk Mitigation Plan/ Matrix)	The contractor shall provide an Integrated Master Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to annual deliverables (key, critical path milestones, with "Go/No Go" decision criteria) and Work Breakdown Structure (WBS) elements that shall be discernable and consistent. The contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans.	Due within 90 days of contract award. Updates are due as requested by the COR or Co-COR.
07	Technology Packages	Technology packages developed under the contract that includes complete protocols must be submitted at the request of the BARDA COR.	Due upon request from the COR or Co-COR.

No.	Deliverable	Description	Due Date
08	Experimental Protocols	The Contractor shall submit to the COR all study/experiment/test plans, designs, and protocols prior to execution for BARDA approval or upon request by the COR or Co-COR when required.	Due upon request from the COR or Co-COR.
09	Annual/Final Invention Report	All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification. If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the CO.	Annual Invention Report Due on or before the 30th calendar day after the completion of each reporting period. Final Invention Report due on or before the expiration of the contract.
10	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission.	Due within 30 calendar days for manuscripts prior to publication and 15 calendar days for abstracts.
11	Press Releases	The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the CO has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.	Reports/Notices due for approval to the CO not less than five (5) business days prior to the issuance of any potential press release.
12	Security Report	The contractor shall report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products	Due within 24 hours after occurrence of an activity or incident.
13	Earned Value Management System Requirements	Subject to the requirements under FAR 52.234-4 Earned Value Management System, the Contract shall use principles of Earned Value Management System (EVMS) in the management of this contract (include this plan as part of the monthly, annual, and final reports). The Contractor shall also submit a Performance Measurement Baseline Review plan electronically via email to the CO and COR for a PMBR to occur within 90 days of contract award, and an Integrated Master Schedule electronically via email as outlined in a format agreed upon by BARDA to the COR and CO. The Offeror shall deliver an Earned Value Contract Performance Report on a monthly basis.	As detailed in Section F.3.2 Subpart F. No Longer Required from the period starting 10/01/2023 onward.

	Milestone #	WBS #	Milestone	Deliverables Summary (Details as specified in the Deliverables)	Quantity	Estimated Completion Date	
CLIN 0001 & CLIN 0012	1	[**]	[**]		1 Electronic Copy to Contract Officer Representative (COR); 1 Electronic Copy to Contracting Officer (CO)	12/19/2017	
	2	[**]	[**]	[**]	See Above	1/18/2018	
	3	[**]	[**]	[**]	See Above	5/24/2018	
	4	[**]	[**]	[**]	See Above	11/6/2018	
	5	[**]	[**]	[**]	See Above	11/8/2018	
	8	[**]	[**]	[**]	See Above	3/21/2021	
	9	[**]	[**]	[**]	See Above	8/18/2020	
	10	[**]	[**]	[**]	See Above	12/31/2021	
	11	[**]	[**]	[**]	See Above	5/12/2021	
	12	[**]	[**]	[**]	See Above	12/15/2021	
	CLIN 0002	16	-	Completion of delivery of [**] doses of AV7909	Delivery of [**] doses of AV7909	See Above	10/24/2019



Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>		1. CONTRACT ID CODE	PAGE OF PAGES 1 1
2. AMENDMENT/MODIFICATION NO. P00007	3. EFFECTIVE DATE 10/06/2022	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
6. ISSUED BY ASPR/SNS ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341	CODE ASPR/SNS	7. ADMINISTERED BY (If other than Item 6) US DEPT OF HEALTH & HUMAN SERVICES ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341	CODE ASPR/SNS
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. Attn: STEVE RAMBO EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR GAITHERSBURG MD 208793419		(x) 9A. AMENDMENT OF SOLICITATION NO.	9B. DATED (SEE ITEM 11)
CODE 1365869 FACILITY CODE		X 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50119C00071	10B. DATED (SEE ITEM 13) 08/30/2019

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended.  is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning \_\_\_\_\_ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)  
See Schedule

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
X	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

**E. IMPORTANT:** Contractor  is not  is required to sign this document and return \_\_\_\_\_ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: [\*\*]

DUNS Number: [\*\*]

Period of Performance: 08/30/2019 to 08/29/2029

The purpose of this modification is to extend Task 1, Option 3001.

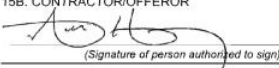

Task 1, Option 3001 pricing is hereby extended from 10/01/21-10/30/2022.

The Contract Year shown on page 6, Table 2, for 3001 and 4001 are updated as follows:

3001 dates are updated from 10/01/21-09/30/22 to 10/01/21-10/30/22.

4001 dates are updated from 10/01/22-09/30/23 to 10/31/22-09/30/23.

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) Adam Havey		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) KIMBERLY L. GOLDEN	
15B. CONTRACTOR/OFFEROR  (Signature of person authorized to sign)	15C. DATE SIGNED 10/6/2022	16B. UNITED STATES OF AMERICA  (Signature of Contracting Officer)	16C. DATE SIGNED 10-6-2022

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)  
Prescribed by GSA FAR (48 CFR) 53.243



Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>		1. CONTRACT ID CODE	PAGE OF PAGES 1 2
2. AMENDMENT/MODIFICATION NO. P00008	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
6. ISSUED BY ASPR/SNS ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341	CODE ASPR/SNS	7. ADMINISTERED BY (If other than Item 6) US DEPT OF HEALTH & HUMAN SERVICES ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341	CODE ASPR/SNS
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. Attn: STEVE RAMBO EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR GAITHERSBURG MD 208793419		(x) 9A. AMENDMENT OF SOLICITATION NO.	9B. DATED (SEE ITEM 11)
CODE 1365869 FACILITY CODE		X 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50119C00071	10B. DATED (SEE ITEM 13) 08/30/2019

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended.  is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning \_\_\_\_\_ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)  
See Schedule

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
X	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

**E. IMPORTANT:** Contractor  is not  is required to sign this document and return \_\_\_\_\_ copies to the issuing office.

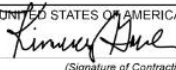
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: [\*\*]  
DUNS Number: [\*\*]  
UEI: CNPVC8DK7M8

This administrative modification is issued to change Section G- Contract administration Data as follows:  
Period of Performance: 08/30/2019 to 08/29/2029

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) KIMBERLY L. GOLDEN	
15B. CONTRACTOR/OFFEROR  (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA  (Signature of Contracting Officer)	16C. DATE SIGNED 11/21/2022

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)  
Prescribed by GSA FAR (48 CFR) 53.243

**CONTINUATION SHEET**

REFERENCE NO. OF DOCUMENT BEING CONTINUED  
75A50119C00071/P00008

PAGE OF  
2 2

NAME OF OFFEROR OR CONTRACTOR  
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. 1365869

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>G.1 Contract Representatives, changes the Contracting Officer's Representative (OR responsible for this contract:</p> <p>1. Correct from David Kelley to Bruce Lee:</p> <p>Bruce Lee ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341 Telephone Number: [**] Email: [**]</p>				





# Emergent BioSolutions Compensation Recovery Policy

## Purpose & Scope

The **purpose** of this Compensation Recovery Policy (the “Policy”), is to:

- Comply with applicable law and any rules or regulations adopted by the Securities and Exchange Commission, including Section 10D-1 under the Securities Exchange Act of 1934, the rules promulgated by the Securities and Exchange Commission thereunder, and the listing standards of the New York Stock Exchange (collectively, the “Applicable Rules”).
- Describe the specific events that trigger a clawback of Excess Compensation from Executive Officers (as each term is defined herein).

This Policy’s **scope**:

- This Policy applies to all Executive Officers and is applicable to all Incentive-Based Compensation received by Executive Officers after October 26, 2023 (the “Effective Date”).
- Each Executive Officer shall be required to execute the acknowledgement in Appendix A of this Policy as soon as practicable after the later of (i) the Effective Date and (ii) the date on which the employee is designated as an Executive Officer; provided, however, that failure to execute such acknowledgement shall have no impact on the enforceability of this Policy.

### OUR COMMITMENT

This policy is based on the following commitments:



We follow all applicable laws and recognize industry codes of practice.



We all own Compliance.



We interact responsibly with all stakeholders.

Following these commitments helps you live our value:

**Lead with Integrity.**

#### Policy Owner:

`\${vault:document\_owner\_\_v}`

#### Policy Sponsor:

Name

#### Policy Contact:

email

#### Last updated:

`\${vault:effective\_date\_\_v}`

## Policy

### Emergent will comply with the Applicable Rules and take action to recoup Excess Compensation from current and former Executive Officers

#### 1. Clawback

In the event the Company is required to prepare an Accounting Restatement, any Executive Officer who received Excess Compensation during the Look-back Period will be required to repay or forfeit any such Excess Compensation reasonably promptly. For purposes of this Policy, the date the Company is required to prepare an Accounting Restatement is deemed to be the earlier of the date (i) the Board concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (ii) a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.

Recovery of erroneously received compensation under this Policy is on a “no fault” basis, meaning that it will occur regardless of whether the Executive Officer engaged in misconduct or was otherwise directly or indirectly responsible, in whole or in part, for the Accounting Restatement. No Executive Officer may be indemnified by the Company, or any of its affiliates, from losses arising from the application of this Policy.

#### 1. Method of Repayment; Conditions for Non-Recovery

To the extent permitted by applicable law, including the Applicable Rules, the Board shall seek to recoup Excess Compensation by all legal means available, including, but not limited to, by requiring any affected Executive Officer to repay such amount to the Company in a lump sum or over time, by set-off, by cancelling outstanding awards, by reducing future compensation of the affected Executive Officer, or by such other means or combination of means as the Board, in its sole discretion, determines to be appropriate. At the direction of the Board, the Company shall take all actions reasonable and appropriate to recover Excess Compensation from any applicable Executive Officer, and such Executive Officer shall be required to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering such Excess Compensation in accordance with this Policy.

The Board may determine that repayment of Excess Compensation (or a portion thereof) is not required only where it determines that recovery would be impracticable and (i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered,

provided the Company has (A) made a reasonable attempt to recover such Excess Compensation, (B) documented such reasonable attempt, and (C) provided such documentation to the New York Stock Exchange, or (ii) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

Any forfeiture or recoupment under this Policy will be in addition to any other remedies that may be available under applicable law or Company policy, plan or agreement, including termination of employment or institution of civil proceedings. Any determination regarding this Policy and any application and implementation thereof need not be uniform with respect to each Executive Officer or payment recovered or forfeited under this Policy. Any determination made by the Board under this Policy will be final and binding on all affected individuals.

## Role & Responsibilities

Role	Responsibilities
<b>Legal</b>	Maintain and implement Policy.
<b>Board of Directors of the Company</b>	Administer the Policy (unless the Board designates the Compensation Committee of the Board (the "Committee") as the administrator of the Policy, in which case references to the Board will be deemed to be references to the Committee).

## Definitions

- Accounting Restatement:** An accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that corrects an error that is not material to previously issued financial statements but would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. Changes to financial statements that do not constitute an Accounting Restatement include retroactive: (i) application of a change from one generally accepted accounting principle to another generally accepted accounting principle; (ii) revisions to reportable segment information due to a change in internal organization; (iii) reclassification due to a discontinued operation; (iv) application of a change in reporting entity, such as from a reorganization of entities under common control; and (v) revisions for stock splits, reverse stock splits, stock dividends, or other changes in capital structure.
- Board:** The Board of Directors of the Company.



- **Company:** Emergent BioSolutions Inc.
- **Excess Compensation:** Any amount of Incentive-Based Compensation received by an Executive Officer after commencement of service as an Executive Officer that exceeds the amount of Incentive-Based Compensation that otherwise would have been received had it been determined based on the Accounting Restatement, computed without regard to any taxes paid. For Incentive Compensation based on stock price or total shareholder return, where the amount to be recovered is not subject to mathematical recalculation directly from information in the Accounting Restatement, the amount to be recovered shall be based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return, as applicable, and the Corporation shall retain documentation of the determination of such estimate and provide such documentation to NYSE if so required by the Applicable Rules. Incentive-Based Compensation is deemed received during the fiscal year during which the applicable financial reporting measure, stock price and/or total shareholder return measure, upon which the payment is based, is achieved, even if the grant or payment occurs after the end of such period.
- **Exchange Act:** Securities Exchange Act of 1934, as amended.
- **Executive Officer:** An individual who is, or was during the Look-back Period, an executive officer of the Company within the meaning of Rule 10D-1(d) under the Exchange Act.
- **Incentive-Based Compensation:** Any compensation that is granted, earned or vested based wholly or in part on stock price, total shareholder return, and/or the attainment of (i) any financial reporting measure(s) that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements and/or (ii) any other measures that are derived in whole or in part from such measures. Compensation that does not constitute "Incentive-Based Compensation" includes equity incentive awards for which the grant is not contingent upon achieving any financial reporting measure performance goal for an individual to receive such award and that vest exclusively upon completion of a specified employment period, without any performance condition, and bonus awards that are discretionary or based on subjective goals or goals unrelated to financial reporting measures.
- **Look-back Period:** The three completed fiscal years preceding the date the Company is required to prepare an Accounting Restatement.

## References and Supporting Documents

- Rule 10D-1 under the Exchange Act
- NYSE Listed Company Manual Rule 303A.14
- Section 16 of the Exchange Act
- Section 304 of the Sarbanes-Oxley Act of 2002
- Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act

**Effective Date:** October 26, 2023



**List of Subsidiaries  
(as of December 31, 2023)**

<b>Name of Subsidiary</b>	<b>Jurisdiction of Incorporation or Organization</b>
<b>Domestic</b>	
400 Professional LLC	Delaware
Cangene bioPharma LLC	Maryland
Emergent Commercial Operations Frederick Inc.	Maryland
Emergent Biodefense Operations Lansing LLC	Delaware
Emergent Devices Inc.	Delaware
Emergent Europe Inc.	Delaware
Emergent International Inc.	Delaware
Emergent Manufacturing Operations Baltimore LLC	Delaware
Emergent Product Development Gaithersburg Inc.	Delaware
Emergent Protective Products USA Inc.	Delaware
Emergent Travel Health Inc.	Delaware
<b>International</b>	
Emergent Acquisition Unlimited Company	Ireland
Emergent BioSolutions Canada Inc.	Ontario
Emergent BioSolutions Ireland Limited	Ireland
Emergent Netherlands B.V.	Netherlands
Emergent Operations Ireland Limited	Ireland
Emergent Sales and Marketing Australia Pty Ltd.	Australia
Emergent Sales and Marketing France S.A.S.	France
Emergent Sales and Marketing Germany GmbH	Germany
Emergent Sales and Marketing Singapore Pte. Ltd.	Singapore
Emergent BioSolutions UK Ltd.	England and Wales



**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

- a. Registration Statement (Form S-8 No. 333-139190) pertaining to the Employee Stock Option Plan, as amended and restated, the 2006 Stock Incentive Plan and individual director options agreements of Emergent BioSolutions, Inc.,
- b. Registration Statement (Form S-8 No. 333-161154) pertaining to the Amended and Restated 2006 Stock Incentive Plan of Emergent BioSolutions Inc.,
- c. Registration Statement (Form S-8 No. 333-184699) pertaining to the 2012 Employee Stock Purchase Plan and the Second Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan,
- d. Registration Statement (Form S-8 No. 333-196232) pertaining to the Third Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan,
- e. Registration Statement (Form S-8 No. 333-216294) pertaining to the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan,
- f. Registration Statement (Form S-8 No. 333-225283) pertaining to the Emergent BioSolutions Inc. Stock Incentive Plan,
- g. Registration Statement (Form S-8 No. 333-256798) pertaining to the Emergent BioSolutions Inc. Amended and Restated Stock Incentive Plan,
- h. Registration Statement (Form S-3ASR No. 333-258634) of Emergent BioSolutions Inc. and Subsidiaries,
- i. Registration Statement (Form S-8 No. 333-272433) pertaining to the Emergent BioSolutions Inc. Amended and Restated Stock Incentive Plan and the Emergent BioSolutions Inc. Amended Employee Stock Purchase Plan, and
- j. Registration Statement (Form S-8 No. 333-275990) pertaining to the Emergent BioSolutions Inc. Inducement Plan

of our reports dated March 8, 2024, with respect to the consolidated financial statements and schedule of Emergent BioSolutions Inc. and subsidiaries and the effectiveness of internal control over financial reporting of Emergent BioSolutions Inc. and subsidiaries included in this Annual Report (Form 10-K) of Emergent BioSolutions Inc. and subsidiaries for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Tysons, Virginia  
March 8, 2024

## CERTIFICATION

I, Joseph C. Papa, certify that:

- (1) I have reviewed this Annual Report on Form 10-K of Emergent BioSolutions Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information, and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2024

/s/ Joseph C. Papa  
Joseph C. Papa  
President and Chief Executive Officer

## CERTIFICATION

I, Richard S. Lindahl, certify that:

- (1) I have reviewed this Annual Report on Form 10-K of Emergent BioSolutions Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information, and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2024

/s/RICHARD S. LINDAHL  
Richard S. Lindahl  
Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Emergent BioSolutions Inc. (the "Company") for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Joseph C. Papa, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 8, 2024

/s/ Joseph C. Papa  
Joseph C. Papa  
President and Chief Executive Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Emergent BioSolutions Inc. (the "Company") for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Richard S. Lindahl, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 8, 2024

/s/RICHARD S. LINDAHL

Richard S. Lindahl  
Chief Financial Officer