

EMERGENT[®]

2024 \ ANNUAL REPORT

PREPAREDNESS TODAY, SAFER TOMORROW.





**WE'RE
PREPARING FOR
TOMORROW BY
TRANSFORMING
OUR COMPANY
TODAY**

Dear fellow shareholders,

When I joined Emergent in February 2024, we embarked on a multi-year plan to stabilize, turnaround, and ultimately transform our business. I am proud to say our stabilization phase was completed this past fall, ahead of schedule, thanks to the dedication and commitment of our entire team.

Our strategic stabilization plan included strengthening the balance sheet and substantially reducing debt to allow for focused, profitable growth around business lines built to compete in today's competitive landscape. Additionally, we implemented a leaner, more flexible organization by streamlining our manufacturing network, including several asset divestitures.

With these actions behind us, I believe Emergent has a strong foundation, momentum, and freedom to operate through our turnaround, the next phase of our multi-year plan.

In 2024, several important product milestones were successfully achieved, including:

- FDA approval of ACAM2000® (Smallpox and Mpox (Vaccinia) Vaccine, Live) for the prevention of mpox disease in individuals determined to be at high risk for mpox infection as the public health outbreak hits Africa and other regions.
- Secured a number of U.S. government contracts for our medical countermeasures business, reinforcing the longstanding partnership between Emergent and the U.S. government to meet the country's preparedness needs.
- Distributed 11 million cartons (includes 2 doses) of NARCAN® Nasal Spray 4 mg to customers and patients across the U.S. and Canada.
- Roughly one year after NARCAN® Nasal Spray became the first FDA-approved over-the-counter naloxone nasal spray, the CDC reported the first annual decrease of opioid overdose deaths since 2018.¹
- Opened a new West Coast distribution center as part of our best-in-class NARCANDirect™ distribution network, deepening our value proposition for public interest customers.
- Implemented actions to further broaden over-the-counter access of NARCAN® Nasal Spray through retailers, public places, businesses, and workplaces.

Our products play a direct role in helping communities prepare for today's health challenges and tomorrow's threats. Emergent's 2024 results and outlook for 2025 demonstrate our ability to adapt and evolve our business, take on new challenges, and innovate to address future urgent health crises. We remain optimistic in our future and aspire to be the leader in solving public health threats for communities around the world as we carry out our mission to protect and save lives.

We look forward to a strong 2025 and beyond.

JOE PAPA
President and CEO

¹ Centers for Disease Control and Prevention. U.S. Overdose Deaths Decrease in 2023, First Time Since 2018. May 15, 2024. https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2024/20240515.htm. Accessed September 26, 2024.

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, 2024

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,

(City)

MD

(State)

20879

(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, 2024 was approximately \$360.7 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 25, 2025, the registrant had 54,337,026 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2025 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, 2024, 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 2025 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, 2024

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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, our ability to achieve the objectives of our restructuring initiatives and divestitures, including our future results, 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 such 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") products, including CYFENDUS[®] (Anthrax Vaccine Adsorbed (AVA), Adjuvanted), previously known as AV7909, ACAM2000[®] (Smallpox (Vaccinia) Vaccine, Live), VIGIV CNJ-016[®] (Vaccinia Immune Globulin Intravenous (Human)), BAT[®] (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)), BioThrax[®] (Anthrax Vaccine Adsorbed) and/or Ebanga[™] (ansuvimab-zykl) among others, as well as contracts related to development of medical countermeasures;
- our ability to meet our commitments to quality and compliance in all of our manufacturing operations;
- our ability to negotiate additional USG procurement or follow-on contracts for our MCM products that have expired or will be expiring;
- the commercial availability and impact of a generic and competitive marketplace on future sales of NARCAN[®] (naloxone HCL) Nasal Spray and over-the-counter NARCAN[®] Nasal Spray;
- our ability to perform under our contracts with the USG, including the timing of and specifications relating to deliveries;
- the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices and other regulatory obligations;
- our ability to negotiate new or further commitments related to the collaboration and deployment of capacity toward future commercial manufacturing related to our bioservices and under existing Bioservices contracts;
- our ability to collect reimbursement for raw materials and payment of service fees from our Bioservices customers;
- the results of pending government investigations and their potential impact on our business;
- our ability to satisfy the conditions of the final settlement, and the potential impact of the final settlement agreement, including the funds to resolve the litigation, on our business;
- our ability to comply with the operating and financial covenants required by (i) our term loan facility under a credit agreement, dated August 30, 2024, among the Company, the lenders from time to time party thereto and OHA Agency LLC, as administrative agent, (ii) our revolving credit facility under a credit agreement, dated September 30, 2024, among the Company, certain subsidiary borrowers, the lenders from time to time party thereto and Wells Fargo, National Association, as Agent, and (iii) our 3.875% Senior Unsecured Notes due 2028 (the "Senior Unsecured Notes");
- our ability to maintain adequate internal control over financial reporting and to prepare accurate financial statements in a timely manner;
- our ability to maintain sufficient cash flow from our operations to pay our substantial debt, both now and in the future;
- our ability to invest in our business operations as a result of our current indebtedness;
- 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 the United States;

- our ability to realize the expected benefits of the sale of our travel health business to Bavarian Nordic, the sale of our Drug Product facility in Baltimore-Camden to Bora Pharmaceuticals Injectables Inc., a subsidiary of Bora Pharmaceuticals Co., Ltd. (“Bora”) and the sale of RSDL[®] (Reactive Skin Decontamination Lotion) to BTG International Inc., a subsidiary of SERB Pharmaceuticals (collectively, “SERB”);
- the impact of the organizational changes we announced in January 2023, August 2023, May 2024 and August 2024;
- 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 need 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 sections entitled “Risk Factor Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Quantitative and Qualitative Disclosures about Market Risk” in this Annual Report on Form 10-K, as well as the risks identified in our other reports filed with the SEC. New factors may 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 TRADE NAMES

Emergent[®], BioThrax[®], BaciThrax[®], 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, including RSDL[®] (Reactive Skin Decontamination Lotion), which was acquired by SERB on July 31, 2024.

PART I

ITEM 1. BUSINESS

OVERVIEW

We are a global life sciences company focused on providing innovative preparedness and response solutions addressing accidental, deliberate and naturally occurring Public Health Threats (“PHTs”). Our solutions include a product portfolio, a product development portfolio, and a contract development and manufacturing (“CDMO”) services portfolio. The types of PHTs we are currently addressing are focused on the following four categories:

- chemical, biological, radiological, nuclear and explosives (“CBRNE”);
- emerging infectious diseases (“EID”);
- emerging health crises; 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.

As of December 31, 2024, the Company has a product portfolio of 10 products that it is actively developing and/or marketing (vaccines, therapeutics, and drug-device combination products). The revenues generated by the products comprise a substantial portion of our revenue. We structure our 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: NARCAN[®] commercial product, Anthrax - Medical Countermeasures (“MCM”) Products, Smallpox - MCM products and Emergent Bioservices (CDMO) (“Bioservices”).

OUR OPERATING SEGMENTS

Our business is organized in three reportable segments:

- our Commercial Product Segment consisting of NARCAN[®] Nasal Spray;
- 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 Product Segment

In the U.S. and Canadian markets, our Commercial business primarily focuses on sales of NARCAN[®] (naloxone HCl) Nasal Spray. NARCAN[®] Nasal Spray is sold commercially over-the-counter (“OTC”) 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 Commercial Products Segment's travel health business, including rights to Vivotif[®], 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 to Bavarian Nordic (the "Bavarian Nordic Transaction"). Bavarian Nordic may be required to pay milestone payments 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. We have achieved all four development milestones. Specifically, on July 18, 2024, Bavarian Nordic announced that the European Medicines Agency had validated the marketing authorization application for CHIKV VLP, which triggered a development milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$10.0 million (the "First Milestone Payment"). On August 13, 2024, Bavarian Nordic announced that the United States ("U.S.") Food and Drug Administration ("FDA") has accepted and granted Priority Review for the Biologics License Application "BLA" for CHIKV VLP, which triggered a milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$20.0 million (the "Second Milestone Payment"). On February 14, 2025, the FDA approved CHIKV VLP under the Priority Review for persons 12 years of age and older, which triggered a milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$30.0 million (the "Third Milestone Payment"). On February 28, 2025, the European Commission approved CHIKV VLP for persons 12 years of age and older, which triggered a development milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$20.0 million (the "Fourth Milestone Payment"). The Company received the First and Second Milestone Payments during the year ended December 31, 2024, and as a result \$30.0 million of up to \$80.0 million total milestone payments have been received as of December 31, 2024. The Company expects to receive the Third and Fourth Milestone Payments in the first half of 2025.

In connection with the divestiture, the Company entered into a Transition Services Agreement (the "Bavarian Nordic TSA") with Bavarian Nordic to help support its ongoing operations. Under the Bavarian Nordic TSA, the Company provided 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. While the services under the Bavarian Nordic TSA were substantially completed in the third quarter of 2024, certain services continue to be provided as of December 31, 2024. For additional information, refer to Note 3, "Divestitures" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K.

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 U.S. Government ("USG"), which is our largest customer. We also sell MCM products and procured product candidates to domestic and international non- and quasi-government organizations and to governments outside of the U.S.

On July 31, 2024, we entered into a Stock and Asset Purchase Agreement (the "RSDL[®] Agreement") with SERB Pharmaceuticals, through its wholly owned subsidiary BTG International Inc. (collectively, "SERB"), pursuant to which, among other things, we sold our worldwide rights to RSDL[®] to SERB (the "RSDL[®] Transaction"). See Note 3, "Divestitures" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K for more information on the RSDL[®] Transaction.

Services Segment

Our services business consists of distinct but interrelated bioservices based on our manufacturing capabilities: 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. Our services utilize diverse technology platforms (mammalian, microbial, viral and plasma) from our development and manufacturing facilities to support internal products and enable us to offer unique capabilities to 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. In May 2024, we initiated a further organizational restructuring plan (the "May 2024 Plan") announcing the closure of our Baltimore-Bayview Drug Substance manufacturing facility and Rockville, Maryland Drug Product facility, which led to a reduction in workforce by approximately 300 employees across all areas of the Company and the elimination of approximately 85 positions that were vacant. In August 2024, the Company initiated an organizational restructuring plan (the "August 2024 Plan") at the Company's Lansing facility, which reduced the Company's workforce by approximately 70 employees, as well as eliminated several open positions. Additionally, on August 20, 2024, pursuant to the previously announced Asset Purchase Agreement (the "Asset Purchase Agreement"), we completed the sale of our Drug Product facility in Baltimore-Camden (the "Camden Transaction") to Bora Pharmaceuticals Injectables Inc., a subsidiary of Bora Pharmaceuticals Co., Ltd. ("Bora"). See Note 3, "Divestitures" and Note 4, "Impairment and restructuring charges" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K for more information related to these announcements.

OUR STRATEGY

In 2024, the Company set a new multi-year strategic plan adopted by management to stabilize, turnaround and transform the Company while maintaining our commitment to protect the public, by providing lifesaving products that address the most critical conditions.

Specifically, throughout 2024, the Company took steps in several areas of the business to strengthen our financial position and de-risk the business. In addition to the sale of RSDL[®], the implementation of the May 2024 and August 2024 Plans, the Camden Transaction, and milestone payments relating to the Bavarian Nordic Transaction, each discussed above, on July 3, 2024, the Company sold an underutilized warehouse at its Canton, Massachusetts facility for approximately \$7.0 million, and on July 31, 2024, the Company's wholly-owned subsidiary, Emergent Manufacturing Operations Baltimore, LLC ("EMOB") entered into a settlement agreement with Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson ("Janssen") (the "Settlement Agreement"). Pursuant to the Settlement Agreement, the Company received \$50.0 million, and all claims among the parties arising from the 2022 termination of the Company's manufacturing services agreement with Janssen (the "Janssen Agreement") were resolved. Together, these steps led to a reduction of the Company's debt of approximately \$200 million and streamlined the Company's operations, with approximately \$130 million in annualized savings.

To further strengthen the Company's financial position, on August 30, 2024, the Company refinanced its credit facility and entered into a Credit Agreement (the "Term Loan Agreement") with the lenders from time to time party thereto, and OHA Agency LLC, as administrative agent. The Term Loan Agreement provides for a term loan (the "Term Loan") of \$250.0 million, which was drawn in full on the date of entry into the Term Loan Agreement (the "Closing Date"). The Term Loan was issued with an original issue discount of 3.00%. The Company used a portion of the proceeds of the Term Loan to repay all amounts outstanding and terminate commitments under the senior term loan facility under the Company's Amended and Restated Credit Agreement, dated October 15, 2018, by and among the Company, the lenders party thereto from time to time, and Wells Fargo Bank, National Association, as the Administrative Agent (the "Prior Credit Agreement"), plus accrued interest and fees. The Company previously repaid all amounts outstanding under the revolving credit facility under the Prior Credit Agreement.

In addition, on September 30, 2024, the Company entered into a credit agreement for asset-based revolving loans (the "Revolving Credit Agreement") with certain subsidiary borrowers (together with the Company, the "Borrowers"), the lenders from time to time party thereto, and Wells Fargo Bank, National Association, as agent (the "Agent"). The Revolving Credit Agreement provides for commitments with respect to asset-based revolver loans (the "Revolving Loans") of up to the lesser of (x) \$100.0 million, which may be increased (but not above \$125.0 million, or the "Maximum Revolver Amount") or decreased (but not below \$50.0 million) by the Borrowers in accordance with the terms of the Revolving Credit Agreement and (y) the Borrowing Base (as defined in the Revolving Credit Agreement). Once reduced, the facility may not be increased. Up to \$5.0 million of capacity under the Revolving Loans may be used for swing loans and up to \$10.0 million may be used for the issuance of letters of credit.

We also achieved a number of positive milestones in our core products business during fiscal year 2024, including the receipt of approximately \$223 million of new USG orders across ACAM2000[®] (discussed more fully below), VIGIV CNJ-016[®] and BAT[®], as well as securing the exercise of an additional option for Ebanga[™] and the continued growth of OTC NARCAN[®] Nasal Spray.

Looking to 2025, the Company plans to advance its multi-year strategic efforts by turning the Company's focus from stabilization to turnaround, while holding firm to its commitment to protect the public, by providing lifesaving products that address the most critical conditions. The Company has identified several priorities for 2025 that it believes will enable profitable growth and improved operating performance, and create long-term and sustainable value for our stakeholders. The priorities are:

- Reinforcing the highest standards of patient safety, quality and compliance;
- Leveraging bipartisan support to drive our business forward;
- Enabling growth of existing segments to maintain revenue diversification;
- Seeking new opportunities aligned to our internal capabilities;
- Strategically focusing on international expansion efforts; and
- Elevating our business lines for today's competitive landscape.

PRIMARY PRODUCTS AND PRODUCT CANDIDATES

Government - MCM Products

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

GOVERNMENT - MCM PRODUCTS		
Product	Indication(s)	Regulatory Approvals, Licensures or Clearances
ACAM2000 [®] (Smallpox (Vaccinia) Vaccine, Live)	Vaccine for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.	Australia, Canada, Singapore
ACAM2000 [®] (Smallpox and Mpox (Vaccinia) Vaccine, Live)	Vaccine for active immunization for the prevention of smallpox and mpox disease in individuals determined to be at high risk for smallpox or mpox infection.	United States
ANTHRASIL [®] [Anthrax Immune Globulin Intravenous (Human)]	Treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs.	United States, Canada
BAT [®] [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)]	Treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients.	United States, Canada, Singapore, Ukraine
BioThrax [®] (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 [®] is approved for: <ol style="list-style-type: none"> 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 [®]), Germany, Singapore
CYFENDUS [®] (Anthrax Vaccine Adsorbed Adjuvanted)	Vaccine 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 [™] (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
TEMBEXA [®] (brincidofovir), (tablet and oral suspension)	Treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates.	United States, Canada
VIGIV CNJ-016 [®] [Vaccinia Immune Globulin Intravenous (Human)]	Treatment of complications due to vaccinia vaccination, including: <ul style="list-style-type: none"> • 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 CNJ-016 [®] is not indicated for postvaccinial encephalitis.	United States, Canada

Description of MCM Products

ACAM2000[®] (Smallpox and Mpox (Vaccinia) Vaccine, Live). ACAM2000[®] vaccine is a smallpox and mpox vaccine licensed by the FDA for active immunization for the prevention of smallpox and mpox disease in individuals determined to be at high risk for smallpox or mpox infection. The mpox indication was approved by the FDA following a supplemental Biological License Application ("sBLA") approval issued on August 29, 2024. On December 5, 2023, ACAM2000[®] 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. ACAM2000[®] is also licensed in Australia and Singapore for the smallpox indication. ACAM2000[®] vaccine is currently stockpiled both in the U.S. and internationally. Smallpox is a highly contagious disease caused by the Variola virus. According to the Centers for Disease Control and Prevention ("CDC"), smallpox is a devastating disease, with a mortality rate as high as 30%. In recent years, there have been global outbreaks of Mpox, which is caused by a virus in the same family as smallpox, increasing the need for vaccine access. This is particularly true in endemic regions. The vaccine stimulates a person's immune system to develop antibodies and cell responses that can then help the body fight off infection if exposure occurs.

On September 3, 2019, we announced the award by the USG of a contract valued at up to approximately \$2.0 billion over 10 years for the continued supply of ACAM2000[®] vaccine into the SNS, assuming all contract options are exercised. This multiple-year contract is intended to support the replacement of the smallpox vaccine stockpile and included a one-year base period of performance in 2019 valued at approximately \$170.0 million, and nine option years. The number of doses under the base period were delivered by year end 2019. On May 28, 2020, we announced the exercise by the U.S. Department of Health and Human Services ("HHS") of the first contract option, valued at \$176.0 million, to procure doses of ACAM2000[®] vaccine. The number of doses under the first contract option were delivered by year end 2020. On July 13, 2021, we announced the exercise by HHS of the second contract option, valued at \$182.2 million, to procure doses of ACAM2000[®] vaccine. We completed the delivery of all ACAM2000[®] doses in 2022. The USG chose to not exercise its option year in 2022. 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[®] to the SNS. The Third Option Exercise is valued at approximately \$120 million. On June 28, 2024, Emergent Product Development Gaithersburg Inc., received a contract modification from the ASPR exercising and funding the fifth contract term extension options (the "Fifth Option Exercise") for Emergent to supply ACAM2000[®] to the SNS. The Fifth Option Exercise is valued at approximately \$99.9 million. The Third and Fifth Option Exercises were made under bilateral modifications of Emergent's existing 10-year contract awarded by ASPR on August 30, 2019. The period of performance under the Third and Fifth Option Exercise required Emergent to deliver doses of ACAM2000[®] into the SNS by June 2023 and September 30, 2024, respectively, and the Company achieved delivery in these periods.

ANTHRASIL[®]. ANTHRASIL[®] (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. In 2024, we continued two contracts with HHS for Anthrasil Anthrax IGIV: 1) a development and procurement contract which was successfully completed as of September 2024, and 2) an active delivery order issued under a multiple award, indefinite delivery/indefinite quantity contract. 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 revenue, Anthrasil solution has been sold to several foreign governments.

BAT[®] [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine)]. BAT[®] antitoxin is the only equine plasma antitoxin licensed by the FDA and Health Canada for the treatment of all seven botulinum neurotoxin serotypes. BAT[®] antitoxin is licensed by the FDA for the treatment of symptomatic botulism following suspected or documented exposure to botulinum neurotoxin serotypes A, B, C, D, E, F or G in adults and pediatric patients. It is also licensed in Canada pursuant to Health Canada's Extraordinary Use New Drugs regulations. BAT[®] antitoxin is the only heptavalent botulism antitoxin available in the U.S. and Canada for treating naturally occurring botulism in adults or pediatric patients. Botulinum toxin is a nerve toxin produced by the bacterium *Clostridium botulinum* that causes botulism, a serious paralytic illness. On May 8, 2020, we announced the finalization of a previously announced contract with HHS, valued at up to \$550.0 million, if all options under the contract are exercised. The contract has two deliverables. The first deliverable, negotiated in September 2019 and valued at up to approximately \$90.0 million, is to supply annual doses of BAT[®] antitoxin into the SNS for 10 years by converting existing bulk drug substance into final drug product. This deliverable also includes options for additional doses valued at up to approximately \$94.0 million over 10 years. The second deliverable, valued at up to approximately \$366.0 million, is for the production of additional doses of bulk drug substance over 10 years to maintain the plasma collection and production capability for botulism response planning. In addition to domestic government sales, BAT[®] antitoxin continues to be sold internationally, with deliveries to 25 foreign countries in 2024.

BioThrax[®] (Anthrax Vaccine Adsorbed). BioThrax[®] vaccine is the only vaccine licensed by the FDA for pre-exposure prophylaxis of anthrax disease in persons at high risk of exposure. BioThrax[®] vaccine is also approved by the FDA for post-exposure prophylaxis administration in combination with antimicrobial therapy in the event of suspected or confirmed exposure to *Bacillus anthracis*. Anthrax is a potentially fatal disease caused by the spore-forming bacterium, *Bacillus anthracis*. Inhalational anthrax is the most lethal form of anthrax. In the U.S., BioThrax[®] vaccine is administered in a pre-exposure prophylaxis setting by intramuscular injection as a three-dose primary series over a six-month period. Per the U.S. label, booster doses are administered six and 12 months after completion of the primary series and at 12-month intervals thereafter. BioThrax[®] vaccine is administered in a post-exposure prophylaxis setting as three subcutaneous injections two weeks apart in conjunction with antibacterial drugs following suspected or confirmed *Bacillus anthracis* exposure. When we report the revenue associated with “anthrax vaccines,” it reflects the combined revenue from the procurement and sale of BioThrax[®] vaccine as well as CYFENDUS[®] vaccine (formerly referred to as AV7909, described below).

On January 11, 2024, the Company announced that it has secured an indefinite-delivery, indefinite-quantity (“IDIQ”) procurement contract with the U.S. Department of Defense (“DoD”) and led by the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, with a maximum value up to \$235.8 million, to supply BioThrax[®] vaccine for use by all branches of the U.S. military as Pre-Exposure Prophylaxis (PrEP) for anthrax disease. The IDIQ contract 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. In 2024, one delivery order was issued, exercising two contract options for \$27.9 million. On January 8, 2025, the Company announced the exercise of a third option and modification to the IDIQ contract valued at approximately \$20 million to supply BioThrax[®] vaccine for use by all branches of the U.S. military as Pre-Exposure Prophylaxis (PrEP) for anthrax disease.

CYFENDUS[®] (Anthrax Vaccine Adsorbed, Adjuvanted) (referred to as investigational product AV7909 prior to FDA approval in July 2023). CYFENDUS[®] 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. In July 2023, we received BLA approval for CYFENDUS[®] from the FDA. Studies have shown that CYFENDUS[®] elicits a stronger immune response using fewer doses than BioThrax[®] vaccine, which is expected to allow patients to reach a protective level of immunity more rapidly. CYFENDUS[®] is designed to provide protection with a two-dose regimen (versus the BioThrax[®] three-dose regimen) for post-exposure prophylaxis of anthrax disease, when administered in combination with the recommended antibacterial drugs.

In September 2016, we signed a combination development and procurement contract with Biomedical Advanced Research and Development Authority (“BARDA”), which included a five-year base period of performance to develop CYFENDUS[®] 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[®] 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 of 3,850 subjects evaluating safety, immunogenicity and lot consistency. The study was completed in 2020. In collaboration with us, the CDC filed with the FDA a pre-EUA submission package related to CYFENDUS[®]. Following this submission, BARDA began procuring CYFENDUS[®], exercising its first three contract options in July 2019, July 2020 and September 2021, respectively, followed by the execution of two contract modifications in 2023. In 2024, two additional contract modifications (valued at approximately \$80.0 million) were executed with BARDA; full delivery under the first modification was completed in 2024, and partial delivery for the second modification occurred in 2024 with the remainder to be delivered in 2025.

Ebanga[™] (ansuvimab-zykl), for injection. Ebanga[™] (ansuvimab-zykl) is a monoclonal antibody with antiviral activity provided through a single IV infusion (over 60 minutes) for the treatment of Zaire ebolavirus in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for Zaire ebolavirus. On July 1, 2022, we entered into an asset purchase agreement and a license agreement with Ridgeback Biotherapeutics (“Ridgeback”) to expand the availability of Ebanga[™] (ansuvimab-zykl). This included a license to the Ebanga[™] trademark and to certain patent rights related to Ebanga[™] (ansuvimab-zykl). We will be responsible for manufacturing, selling and distributing Ebanga[™] (ansuvimab-zykl) in the U.S. and Canada and Ridgeback will serve as the global access partner. In July 2023, we announced we were 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[™]. In September 2024, BARDA elected to exercise Option 1 (valued at approximately \$41.9 million) under the contract for work related to drug substance engineering, scale-up, stability, process validation and commercial readiness.

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.

TEMBEXA[®] (brincidofovir) tablets and oral suspension. TEMBEXA[®] is the first oral antiviral approved by the FDA for the treatment of smallpox disease caused by variola virus in adult and pediatric patients, including neonates. On September 26, 2022, we acquired exclusive worldwide rights to brincidofovir from Chimerix Inc. for the treatment of any human smallpox disease or any other disease caused by any orthopox virus. Following the acquisition, the 10-year contract with BARDA, valued at up to \$680.0 million, to supply up to 1.7 million tablet and suspension formulations of TEMBEXA[®] was novated to the Company, which contract was modified in September 2024 to execute additional procurement options valued at approximately \$67.4 million. 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. On November 6, 2024, Emergent announced that TEMBEXA[®] will be included in a clinical trial conducted and sponsored by PANTHER, under the leadership of the Africa Centers for Disease Control and Prevention, as part of the MpOx Study in Africa. The Company has two patent families relating to the TEMBEXA[®] 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.

VIGIV CNJ-016[®] (Vaccinia Immune Globulin Intravenous (Human)). VIGIV CNJ-016[®] 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 CNJ-016[®] 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 CNJ-016[®] into the SNS for smallpox preparedness. VIGIV CNJ-016[®] has also been procured by a limited number of foreign governments.

Commercial Product

Our current Commercial portfolio consists of the following product:

COMMERCIAL PRODUCTS		
Product	Indication(s)	Regulatory Approvals
NARCAN [®] (naloxone HCl) Nasal Spray	Emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression.	United States, Canada

Description of Commercial Product

NARCAN[®] Nasal Spray. NARCAN[®] Nasal Spray, a product we obtained in connection with our acquisition of Adapt Pharma Inc. in 2018, is an intranasal formulation of naloxone approved by the FDA and Health Canada for the emergency treatment of known or suspected opioid overdose as demonstrated by respiratory and/or central nervous system depression. We have rights to formulations of naloxone used in NARCAN[®] Nasal Spray from Indivior PLC (f/k/a Opiant Pharmaceuticals Inc.). The primary customers for NARCAN[®] Nasal Spray are state health departments, local law enforcement agencies, community-based organizations, substance abuse centers, federal agencies, and consumers. We launched the Generation II NARCAN[®] Nasal Spray device, which has a claim for enhanced temperature excursions and storage below 25°C. On January 18, 2024, the Company announced that the FDA has acknowledged the shelf-life extension of NARCAN[®] Nasal Spray from 36 months to 48 months based on the Company's four-year stability data.

On February 15, 2023, the 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[®] 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 OTC product was shipped out to retailers and e-commerce providers nationwide beginning in August of 2023 and continues to be available nationwide across grocery, drug stores and mass merchant.

On January 14, 2025, the Company announced an agreement with Hikma Pharmaceuticals Inc. ("Hikma") in which the Company obtained exclusive commercial rights for product sales and marketing in the United States and Canada to Hikma's KLOXXADO[®] (Naloxone HCl) Nasal Spray, an 8 mg naloxone agent.

Product Candidates

The table below highlights our current portfolio of product candidates:

PRODUCT CANDIDATES		
Product Candidate	Target Indication	Stage of Development
EBS-LASV (rVSV-vectored vaccine for Lassa fever)	Active immunization to prevent Lassa fever.	Phase 1 - Completed
EBS-MARV (rVSV-vectored vaccine for Marburg virus disease)	Active immunization to prevent Marburg virus disease.	Pre-Clinical
EBS-SUDV (rVSV-vectored vaccine for Sudan virus disease)	Active immunization to prevent Sudan virus disease.	Pre-Clinical
Pan-Ebola mAbs	Treatment of ebola virus disease caused by infection in patients with confirmed Sudan virus.	Pre-Clinical
WEVEE-VLP	To prevent disease caused by Western, Eastern, and Venezuelan equine encephalitis virus infections.	Phase 1 - Completed

Description of Product Candidates

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 while no safety concerns were observed, the vaccine did not meet the specified immunogenicity endpoint. This candidate will not progress into Phase 2.

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. Phase 1 GMP material is expected to be manufactured in 2025.

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. Phase 1 GMP material is expected to be manufactured in 2025.

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. Phase 1 GMP material is expected to be manufactured in 2025.

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.

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

We currently have four development and manufacturing sites located in the U.S. and Canada. These sites allow us to meet our internal manufacturing needs as well as perform targeted services for our external customers.

- Our Winnipeg and Gaithersburg sites house our development services expertise;
- Our Canton, Lansing and Winnipeg sites house our commercial drug substance expertise; and

- Our Winnipeg site houses our drug product and packaging expertise.

Marketing and Sales

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

Government - MCM Products

Our dedicated team possesses specialized knowledge and experience in both the public and private sectors, focusing on counter terrorism, CBRNE preparedness and public health. We facilitate the entire procurement process for our MCM products and procured product candidates globally through partnerships with the USG, international and domestic NGOs and foreign governments.

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.
BaciThrax [®]	France
CYFENDUS [®]	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.

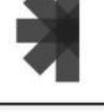
Commercial Product

In the U.S. market, NARCAN[®] (naloxone HCl) Nasal Spray is sold directly to state and local governments and used by first responders, including: police, firefighters and emergency medical teams. In addition, NARCAN[®] Nasal Spray is sold to consumers online and through retailers nationwide. 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.

On December 10, 2024, Emergent completed its FDA establishment registration (per Title 21 CFR Part 807) to authorize Emergent to distribute imported convenience kits containing medical devices (gloves and CPR mask) in the U.S. These convenience kits provide devices that support treatment of opioid overdose.

In the Canadian market, NARCAN[®] (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[®] Nasal Spray is sold to businesses 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 naloxone convenience kits containing medical devices (gloves and CPR mask) and Narcan[®] Nasal Spray (4mg) to comply with provincial legislative requirements. On December 22, 2023, Emergent Canada Inc. received the MDEL, enabling the direct distribution of naloxone convenience kits containing medical devices and NARCAN[®] Nasal Spray in Canada, which distribution was launched in 2024.

The following table lists the registered trademarks for NARCAN[®] (naloxone HCl) Nasal Spray:

Trademark	Country of Registration
NARCAN [®]	Benelux, Canada, Denmark, Estonia, EU, Finland, Germany, Ireland, Italy, Norway, Spain, Sweden, United Kingdom, U.S.
NARCAN	EU, Norway, United Kingdom, U.S.
NarcanNasalSpray	Benelux, Germany, Denmark, Spain, Estonia, Finland, United Kingdom, Ireland, Italy, Norway, Sweden
NARCAN TWINDOSE	EU, Norway, United Kingdom
NARCAN DIRECT	U.S.
	Canada, U.S.
	Canada, U.S.
	Canada
	EU, United Kingdom
	EU, United Kingdom
	EU, United Kingdom
	U.S.
	U.S.

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*[®]. *ACAM2000*[®] vaccine, which is licensed by the FDA for smallpox and mpox, and is licensed in Australia, Canada and Singapore for smallpox, remains the primary smallpox vaccine stockpiled by the USG and offers key features for public health mass vaccination programs that are critical, including a single dose vaccination schedule and multi-dose vial presentation. *ACAM2000*[®] vaccine faces competition from *JYNNEOS*[™] vaccine, which is licensed by the FDA for the prevention of smallpox and mpox disease in adults 18 years of age and older determined to be at high risk for smallpox or mpox infection. *JYNNEOS*[®] vaccine is also approved in Switzerland, Singapore and Mexico. *JYNNEOS*[®] vaccine is approved in Canada and in the EU and United Kingdom under the trade names *IMVAMUNE*[®] and *IMVANEX*[®], respectively. *ACAM2000*[®] vaccine also faces competition from *KM Biologics LC16m8* vaccine, which is approved in Japan for smallpox and mpox.
- *CYFENDUS*[®] and *BioThrax*[®]. *CYFENDUS*[®] and *BioThrax*[®] vaccines are currently procured, primarily by the USG, for prevention of anthrax disease. *BioThrax*[®] and *CYFENDUS*[®] vaccines are currently the only two anthrax vaccines approved by the FDA for prevention of anthrax disease, and *CYFENDUS*[®] and *BioThrax*[®] are the only anthrax vaccines procured by the USG for the SNS to date. We face potential future competition for the supply of anthrax vaccines if the USG chooses to procure alternative products or product candidates. *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 I trials.
- *BAT*[®]. Our botulinum antitoxin immune globulin product is the only heptavalent antitoxin licensed by the FDA and Health Canada for the treatment of symptomatic botulism for all seven botulinum neurotoxin serotypes. Direct competition is currently limited.
- *CNJ-016*[®]. Our *VIGIV* product is the only therapeutic licensed by the FDA and Health Canada to address adverse events from smallpox vaccination with replicating virus smallpox vaccines. While direct competition in terms of the treatment of smallpox vaccination side effects is limited, *SIGA* has obtained EU approval for *TPOXX*[®] (tecovirimat), an oral therapy, for the treatment of complications following vaccination against smallpox. *TPOXX*[®] is currently procured by the USG for the SNS.
- *Ebanga*[™] (ansuvimab-zykl). A monoclonal antibody therapeutic approved by the FDA in December 2020 for the treatment of infection caused by *Zaire Ebolavirus* in adult and pediatric patients, including neonates born to RT-PCR+ mother for *Zaire Ebolavirus* infection. *Ebanga* faces competition from another monoclonal antibody, *Inmazeb*[®] (atoltivimab, maftivimab and odesivimab-ebgn), which was approved by the FDA in October 2020 with the same indication. *Inmazeb*[®] is currently procured by the USG for the SNS.
- *NARCAN*[®]. *NARCAN*[®] (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*[®] 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*[®] Nasal Spray approved by the FDA. *Padagis* launched its generic naloxone nasal spray in 2022. *NARCAN*[®] Nasal Spray also faces branded competition: *Kloxxado*[™] (naloxone HCl) nasal spray 8mg, a branded product developed by *Hikma*, *Rextovy*[™] (naloxone HCL nasal spray 4 mg), a branded product developed by *Amphastar Pharmaceuticals, Inc.* and its naloxone injection product, *Teleflex Medical Inc.*'s *Intranasal Mucosal Atomization Device* and *Zimhi*[™] (naloxone), a branded injectable product developed by *Adamis* and *RiVive*[™] 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*[®] (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. In April 2024, the FDA approved *Rezenopy*[®] (naloxone HCL nasal spray 10mg), a branded product manufactured by *Summit Biosciences Inc.* In addition, in April 2024, the FDA

approved an additional ANDA for nasal naloxone 4mg from Amneal Pharmaceuticals, Inc., which was the first generic equivalent to OTC NARCAN[®] Nasal Spray to be launched. NARCAN[®] Nasal Spray may face additional generic and branded competition in the future.

- *Raxibacumab and Anthrasil[®] [Anthrax Immune Globulin Intravenous (Human)]*. Our raxibacumab product is the first FDA-licensed fully human anthrax monoclonal antibody therapeutic and Anthrasil[®] [Anthrax Immune Globulin Intravenous (Human)] is the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs. Elusys Therapeutics, Inc. has obtained FDA licensure for Anthim[®] (obiltoxaximab) injection, a monoclonal antibody indicated for the treatment and prophylaxis of inhalational anthrax. Obiltoxaximab is also approved in Canada.
- *TEMBEXA[®] (brincidofovir)*. TEMBEXA[®] 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[®] received approval by Health Canada. TEMBEXA[®] faces competition from TPOXX[®] (tecovirimat), an oral therapy for the treatment of smallpox disease that was approved by the FDA in July 2018 and is currently procured by the USG for the SNS. TPOXX[®] is also approved in Canada and the EU. In the EU and Japan, TPOXX[®] is indicated for the treatment of smallpox, mpox and cowpox, as well as the treatment of complications following vaccination against smallpox.

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., National Resilience, Grand River Aseptic Manufacturing, Berkshire Sterile Manufacturing, Jubilant HollisterStearns 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 and test its commercial and clinical supply of products. The following products are manufactured internally: ACAM2000[®], Anthrasil[®], BAT[®] and VIGIV CNJ-016[®].

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%, which is used in the manufacture of 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 believe 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 Supplement ("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[®], ACAM2000[®], Anthrasil[®], BAT[®], VIGIV CNJ-016[®] 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 CYFENDUS[®] (Anthrax Vaccine Adsorbed (AVA), Adjuvanted).

Public Readiness and Emergency Preparedness Act. The Public Readiness and Emergency Preparedness Act ("PREP Act") creates certain liability protections for manufacturers of MCMs when the Secretary of HHS issues a declaration related to a specific disease, condition or public health threat. The PREP Act 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 scope of protection will be defined by the specific PREP Act declaration. The only statutory exception to the immunity granted by the PREP Act 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, among other pathogens. These declarations could apply to ACAM2000[®], Anthrasil[®], BAT[®], BioThrax[®], CYFENDUS[®], raxibacumab and VIGIV CNJ-016[®] 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[®] in 2006 and has continued to renew those determinations. Any future renewals of the SAFETY Act designation and certification for BioThrax[®] 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 studies involve introduction of the drug into human subjects (usually healthy, but in some circumstances may include patients) 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 to explore preliminary efficacy, tolerance, optimal dosage, and safety.
- Phase 3 involves pivotal trials to assess clinical efficacy and safety in a larger number of healthy subjects or patients. These trials are intended to permit the FDA to evaluate the overall benefit-risk relationship of the product, and provide adequate information for approval and 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 and International Conference on Harmonization ("ICH") Guidelines. All phases of clinical studies must be conducted in conformance with the FDA's bioresearch monitoring regulations and Good Clinical Practices ("GCP"), which include applicable ICH Guidelines and are collectively ethical and scientific quality standards for the conduct and reporting of clinical trials in human subjects.

Marketing Approval – Biologics, Drugs and Vaccines

Biologics License Application ("BLA")/New Drug Application ("NDA"). 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 Under Section 505(j) 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 generally require ANDA applicants to provide preclinical and full clinical data to establish safety and effectiveness. However, a generic manufacturer is required to demonstrate bioequivalence (i.e., it provides the equivalent rate and extent of absorption as the innovator product) and meet other requirements (including that the generic product provides the same active ingredient in the same dose and dosage form via the same route of administration).

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, new strengths, new routes of administration 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 PHS Act, the product may be entitled to exclusivity barring FDA from accepting or approving an application under section 351(k) of the PHS Act 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 PHS Act, 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. 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 substitution 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 potentially 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 for seven years after approval of the product that received such exclusivity. 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.

After an appellate court decision issued in 2021 called into question the continued validity of FDA's approach to determining the scope of orphan-drug exclusivity, 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 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. In January 2024, the FDA issued a final rule amending the QSR to align more closely with the international consensus standard for Quality Management Systems for medical devices used by many other regulatory authorities around the world, ISO 13485:2016. The revised regulation is referred to as the Quality Management System Regulation ("QMSR") and becomes effective on January 2, 2026.

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. When issuing the QMSR, the FDA made conforming edits to the combination product regulation to clarify the device Quality Management System ("QMS") requirements for combination products. 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. These processes must be performed in compliance with the applicable portions of the QSR, which covers the methods and the facilities and controls for the manufacture, testing, production, 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 or announced 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. 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 new 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 its withdrawal in “Brexit.” At the time of withdrawal, all existing EU law in force as of December 31, 2020, was incorporated into UK domestic law, subject to modifications necessary due to Brexit. As a result, UK and EU regulatory requirements initially remained aligned; however, subsequent regulatory divergence has occurred and is expected to continue.

Until recently, the Medicines and Healthcare Products Regulatory Agency (the “MHRA”) served as the regulatory authority overseeing medicines and medical devices in Great Britain (England, Scotland, and Wales), while Northern Ireland remained subject to EU regulations under the Windsor Framework, which replaced the previous Northern Ireland Protocol in February 2023. As of January 1, 2025, the MHRA assumed full regulatory oversight for all medicinal products in the UK, including Northern Ireland, and the European Medicines Agency (the “EMA”) no longer has a role in approving products for the Northern Ireland market.

Additionally, an International Recognition Procedure (the “IRP”) took effect on January 1, 2024, designed to facilitate marketing authorizations in the UK for products already approved by a recognized regulatory authority. The IRP applies to products authorized by the EMA (for EU centralized approvals), national regulators in the European Economic Area (the “EEA”), and the FDA, among others. However, reliance-based or recognition-based regulatory decisions are not eligible under this procedure.

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.

We have a global corporate compliance program designed to identify, prevent, and mitigate healthcare fraud and abuse risk through, among other things, policies, systems and promoting a culture of compliance. Our 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"), among other provisions, gives 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 pay to HHS rebates based on certain calculations and triggers (i.e., when drug prices increase and outpace the rate of inflation). The Medicare Drug Price Negotiation 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, 2024, State Consumer Privacy Laws were effective in eight U.S. states. 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. Certain states, such as Nevada and Washington, have recently enacted consumer health data laws for the protection of consumers' personal health data by outlining broad definitions of consumer health data, a range of consumer rights and valid consent and other compliance requirements. Although similar to state consumer privacy laws, these consumer health data laws impose restrictions and obligations beyond state consumer privacy laws. Additionally, the Federal Trade Commission and many state attorneys general 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 save lives. 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. Our commitment to attracting, developing, and retaining talented employees helps us to fuel our business growth, drive innovation in the products and services we develop, and inform the way we solve problems and how we serve the needs of a global and diverse patient, customer and partner base. We believe that our investments in employee engagement and leadership development are essential to building the capabilities needed to realize our business strategy.

As of December 31, 2024, we had approximately 900 employees globally. During 2024, our number of employees declined by approximately 700 due to the organizational restructurings announced in May and August 2024, the sale of our Hattiesburg facility in July 2024, and the sale of our Camden Manufacturing facility to Bora in August 2024. For employees who were impacted by organizational restructuring, the Company provided transition services, severance and employee benefits.

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 employee engagement survey and administer "pulse surveys" throughout the year to gather feedback on matters of interest and importance to our employees and our business.

Our total rewards plan consists of comprehensive benefits and salaries, bonuses, and for employees in eligible roles, equity awards. 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.

In addition, we are deeply committed to the health and well-being of our employees. We provide a comprehensive range of benefits and resources to support their physical, mental, and financial wellness. Additionally, our safety programs comply with regional requirements and are designed to ensure a safe and comfortable work environment, including a strong culture of safety in our day-to-day operations.

SUSTAINABILITY AND CORPORATE RESPONSIBILITY

Our mission to protect and save lives has motivated us to explore our impact at a broader scale. Our approach to these issues is the foundation of good governance and strengthens accountability in all aspects of our business activities and relationships. In 2024, our EVP, Chief Quality and Compliance Officer joined the Chief Financial Officer as co-executive sponsor of our sustainability and corporate responsibility initiatives, further weaving corporate responsibility efforts into business operations. We also updated several policies, including our Combating Trafficking in Persons Standard and U.S. Government Contracting Policy as well as implemented a Supplier Code of Conduct, and will continue making similar improvements to support our responsible growth and to align with stakeholder expectations.

Along with continued work on a multi-year strategy that supports company objectives, we invested additional resources in assessing and preparing for emerging sustainability regulations in the U.S. and globally. We will continue to monitor and prepare for disclosure requirements. Our approach is influenced by the framework developed by the Task Force on Climate-Related Disclosures 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.

Priority Issues

We updated our priority issues in 2023, with small adjustments in 2024. They are as follows:

- Top Priorities
 - Talent Attraction, Engagement & Development
 - Ethics & Compliance
 - Product Quality & Patient Safety
 - Sustainable Innovation
 - Product Affordability & Accessibility
 - Responsible Supply Chain
- Relative Priorities
 - Supplier Product Quality, Reliability and Compliance
 - Clinical Trial Practices
 - Employee Health and Safety
 - Climate Impact
 - Sustainability and Corporate Responsibility Oversight

Corporate Responsibility for Environmental Management

We recognize that our operations have an impact on both local and global communities from the energy we source, the waste we generate, and the water we discharge. When improving and innovating our operational infrastructure across our enterprise, we give due consideration to the extent to which they may adversely threaten the environment and human health.

We gather data associated with our material operations as a critical step to prioritize future footprint reductions and to be prepared for potential reporting requirements. This data is used to calculate our Scope 1 and Scope 2 greenhouse gas (GHG) emissions, and we are continually expanding our data collection efforts to garner the most comprehensive view of our environmental impacts. This allows us to make informed decisions regarding potential goals, which could include setting science-based targets and creating an accompanying roadmap for enterprise environmental goals. We will continue to monitor to determine the relevant future disclosures, if any, necessary to provide transparency surrounding possible financial impacts to our company through sound governance, strategy, risk management, and performance monitoring.

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. 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

This risk factor summary contains a high-level summary of risks associated with our business. It does not contain all of the information that may be important to you, and you should read this risk factor summary together with the more detailed discussion of risks and uncertainties set forth following this summary. A summary of our risks includes, but is not limited to, the following:

- Reduced demand for and/or funding for procurement of CYFENDUS[®], ACAM2000[®], VIGIV CNJ-016[®], BAT[®] and/or BioThrax[®], discontinuation of funding of our 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.
- Our inability to maintain quality and compliance in all of our manufacturing operations.
- Damage to, destruction of, or any unplanned disruption at 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.
- 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.
- 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.
- Development and commercialization of pharmaceutical products and our biologic products are subject to evolving competition from private and public sector competition, or biosimilar manufacturers.
- NARCAN[®] (naloxone HCl) Nasal Spray is currently subject to generic and branded competition and may be subject to additional branded and generic competition in the future.
- Biologic products may be affected by the approval and entry of follow-on biologics, or biosimilars in the United States and other jurisdictions.
- 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 expiration of patents and/or regulatory exclusivity or with patents no longer in force.
- 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.

- 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.
- Our ability to maintain sufficient cash flow from our operations to pay our substantial debt, both now and in the future.
- Restrictions on the operation of our business and limitations on cash available for investment in our business operations as a result of our current indebtedness.
- 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.
- 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 our divestitures.
- 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, and historically derived a substantial portion of our revenue from USG procurement of CYFENDUS[®], ACAM2000[®], VIGIV CNJ-016[®], BAT[®] and/or BioThrax[®]. If the USG's demand for and/or funding for procurement of these products 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[®]. 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[®] or BioThrax[®] vaccines may be delayed, limited or not available, BARDA may never complete the anticipated full transition to stockpiling CYFENDUS[®] in support of anthrax preparedness, and our future business, financial condition, operating results and cash flows could be materially harmed.

In addition, we derive a substantial portion of our revenues from sales of ACAM2000[®] vaccine to the USG. In the past, the priorities of the SNS have changed with respect to ACAM2000[®] vaccine and if the priorities of the SNS change for ACAM[®] vaccine in the future or the USG decides not to exercise additional options under our ACAM2000[®] contract, our future business, financial condition, operating results and cash flows could be materially harmed.

As with any approved product, there is a risk that we may encounter challenges causing delays or an inability to deliver CYFENDUS[®], ACAM2000[®], VIGIV CNJ-016[®], BAT[®] and/or BioThrax[®], which may have a material effect on our ability to generate and recognize revenue.

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[®] 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[™] (ansuvimab-zykl) treatment for Ebola. The contract consists of a base period of performance with two option periods valued at approximately \$121 million, which were exercised on September 5, 2024 and January 10, 2025, respectively, and option periods for procurement of Ebanga[™] over five years valued at up to \$583 million, one of which was awarded in September 2024 (valued at \$41.9 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. For example, ACAM2000[®] vaccine faces competition from JYNNEOS[™] vaccine, which product has been procured by the USG in recent years. 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 contracts with the USG 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 contracts with the USG, 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 damage our reputation and 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 August 2023, the FDA inspected Emergent's Canton, Massachusetts facility and in December 2023, the FDA inspected Emergent's Lansing, Michigan facility, and in each case the FDA issued a Form FDA 483 and both facilities were classified as "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. In February 2024, the FDA inspected Emergent's Bayview facility in Baltimore, Maryland. The Bayview facility inspection was classified as "no action indicated" or NAI.

The failure to remedy any objectionable conditions at Emergent's manufacturing facilities, any additional failures to maintain compliance with CGMP requirements at any of our manufacturing facilities, or any administrative or regulatory action or recommendation to take any such action by the FDA could damage our reputation and adversely affect our business, financial condition, operating results and cash flows.

Damage to, destruction of, or any disruption at our manufacturing facilities could impede our ability to manufacture our products or product candidates, as well as impact the delivery of bioservices to third parties, 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 destruction of, or disruption at 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 product development, manufacturing and shipment or other factors. Significant delays in product development or manufacturing 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, including as a result of regulatory action, 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.

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 product 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 regulatory authority and/or 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

finances 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 internally or for third-party 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 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 initiation of stockholder litigation and government investigations described elsewhere in this Annual Report. In June 2022, we became involved in a contractual dispute with Janssen regarding the manufacture of its COVID-19 vaccine, which resulted in arbitration proceedings. See Note 19, "Litigation" in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K for more detail. While the dispute initially created additional financial and operational uncertainty, the matter was resolved in July 2024. Pursuant to the Settlement Agreement, the Company received \$50.0 million from Janssen, and all claims among the parties arising from the Janssen Agreement were resolved; however, the dispute, litigation, the associated cost and reputational harm have had a material adverse effect on our business. Further, as we have reduced the emphasis on our Bioservices business, concerns may exist 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. As part of our stabilization efforts in 2024 related to our multi-year strategic plan, we changed and refocused several areas of our business, and may continue to change or refocus our business activities, including product development, commercialization and manufacturing activities based on government funding decisions and other factors. This required changes, and may require changes in the future, 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 operate our business and transact business with our government clients and impose compliance costs on our operations. In addition, these laws and regulations may be subject to sudden change, which may impose additional costs and related obligations on our operations or require us to make changes to the way we operate our business or transact business with our government clients. 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. 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. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and approved by necessary government agencies, which could adversely affect our business. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

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, any EU Member State, or UK 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 European 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 policy or legislation may increase the difficulty and cost for us and our collaborators to obtain marketing approval of and commercialize our product candidates, which may affect the prices we, or our collaborators, may obtain.

In the United States and foreign jurisdictions, there have been a number of policy, 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 approved products. 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.

There has been continued heightened federal governmental scrutiny over the manner in which manufacturers set prices for their marketed products. This includes Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

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 (and currently is being implemented through guidance documents from the responsible federal agencies), the IRA, as written, among other changes, gives HHS the ability and authority to directly negotiate with manufacturers the price that Medicare will pay for certain high-priced drugs. The IRA also requires 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). While we are not directly affected by the IRA at this time, 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.

A number of states have passed legislation and implemented 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. These measures could reduce the ultimate demand for approved products, 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 products 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 U.S. regulatory authorities, a practice which we followed in connection with CYFENDUS[®] prior to its approval by the FDA. 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. 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 RSDL[®] kits were 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. The FDA terminated the November 2022 Recall in October 2024.

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. We currently have market authorization under the mutual recognition procedure to sell BioThrax[®] in France and Germany. 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, in Canada by Health Canada, 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") serves as the regulatory authority overseeing medicines and medical devices in Great Britain (England, Scotland, and Wales), while Northern Ireland is subject to EU regulations under the Windsor Framework (replacing the Northern Ireland Protocol in February 2023). As of January 1, 2025, the MHRA will assume full regulatory oversight for all medicinal products in the UK, including Northern Ireland, and the European Medicines Agency ("EMA") will no longer have a role in approving products for the Northern Ireland market.

Additionally, a new International Recognition Procedure ("IRP") took effect on January 1, 2024, designed to facilitate marketing authorizations in the UK for products already approved by a recognized regulatory authority. The IRP applies to products authorized by the EMA (for EU centralized approvals), national regulators in the European Economic Area ("EEA"), and the U.S. Food and Drug Administration ("FDA"), among others. However, reliance-based or recognition-based regulatory decisions are not eligible under this procedure.

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 or elsewhere for our product candidates, which could significantly and materially harm our business. In addition, due the evolving nature of UK regulations, further divergence from EU requirements may impact the development, approval, and commercialization of our products in these markets.

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 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. We may be held responsible for conduct of the third parties with which we interact. 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. In addition, actions that the U.S. government and other governments have taken or threatened to take regarding tariffs and trade, and the associated uncertainty of how such actions may be implemented, may have adverse effects on the global economic environment and could also amplify these risks.

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[®], BioThrax[®] and ACAM2000[®]. If a biosimilar version of one of our Biologic Products were approved, it could have a material adverse effect on the sales and gross profits of the affected Biologic Product and could adversely affect our business, financial condition, operating results and cash flows.

NARCAN[®] (naloxone HCl) 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[®] Nasal Spray outpaces current estimations, there could be supply challenges to meet demand.

NARCAN[®] Nasal Spray was approved as an over-the-counter (“OTC”) medication in the U.S. on March 29, 2023 and became available to retailers and e-commerce providers nationwide in August 2023. If demand for NARCAN[®] Nasal Spray increases beyond our current estimates, there could be supply interruptions. Although we have contingency plans to continue to provide product to those at the highest need and increase production to meet the anticipated increase in demand, such contingency plans may be unsuccessful or the implementation of such plans delayed, which could cause supply interruptions and adversely affect our business, financial condition, operating results and cash flows,

NARCAN[®] 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[®] 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[®] 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 April 2024, the FDA approved an ANDA filed by Amneal Pharmaceuticals, Inc. (“Amneal”) for generic naloxone nasal spray.

Sales of generic versions of NARCAN[®] Nasal Spray at prices lower than our branded product or provided at no cost by Teva, Padagis and Amneal have the potential to erode our sales and could impact our product revenue related to NARCAN[®] Nasal Spray.

NARCAN[®] Nasal Spray also faces branded competition from prescription products, such as Kloxxado[™] (naloxone HCl nasal spray 8mg), a branded product developed by Hikma, Zimhi[™] (naloxone), a branded injectable product developed by Amnis Pharmaceuticals Corporation, Rextovy[™] (naloxone HCL nasal spray 4 mg), a branded product developed by Amphastar Pharmaceuticals, Inc. and its naloxone injection product, Teleflex Medical Inc.’s Intranasal Mucosal Atomization Device, OPVEE[®] (nalmefene nasal spray 2.7mg), a branded product developed by Opiant Pharmaceuticals Inc. (now a wholly owned subsidiary of Indivior PLC), and Rezenopy[®] (naloxone HCL nasal spray 10mg), a branded product manufactured by Summit Biosciences Inc., as well as OTC products, such as RiVive[™] (naloxene HCl nasal spray 3mg), a branded product developed by Harm Reduction Therapeutics.

NARCAN[®] (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 them 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 intellectual property rights. Our existing patents could be invalidated, found unenforceable, or narrowed in scope. Our trademark and trade name rights and related registrations may be challenged, opposed, infringed, diluted, canceled, circumvented, declared generic or determined to be infringing on other marks.

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 materials 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, manufacturing and other services necessary to produce and release the majority of our products and certain product candidates. For example, we rely on a single-source supplier to provide us with Alhydrogel[®] in sufficient quantities to meet our needs to manufacture CYFENDUS[®] and BioThrax[®] vaccines and the specialty plasma in our hyperimmune specialty plasma products and certain ingredients for the ACAM2000[®] vaccine. We also rely on single-source suppliers for the materials necessary to produce NARCAN[®] (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, in 2021, multiple purported class action lawsuits were 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 alleged, 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. In September 2024, we and the lead plaintiffs entered into an agreement in principle to settle these claims, and on October 4, 2024, the Court granted preliminary approval of the proposed settlement, ordered notice to the settlement class and scheduled a fairness hearing to consider whether to grant final approval of the settlement. At the scheduled fairness hearing on February 27, 2025, the Court granted final approval of the settlement. 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 cybersecurity 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 cybersecurity incidents. We are not aware of any significant impact on our operations or financial results from such incidents.

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. Cybersecurity 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 cybersecurity 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[®], ACAM2000[®], CYFENDUS[®], raxibacumab, Anthrasil[®], BAT[®] and VIGIV CNJ-016[®] 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[®], 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[®] is designated and certified under the SAFETY Act, the law may not provide adequate protection from claims made against us.

If we cannot successfully defend ourselves against future claims that our products or product candidates caused injuries and if we are not entitled to indemnity by the USG, or the USG does not honor its obligations to us under the PREP Act or SAFETY Act, or if the liability protections under the PREP Act and SAFETY Act are not adequate to cover all claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand or withdrawal of a product;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- an inability to commercialize products that we may develop.

The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. Further product liability insurance may be difficult and expensive to obtain. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy all potential liabilities. For example, we may not have sufficient insurance against potential liabilities associated with a possible large-scale deployment of BioThrax[®] vaccine as a countermeasure to a bioterrorism threat. We rely on PREP Act protection for BioThrax[®], raxibacumab, ACAM2000[®], CYFENDUS[®], Anthrasil[®], BAT[®] and VIGIV CNJ-016[®] products, and SAFETY Act protection for BioThrax[®] 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[®] (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

Our level of indebtedness and the terms of our indebtedness could adversely affect our business and liquidity position. We may not have sufficient cash flow from our operations to pay our substantial debt.

As described in Note 10, "Debt" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report on Form 10-K, as of December 31, 2024, we have approximately \$700.0 million of total indebtedness, which includes our outstanding Senior Unsecured Notes.

Our level of indebtedness could have important consequences for us, including:

- limiting our ability to obtain additional financing, if needed, for working capital, capital expenditures, acquisitions, debt service requirements or other purposes;
- increasing our vulnerability to adverse economic, industry or competitive developments;
- limiting our flexibility in planning for, or reacting to, changes in our business and industry; and
- placing us at a competitive disadvantage compared to our competitors with less debt.

Our indebtedness may increase from time to time for various reasons, including fluctuations in operating results, working capital needs, capital expenditures, acquisitions and/or joint ventures. The cost and level of our debt could negatively impact our liquidity, future financing costs and financial results, while potential credit rating downgrades or adverse market conditions could increase borrowing costs or limit access to capital. Our cash flow and capital resources may not be sufficient to meet our debt obligations, and alternative financing measures may not be available on terms that are acceptable to us, or at all.

Our ability to service or refinance our debt 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 reduce financial flexibility; and
- increasing our exposure to adverse economic and industry conditions, furthering disadvantaging us against our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

In addition, failure to comply with the covenants under our Senior Secured Credit Facilities and other debt agreements, including the maintenance of a specified gross leverage ratio, fixed charge coverage ratio and minimum liquidity level, could result in an event of default. 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. If such events occur, we may not have sufficient funds to pay or financing options to meet these obligations.

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 \$250.0 million as of December 31, 2024, and the ability to borrow up to \$100.0 million under the Revolving Credit Agreement (subject to certain adjustments described therein). In addition, we have outstanding an aggregate principal amount of \$450.0 million of our 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. For example, if we default under the Senior Secured Credit Facilities, the lenders would have the right to accelerate the repayment of borrowings under the Senior Secured Credit Facilities, which would result in a cross-default and acceleration of the Company's obligations under the Senior Unsecured Notes. 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 may be unable to continue to progress on or implement our strategic plans and sustain our current operating performance, in which case our business, results of operations, financial condition and prospects could be adversely affected, and which may give rise to substantial doubt regarding our ability to continue as a going concern.

As of December 31, 2024, we had unrestricted cash and cash equivalents of \$99.5 million and remaining capacity under the Revolving Credit Agreement of \$100.0 million. Also as of December 31, 2024, we had borrowings of \$250.0 million on our Term Loan Facility and \$450.0 million of Senior Unsecured Notes outstanding. The Company may be unable to comply with debt covenants in future periods without additional sources of liquidity.

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. Our Registration Statement on Form S-3 that related to our ATM Program expired on August 9, 2024. We cannot sell any shares under the ATM Program until a new Registration Statement on Form S-3 is filed and becomes effective. There can be no assurance that we will have such a shelf registration statement become effective in the future, which may inhibit our ability to access the capital markets to raise funds.

If we raise funds by issuing equity securities, including through a new shelf registrations statement, 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 the Bayview and Rockville asset groups within the Bioservices reporting unit during the three months ended June 30, 2024, and recognized a non-cash impairment charge of \$27.2 million during the three months ended June 30, 2024 related to certain Bioservices long-lived assets.

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. Any material weakness in our internal control over financial reporting could have an adverse effect on our business and financial results and our

ability to meet our reporting obligations could be negatively affected, each of which could negatively affect the trading price of our common stock.

Internal control over financial reporting can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements and may not prevent or detect misstatements. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Failure to maintain effective internal control over financial reporting, or lapses in disclosure controls and procedures, could impact our financial information and disclosures, require significant resources to remediate, and expose us to legal or regulatory proceedings.

We regularly review and update our internal controls and disclosure controls and procedures. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting.

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, the sale of RSDL[®] to SERB, and the sale of our drug product facility in Baltimore-Camden to Bora.

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.

On June 20, 2024, Cangene bioPharma LLC (“Cangene”), a subsidiary of the Company (together with Cangene, the “Seller”), entered into an Asset Purchase Agreement with Bora, under which the Seller sold its drug product facility in Baltimore-Camden for a cash purchase price of approximately \$35.0 million. The transaction closed on August 20, 2024.

On July 31, 2024, we entered into the Stock and Asset Purchase Agreement with SERB Pharmaceuticals, through its wholly owned subsidiary BTG International Inc. (collectively, “SERB”), pursuant to which, among other things, we sold our worldwide rights to RSDL[®], to SERB (the “RSDL[®] Transaction”) for a cash purchase price of \$75.0 million, exclusive of customary closing adjustments related to inventory. In addition, SERB will pay us a \$5.0 million payment upon achievement of a milestone relating to sourcing of a certain component of RSDL[®] decontamination lotion. The Transaction also included the sale to SERB of all the outstanding capital stock of Emergent Protective Products USA Inc. (“EPPU”), a wholly owned subsidiary of the Company, which leases a manufacturing facility in Hattiesburg, Mississippi, as well as certain assets related to RSDL[®], including intellectual property rights, contract rights, inventory and marketing authorizations. In addition, the employees of EPPU joined SERB in connection with the RSDL[®] Transaction.

There can be no assurance that we will be able to realize in full the expected benefits of these transactions, including as to whether any milestone payments will be received. If we are unable to or do not realize the expected strategic, economic, or other benefits of these transactions, 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, certain institutional investors may continue to focus on sustainability and corporate responsibility 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. For the five-year period beginning January 1, 2020 and ending December 31, 2024, our common stock traded as high as \$134.94 per share and as low as \$1.50 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. We may require or desire additional funding in the future 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, 2024, we had 54,329,542 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 Chief Executive Officer is critical to executing on and achieving our vision, strategic direction, and business objectives. 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 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. 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. As part of our ongoing Enterprise Risk Management ("ERM") enhancements, our ERM intranet page was launched in 2024 to centralize risk-related resources and policies. During the third quarter of 2024, a comprehensive reassessment of the Company's enterprise risks was conducted, with results thoroughly reviewed and communicated to executive leadership (VP and above) to align on key risks and strategic priorities. Annually, we provide an ERM training 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 and 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. Additionally, the Company maintains a cybersecurity insurance policy to help mitigate the impacts of potential cybersecurity incidents.

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 cybersecurity 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; and
- 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 Board of Directors. 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 certified in Risk and Information Systems Control[®] (CRISC) and Certified Information Privacy Professional/United States (CIPP/US). 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; and
- Performed an internal phishing campaign and awareness program.

ITEM 2. PROPERTIES

We own and lease approximately 1.2 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 12 locations in North America and Europe. Properties that have been leased expire on various dates between 2025 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.	47,000 (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
Rockville, Maryland	Manufacturing facilities, office and warehouse space.	84,295	Owned	Products & Services

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 25, 2025, the closing price per share of our common stock on the New York Stock Exchange was \$7.21 and we had 41 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

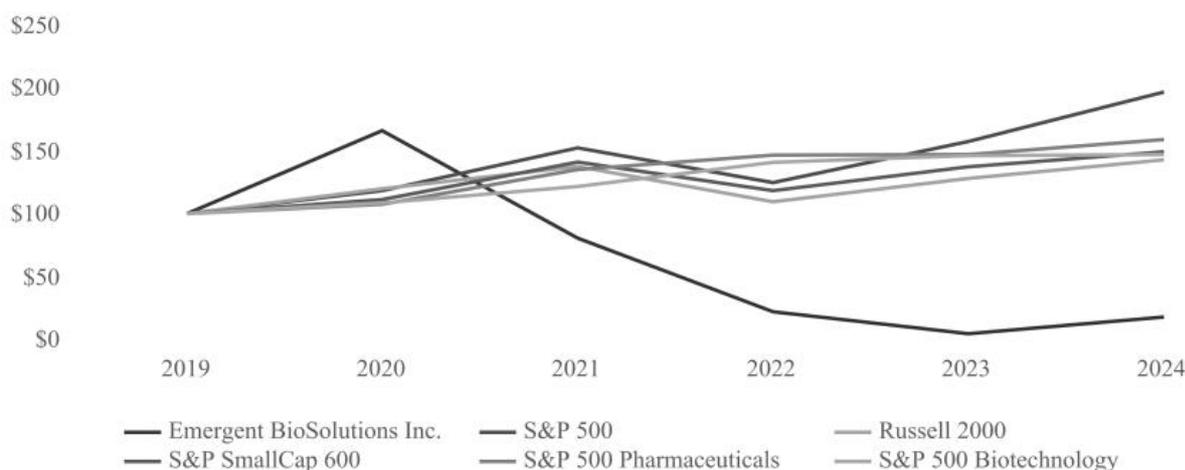
We have not declared or paid any cash dividends on our common stock since becoming a publicly traded company in November 2006. We currently have no plans to pay dividends.

The remaining information required by Item 5 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2025 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, 2019, all fiscal years end December 31st and all dividends were reinvested.

Comparison of Five Year Cumulative Total Return



Company / Index	Market Performance					
	2019	2020	2021	2022	2023	2024
Emergent BioSolutions Inc.	\$ 100.00	\$ 166.08	\$ 80.57	\$ 21.89	\$ 4.45	\$ 17.72
S&P 500	\$ 100.00	\$ 118.40	\$ 152.39	\$ 124.79	\$ 157.59	\$ 197.02
Russell 2000	\$ 100.00	\$ 119.96	\$ 137.74	\$ 109.59	\$ 128.14	\$ 142.93
S&P SmallCap 600	\$ 100.00	\$ 111.29	\$ 141.13	\$ 118.41	\$ 137.42	\$ 149.37
S&P 500 Pharmaceuticals	\$ 100.00	\$ 107.53	\$ 135.21	\$ 146.65	\$ 147.13	\$ 159.21
S&P 500 Biotechnology	\$ 100.00	\$ 108.63	\$ 121.80	\$ 140.85	\$ 146.27	\$ 147.24

ITEM 6. [RESERVED]

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and accompanying 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 includes information with respect to our plans and strategy for our business and financing, as well as forward-looking statements that involve risks and uncertainties. You should carefully review the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in 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"); emerging health crises; and acute, emergency and community care. We have a product portfolio of 10 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[®], 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 Product segment consisting of our NARCAN[®]; (2) a MCM Products segment consisting of the Anthrax - MCM, Smallpox - MCM and Other Products and (3) a Services segment consisting of our Bioservices portfolio.

Commercial Product Segment:

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

NARCAN[®]

- NARCAN[®] (naloxone HCl) Nasal Spray, an intranasal formulation of naloxone approved by the United States Food and Drug Administration ("FDA") (including in over-the-counter ("OTC") 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 Vivotif[®], 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, "Divestitures" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K.

MCM Products Segment:

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

Anthrax - MCM Products

- Anthrasil[®] (Anthrax Immune Globulin Intravenous (human)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of inhalational anthrax in combination with appropriate antibacterial drugs;
- 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[™] (ansuvmab-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[™]; and
- Trobigard[®] atropine sulfate, obidoxime chloride auto-injector, a combination drug-device auto-injector procured product candidate that contains atropine sulfate and obidoxime chloride. On April 2, 2024, the Belgium Federal Agency for Medicines and Health Products (“FAMHP”) acknowledged and confirmed Emergent’s request to revoke the Market Authorization for the Trobigard Auto-Injector.

Services Segment:

Bioservices - contract development and manufacturing

The Company's 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 the Company refers to as "molecule-to-market" offerings, employ diverse technology platforms (mammalian, microbial, viral and plasma) across a network of development and manufacturing sites operated by the Company for its internal products and pipeline candidates and third-party bioservices. The Company offers services for 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. In May 2024, the Company initiated a further organizational restructuring plan (the "May 2024 Plan") announcing the closure of the Company's Baltimore-Bayview Drug Substance manufacturing facility and Rockville, Maryland Drug Product facility. Additionally, on August 20, 2024, pursuant to the previously announced Asset Purchase Agreement (the "Asset Purchase Agreement"), the Company completed the sale of its Drug Product facility in Baltimore-Camden (the "Camden Transaction") to Bora Pharmaceuticals Injectables Inc., a subsidiary of Bora Pharmaceuticals Co., Ltd. ("Bora"). See Note 3, "Divestitures" and Note 4, "Impairment and restructuring charges" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K for more information related to these announcements.

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 charges related to the January 2023 Plan consisted primarily of employee transition, severance payment and employee benefit charges. The cumulative amount of restructuring charge related to the January 2023 Plan since inception is \$9.3 million. 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 charges related to the August 2023 Plan consisted primarily of employee transition, severance payment and employee benefit charges. The cumulative amount of restructuring charge related to the August 2023 Plan since inception is \$19.4 million. 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.

Trobigard Revocation

On April 2, 2024, Emergent submitted its revocation of the Market Authorization for the Trobigard Auto-Injector to the Belgium FAMHP. The FAMHP subsequently acknowledged and confirmed the revocation date as being April 2, 2024.

May 2024 Organizational Restructuring Plan

In May 2024, the Company initiated the May 2024 Plan. These strategic actions led to a reduction of the Company's workforce by approximately 300 employees across all areas of the Company and the elimination of approximately 85 positions that were vacant, as well as the closure of the Company's Baltimore-Bayview Drug Substance manufacturing facility and Rockville, Maryland Drug Product facility. Decisions regarding the elimination of positions and the closure of manufacturing facilities were subject to local law and consultation requirements in certain countries, as well as the Company's business needs. The cumulative amount of restructuring charge related to the May 2024 Plan since inception is \$19.8 million. All activities related to the May 2024 Plan were substantially completed during the third quarter of 2024. 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.

Confidential arbitration settlement with Janssen

On July 3, 2024, the Company and its wholly owned subsidiary, Emergent Manufacturing Operations Baltimore, LLC (“EMOB”), entered into a settlement agreement with Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson (“Janssen”) (the “Settlement Agreement”) to resolve all claims among the Parties arising from the 2022 termination of the manufacturing services agreement with Janssen (the “Janssen Agreement”). The Settlement Agreement also resolves the Parties’ related and previously disclosed arbitration.

Pursuant to the terms of the Settlement Agreement, Janssen paid the Company \$50.0 million on July 31, 2024. In addition, the Settlement Agreement contains broad releases of the parties, their affiliates and subsidiaries, representatives, officers, directors and shareholders, including releases of all claims related to the manufacture of the Product by EMOB, the Janssen Agreement, or any agreement or understanding between the parties concerning the investigational SARS-CoV-2 vaccine, Ad26.COV2-S, recombinant based on the AdVac technology, and the matters at issue in the arbitration.

Development milestone payments for CHIKV VLP

On July 18, 2024, Bavarian Nordic announced that the European Medicines Agency had validated the marketing authorization application for CHIKV VLP, which was submitted in June 2024. This approval triggered a milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$10.0 million.

On August 13, 2024, Bavarian Nordic announced that the FDA had accepted and granted priority review for the Biologics License Application for CHIKV VLP, which triggered a milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$20.0 million.

On February 14, 2025, Bavarian Nordic announced that the FDA approved CHIKV VLP under the Priority Review, which triggered a development milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$30.0 million, which is expected to be received in the first half of 2025.

On February 28, 2025, Bavarian Nordic announced that the European Commission approved CHIKV VLP, which triggered a development milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$20.0 million, which is expected to be received in the first half of 2025.

Sale of RSDL[®]

On July 31, 2024, the Company, through its wholly owned subsidiary Emergent BioSolutions Canada Inc., entered into the RSDL[®] Agreement with SERB pursuant to which, among other things, the Company sold its worldwide rights to RSDL[®] to SERB. The RSDL[®] Transaction also included the sale to SERB of all the outstanding capital stock of Emergent Protective Products USA Inc. (“EPPU”), a wholly owned subsidiary of the Company, which leases a manufacturing facility in Hattiesburg, Mississippi, as well as certain assets related to RSDL[®], including intellectual property rights, contract rights, inventory and marketing authorizations. In addition, the employees of EPPU joined SERB in connection with the RSDL[®] Transaction.

Pursuant to the RSDL[®] Transaction, SERB assumed certain government contracts related to RSDL[®] decontamination lotion, including the Company’s existing contract to supply RSDL[®] to the U.S. Department of Defense, through a new contract award to the Canadian Commercial Corporation.

At the closing, SERB paid a cash purchase price of \$75.0 million, exclusive of customary closing adjustments related to inventory. In addition, SERB will owe the Company a \$5.0 million payment upon achievement of a milestone relating to sourcing of a certain component of RSDL[®] decontamination lotion. The Company recognized a gain on sale of business of \$60.8 million, net of transaction costs of \$4.1 million, during the year ended December 31, 2024.

The Company and SERB entered into a transition services agreement (the “SERB TSA”) to ensure the orderly transition of RSDL[®] decontamination lotion and the related assets to SERB, and a supply agreement (the “SERB Supply Agreement”) pursuant to which SERB has a suite reservation at the Company’s Winnipeg facility where the Company will perform Bioservices activities to manufacture and supply bulk lotion to SERB. The Company and SERB also entered into a reverse supply agreement (together with the SERB TSA and the SERB Supply Agreement, the “SERB Agreements”) pursuant to which SERB supplies finished RSDL[®] to the Company for the Company’s performance of certain transitional distribution services under customer contracts that have not yet transferred to SERB. Under the SERB Agreements, the Company will retain a portion of net sales received upon delivery of RSDL[®] to the delayed transfer customers.

Sale of Baltimore-Camden Facility

On August 20, 2024, pursuant to the Asset Purchase Agreement, the Company completed the sale of its Drug Product facility in Baltimore-Camden to an affiliate of Bora. The Camden site, which was part of the Company's Bioservices segment, has clinical and commercial non-viral aseptic fill/finish services on four fill lines, including lyophilization, formulation development, and support services. Alongside the facility, approximately 350 Emergent employees joined Bora as part of the transaction.

At closing, Bora paid a cash purchase price of approximately \$35.0 million, which included customary closing adjustments for working capital and transaction expenses of the business. As a result of the divestiture, the Company recognized a loss on sale of business of \$36.5 million, net of transaction costs of \$3.8 million, during the year ended December 31, 2024.

August 2024 Organizational Restructuring Plan

In August 2024, the Company initiated the August 2024 Plan at the Company's Lansing facility, which reduced the Company's workforce by approximately 70 employees, as well as eliminated several open positions. The Company also implemented non-labor optimization efforts, such as reducing the Company's external and vendor spend. The cumulative amount of restructuring charges related to the August 2024 Plan since inception is \$3.3 million. All activities related to the August 2024 Plan were substantially completed during the fourth quarter of 2024. 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.

Term Loan Agreement

On August 30, 2024, the Company entered into a Credit Agreement (the "Term Loan Agreement") with the lenders from time to time party thereto, and OHA Agency LLC, as administrative agent. The Term Loan Agreement provides for a term loan (the "Term Loan") of \$250.0 million, which was drawn in full on the date of entry into the Term Loan Agreement (the "Closing Date"). The Term Loan was issued with an original issue discount of 3.00%.

On the Closing Date, the Company used a portion of the proceeds of the Term Loan to repay all amounts outstanding and terminate commitments under the senior term loan facility under the Company's Amended and Restated Credit Agreement, dated October 15, 2018, by and among the Company, the lenders party thereto from time to time, and Wells Fargo Bank, National Association, as the Administrative Agent (the "Prior Credit Agreement"), plus accrued interest and fees. The Company previously repaid all amounts outstanding under the revolving credit facility under the Prior Credit Agreement.

Securities and shareholder litigation

On September 12, 2024, the Company and the lead plaintiffs in stockholder litigation against the Company entered into an agreement in principle to settle the claims against the Company and each of the Company's current and former officers and directors. On October 4, 2024, the Court granted preliminary approval of the proposed settlement, ordered notice to the settlement class and scheduled a fairness hearing for February 27, 2025. On February 6, 2025, the lead plaintiffs filed a Motion for Final Approval of Class Action Settlement, Certification of the Settlement Class and Approval of Plan of Allocation and Motion for Award of Attorneys' Fees, Reimbursement of Expenses and Compensatory Awards for lead plaintiffs. Under the proposed settlement, the claims against the Company and its officers and directors will be dismissed with prejudice and released in exchange for a payment from the Company of \$40.0 million, \$30.0 million of which was paid from insurance proceeds, and was funded in the fourth quarter of 2024. At the scheduled fairness hearing on February 27, 2025, the Court granted final approval of the settlement. The Company recorded the settlement and insurance recoverable amounts as pre-tax operating expense and income, respectively, within "Selling, general and administrative" expenses on the Consolidated Statement of Operations for the year ended December 31, 2024.

Asset-Based Revolving Loan

On September 30, 2024, the Company entered into a credit agreement for asset-based revolving loans (the "Revolving Credit Agreement") with certain subsidiary borrowers (together with the Company, the "Borrowers"), the lenders from time to time party thereto, and Wells Fargo Bank, National Association, as agent (the "Agent"). The Revolving Credit Agreement provides for commitments with respect to asset-based revolver loans (the "Revolving Loans") of up to the lesser of (x) \$100.0 million, which may be increased (but not above \$125.0 million, or the "Maximum Revolver Amount") or decreased (but not below \$50.0 million) by the Borrowers in accordance with the terms of the Revolving Credit Agreement and (y) the Borrowing Base (as defined in the Revolving Credit Agreement). Once reduced, the facility may not be increased. Up to \$5.0 million of capacity under the Revolving Loans may be used for swing loans and up to \$10.0 million may be used for the issuance of letters of credit.

2024 Triggering Events

2024 Impairment of long-lived assets

During the preparation of our financial statements for the quarter ended June 30, 2024, due to the decision to close the Company's Baltimore-Bayview Drug Substance manufacturing facility and Rockville, Maryland Drug Product facility, the Company determined there were indicators of impairment for the Bayview and Rockville asset groups within the Bioservices reporting unit. As a result, the Company performed recoverability tests on those asset groups and concluded that the Bayview and Rockville 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, each representing Level 3 non-recurring fair value measurements. Based on these analyses, the Company allocated and recognized a non-cash impairment charge of \$27.2 million during the second quarter of 2024.

FINANCIAL OPERATIONS OVERVIEW

Revenues

We generate Commercial Product revenues through sale of NARCAN[®] 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 U.S. government ("USG") is the largest purchaser of our Government - MCM products and primarily purchases our products for the Strategic National Stockpile, 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 from 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 our NARCAN[®] and MCM 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 (“R&D”) Expenses

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 associated with technology transfer and scale up activities throughout the development stage, including internally and through third-party contract manufacturers;
- 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 (“SG&A”) 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.

Changes in tax laws, rulings, policies, or related legal and regulatory interpretations occur frequently and may have significant favorable or adverse impacts on our effective tax rate. In 2021, the Organization for Economic Cooperation and Development released model rules for a 15% global minimum tax applied to cross-border profits of certain large multinational corporations, known as Pillar Two. Pillar Two has now been enacted by approximately 36 countries, including Ireland. This minimum tax is treated as a period cost beginning in 2024 and its impact is included on the Company's financial results of operations for the current period. The Company is monitoring legislative developments, as well as additional guidance from countries that have enacted legislation. We anticipate further legislative activity and administrative guidance in 2025.

Management believes that the assumptions and estimates related to the provision for income taxes are critical to the Company's results of operations.

RESULTS OF OPERATIONS

Consolidated and Segment Operating Results:

<i>(in millions, except %)</i>	Year Ended December 31,			
	2024	2023	\$ Change	% Change
Revenues:				
Commercial Product sales, net:				
NARCAN [®]	\$ 398.9	\$ 487.5	\$ (88.6)	(18)%
Other Commercial Products	—	9.8	(9.8)	(100)%
Total Commercial Product sales, net	398.9	497.3	(98.4)	(20)%
MCM Product sales, net:				
Anthrax MCM	138.5	187.6	(49.1)	(26)%
Smallpox MCM	277.3	167.4	109.9	66 %
Other Products	94.0	92.2	1.8	2 %
Total MCM Product sales, net	509.8	447.2	62.6	14 %
Services:				
Bioservices - Services	103.5	72.8	30.7	42 %
Bioservices - Leases	1.4	5.7	(4.3)	(75)%
Total Services revenues	104.9	78.5	26.4	34 %
Contracts and grants	30.0	26.3	3.7	14 %
Total revenues	<u>\$ 1,043.6</u>	<u>\$ 1,049.3</u>	<u>\$ (5.7)</u>	<u>(1)%</u>
Operating expenses:				
Cost of Commercial Product sales ⁽¹⁾	185.9	210.3	(24.4)	(12)%
Cost of MCM Product sales ⁽¹⁾	219.4	305.6	(86.2)	(28)%
Cost of Bioservices ⁽¹⁾	276.0	189.5	86.5	46 %
Research and development	70.7	111.4	(40.7)	(37)%
Selling, general and administrative	308.0	368.4	(60.4)	(16)%
Amortization of intangible assets	65.1	65.6	(0.5)	(1)%
Goodwill impairment	—	218.2	(218.2)	(100)%
Impairment of long-lived assets	27.2	306.7	(279.5)	(91)%
Total operating expenses	<u>1,152.3</u>	<u>1,775.7</u>	<u>(623.4)</u>	<u>(35)%</u>
Loss from operations	(108.7)	(726.4)	617.7	85 %
Other income (expense):				
Interest expense	(71.0)	(87.9)	16.9	19 %
Gain on sale of business	24.3	74.2	(49.9)	(67)%
Other, net	12.5	8.9	3.6	40 %
Total other income (expense), net	<u>(34.2)</u>	<u>(4.8)</u>	<u>(29.4)</u>	<u>NM</u>
Loss before income taxes	(142.9)	(731.2)	588.3	80 %
Income tax provision	47.7	29.3	18.4	63 %
Net loss	<u>\$ (190.6)</u>	<u>\$ (760.5)</u>	<u>\$ 569.9</u>	<u>75 %</u>

⁽¹⁾ Exclusive of intangible assets amortization

NM - Not meaningful

Year Ended December 31, 2024 Compared with Year Ended December 31, 2023

Revenues and gross margin

<i>(dollars in millions)</i>	Year Ended December 31,		
	2024	2023	% Change
Total revenues	\$ 1,043.6	\$ 1,049.3	(1)%
Contracts and grants	30.0	26.3	14 %
Total segment revenues ⁽¹⁾	\$ 1,013.6	\$ 1,023.0	(1)%
Cost of sales or services			
Cost of Commercial Product sales	\$ 185.9	\$ 210.3	(12)%
Cost of MCM Product sales	219.4	305.6	(28)%
Cost of Bioservices	276.0	189.5	46 %
Total cost of sales or services	\$ 681.3	\$ 705.4	(3)%
Intangible asset amortization:			
Commercial Products	\$ 37.8	\$ 38.6	(2)%
MCM Products	27.3	27.0	1 %
Total intangible asset amortization	\$ 65.1	\$ 65.6	(1)%
Total segment gross margin ⁽¹⁾	\$ 267.2	\$ 252.0	6 %
Total segment gross margin % ⁽¹⁾	26 %	25 %	

⁽¹⁾ We define total segment revenues, which is a non-GAAP financial measure, as our total revenues, less contracts and grants revenue. 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 and intangible asset amortization. We define total segment gross margin percentage, which is a non-GAAP financial measure, as total segment gross margin as a percentage of total segment revenues. 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.

Total revenues decreased \$5.7 million, or 1%, to \$1.0 billion in 2024. The decrease was due to a decrease in Commercial Products revenue of \$98.4 million, partially offset by increases in MCM Products revenue of \$62.6 million, Bioservices revenue of \$26.4 million and Contracts and grants revenue of \$3.7 million.

Total segment gross margin increased \$15.2 million, or 6%, to \$267.2 million in 2024. Total segment gross margin percentage increased 2 percentage points to 26%. The increase was primarily due to an increase in the MCM Products segment gross margin of \$148.5 million, partially offset by decreases in the Commercial Products segment gross margin and Bioservices segment gross margin of \$73.2 million and \$60.1 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

R&D Expenses

R&D expenses decreased \$40.7 million, or 37%, to \$70.7 million in 2024. The decrease was primarily due to the sale of our development program for CHIKV VLP to Bavarian Nordic during the second quarter of 2023 and reduction in related overhead costs driven by the headcount reductions, which were significant contributors to prior period R&D expense. The decrease was also driven by the wind-down of funded projects, excluding Ebanga™. The decrease was partially offset by increases in the allocation of R&D overhead costs and funded R&D related to Ebanga™.

SG&A Expenses

Selling, general and administrative expenses decreased \$60.4 million, or 16%, to \$308.0 million in 2024. The decrease was primarily due to lower employee related expenses and compensation as a result of restructuring initiatives during 2023 and 2024, lower professional services fees related to corporate initiatives, including organizational transformation consulting fees, lower legal fees due to the wind-down of various legal matters and lower marketing costs. This decrease was partially offset by the settlement charge related to the stockholder litigation matter, net of expected insurance proceeds. Selling, general and administrative costs as a percentage of total revenue decreased 6 percentage points to 30% for the year ended December 31, 2024. The decrease was due to a decrease in selling, general and administrative expenses, partially offset by a decrease in revenues during the period.

Goodwill Impairment

Goodwill impairment decreased \$218.2 million, or 100%, in 2024. The decrease was due to the \$218.2 million impairment charge to goodwill in the MCM Products segment in the third quarter of 2023, which reduced the goodwill balance of the reporting unit and segment to zero as of December 31, 2024 and 2023.

Impairment of Long-lived Assets

Impairment of long-lived assets decreased \$279.5 million, or 91%, to \$27.2 million in 2024. The decrease was due to a \$27.2 million non-cash impairment charge in the second quarter of 2024 related to our Bayview and Rockville asset groups within the Bioservices reporting unit, compared with a \$306.7 million non-cash impairment charge recorded in the second quarter of 2023 related to our Camden, Bayview and Rockville asset groups within the Bioservices reporting unit.

Interest expense

Interest expense decreased \$16.9 million, or 19%, to \$71.0 million in 2024. The decrease was primarily due to a decrease in interest expense related to our syndicated borrowings and a decrease in amortization of debt service costs, partially offset by higher interest expense related to our Term Loan Agreement and the termination of our interest rate swap hedging agreements in 2023.

Gain on sale of business

Gain on sale of business decreased \$49.9 million, or 67%, to \$24.3 million in 2024. The gain on sale of business in the current year is related to the sale of RSDL[®] to SERB, partially offset by a loss the sale of the Company's drug product facility in Baltimore-Camden to Bora. The gain on sale of business in the prior year is attributable to the sale of our travel health business to Bavarian Nordic during the second quarter of 2023.

Other, net

Other, net was \$12.5 million in income in 2024 compared to \$8.9 million in income in 2023. The change of \$3.6 million was primarily due to income associated with development milestone achievements related to CHIK VLP, partially offset by a loss on the sale of a building at our Canton facility, unfavorable foreign exchange revaluations, lower interest income, due to lower balances in our money market accounts, and a write-off of an equity method investment.

Income tax provision (benefit)

Income tax provision of \$29.3 million for the year ended December 31, 2023 increased \$18.4 million to a provision of \$47.7 million for the year ended December 31, 2024. The effective tax rate was (33)% for the year ended December 31, 2024 as compared to (4)% in 2023. The effective annual tax rate decreased largely due to jurisdictional mix of income and losses, GILTI, and other permanent items.

SEGMENT RESULTS

COMMERCIAL PRODUCT SEGMENT

<i>(dollars in millions)</i>	Year Ended December 31,		
	2024	2023	% Change
Revenues	\$ 398.9	\$ 497.3	(20)%
Cost of sales	185.9	210.3	(12)%
Intangible asset amortization	37.8	\$ 38.6	(2)%
Gross margin ⁽¹⁾	\$ 175.2	\$ 248.4	(29)%
Gross margin % ⁽¹⁾	44 %	50 %	
Add back:			
Intangible asset amortization	37.8	38.6	(2)%
Segment adjusted gross margin ⁽²⁾	\$ 213.0	\$ 287.0	(26)%
Segment adjusted gross margin % ⁽²⁾	53 %	58 %	

⁽¹⁾ Gross margin is calculated as revenues less cost of sales and intangible asset amortization. Gross margin percentage is calculated as gross margin divided by revenues.

⁽²⁾ Segment adjusted gross margin, which is a non-GAAP financial measure, for our Commercial Products segment is calculated as gross margin plus intangible asset amortization. Segment adjusted gross margin percentage, 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 percentage 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, 2024 Compared with Year Ended December 31, 2023

NARCAN[®]

NARCAN[®] sales decreased \$88.6 million, or 18%, to \$398.9 million in 2024. The decrease was primarily driven by the discontinuation of prescription NARCAN[®] due to the launch of OTC NARCAN[®] in the third quarter of 2023 and lower Canadian retail sales, partially offset by higher sales of OTC NARCAN[®].

Other Commercial Products

Other Commercial Products sales decreased \$9.8 million, or 100%, to no sales in 2024. During the second quarter of 2023, we sold Vivotif[®] and Vaxchora[®] to Bavarian Nordic as part of our travel health business.

Cost of Sales, Intangible Asset Amortization and Gross Margin

Cost of Commercial Product sales decreased \$24.4 million, or 12%, to \$185.9 million in 2024. The decrease was primarily due to lower prescription NARCAN[®] unit volume and no current period costs related to Vivotif[®] and Vaxchora[®], which were sold to Bavarian Nordic as part of our travel health business in 2023, partially offset by the higher OTC NARCAN[®] unit volume.

Intangible asset amortization allocated to Commercial Product segment decreased \$0.8 million, or 2%, to \$37.8 million in 2024. The decrease was due to lower amortization expense resulting from the intangibles sold as part of our travel health business to Bavarian Nordic during the second quarter of 2023.

Commercial Product segment gross margin decreased \$73.2 million, or 29%, to \$175.2 million in 2024. Commercial Product segment gross margin percentage decreased 6 percentage points to 44% in 2024. The decrease was largely due to an unfavorable price and volume mix in 2024 for NARCAN[®] products, partially offset by the sale of the products associated with our travel health business to Bavarian Nordic. Commercial Product segment adjusted gross margin excludes the impact of intangible asset amortization of \$37.8 million.

MCM PRODUCTS SEGMENT

<i>(dollars in millions)</i>	Year Ended December 31,		
	2024	2023	% Change
Revenues	\$ 509.8	\$ 447.2	14 %
Cost of sales	219.4	305.6	(28)%
Intangible asset amortization	27.3	27.0	1 %
Gross margin ⁽¹⁾	<u>\$ 263.1</u>	<u>\$ 114.6</u>	130 %
Gross margin % ⁽¹⁾	52 %	26 %	
Add back:			
Intangible asset amortization	27.3	27.0	1 %
Changes in fair value of financial instruments	0.6	0.2	200 %
Restructuring costs	7.2	5.6	29 %
Inventory step-up provision	6.2	3.9	59 %
Segment adjusted gross margin ⁽²⁾	<u>\$ 304.4</u>	<u>\$ 151.3</u>	101 %
Segment adjusted gross margin % ⁽²⁾	60 %	34 %	

⁽¹⁾ Gross margin is calculated as revenues less cost of sales and intangible asset amortization. Gross margin percentage is calculated as gross margin divided by revenues.

⁽²⁾ Segment adjusted gross margin, which is a non-GAAP financial measure, for our MCM Products segment is calculated as gross margin plus intangible asset amortization, restructuring costs and non-cash items related to changes in fair value of financial instruments and inventory step-up provision. Segment adjusted gross margin percentage, 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 percentage 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, 2024 Compared with Year Ended December 31, 2023

Anthrax MCM

Anthrax MCM sales decreased \$49.1 million, or 26%, to \$138.5 million in 2024. The decrease was due to the impact of timing of sales related to CYFENDUS[®] and lower sales of Anthrasil[®], coupled with a decrease in BioThrax[®] sales, due to timing. 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 of USG purchases, the availability of governmental funding and the Company's delivery of orders that follow.

Smallpox MCM

Smallpox MCM sales increased \$109.9 million, or 66%, to \$277.3 million in 2024. The increase was due to higher ACAM2000[®] sales to non-U.S. customers and higher VIGIV CNJ-016[®] sales, primarily related to USG, partially offset by lower USG purchases of ACAM2000[®], due to timing. 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 Company delivery of orders that follow.

Other Product Sales

Other Product sales increased \$1.8 million, or 2%, to \$94.0 million in 2024. The increase was primarily due to higher BAT[®] product sales to USG and non-U.S. customers, partially offset by lower sales of RSDL[®], which was sold to SERB during the third quarter of 2024.

Cost of Sales, Intangible Asset Amortization and Gross Margin

Cost of MCM Product sales decreased \$86.2 million, or 28%, to \$219.4 million in 2024. The decrease was primarily due to lower allocations to Cost of MCM Product sales at our Bayview facility, lower shutdown costs, and a reduction in Trobigard[®]-related costs due to the Belgium FAMHP's approval of the Trobigard[®] revocation, partially offset by higher BioThrax[®] and VIGIV CNJ-016[®] sales as well as higher allocations to Cost of MCM Product sales at our Winnipeg and Gaithersburg facilities.

Intangible asset amortization allocated to MCM Products increased \$0.3 million, or 1%, to \$27.3 million in 2024. The increase was due to an increase in amortization expense for intangible assets related to Ebanga[™], which were acquired during the second half of 2023.

MCM Products segment gross margin increased \$148.5 million, or 130%, to \$263.1 million in 2024. MCM Products segment gross margin percentage increased 26 percentage points to 52% in 2024. In addition to the MCM Product sales and Cost of MCM Product sales items as discussed above, the increase was largely due to overall higher sales volumes with a favorable product mix weighted more heavily to higher margin products, coupled with a realization of previously adjusted inventory values. MCM Product segment adjusted gross margin excludes the impacts of intangible asset amortization of \$27.3 million, restructuring costs of \$7.2 million, inventory step-up provision of \$6.2 million and the changes in the fair value of financial instruments of \$0.6 million.

SERVICES SEGMENT

(dollars in millions)	Year Ended December 31,		
	2024	2023	% Change
Revenues	\$ 104.9	\$ 78.5	34 %
Cost of services	276.0	189.5	46 %
Gross margin ⁽¹⁾	<u>\$ (171.1)</u>	<u>\$ (111.0)</u>	(54)%
Gross margin % ⁽¹⁾	(163)%	(141)%	
Add back:			
Settlement charges, net	110.2	—	NM
Restructuring costs	0.2	8.4	(98)%
Segment adjusted gross margin ⁽²⁾	<u>\$ (60.7)</u>	<u>\$ (102.6)</u>	41 %
Segment adjusted gross margin % ⁽²⁾	(58)%	(131)%	

⁽¹⁾ Gross margin is calculated as revenues less cost of sales and intangible asset amortization. Gross margin percentage is calculated as gross margin divided by revenues.

⁽²⁾ Segment adjusted gross margin, which is a non-GAAP financial measure, for our Services segment is calculated as gross margin plus restructuring costs and settlement charges, net. Segment adjusted gross margin percentage, 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 percentage 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, 2024 Compared with Year Ended December 31, 2023

Services Revenues

Bioservices revenue increased \$30.7 million, or 42%, to \$103.5 million in 2024. The increase was primarily attributable to the \$50.0 million arbitration settlement with Janssen related to the Settlement Agreement, coupled with an increase in production at the Camden facility prior to the sale of the facility to Bora. The increase was partially offset by reduced production activities at the Company's Canton and Winnipeg facilities.

Bioservices lease revenue decreased \$4.3 million, or 75%, to \$1.4 million in 2024. The decrease was related to the completion of a lease for a Bioservices customer at our Canton facility, partially offset by new lease revenue for SERB at our Winnipeg facility.

Cost of Services and Gross Margin

Cost of Services increased \$86.5 million, or 46%, to \$276.0 million in 2024. The increase was primarily due to the Settlement Agreement with Janssen and resulting write-down of related assets to net realizable value of \$110.2 million, coupled with higher costs at the Company's Winnipeg facility due to a bad debt charge. These increases were partially offset by lower costs as a result of the sale of the Camden facility to Bora, lower costs associated with production activities at the Company's Canton facility and higher allocations to R&D at the Company's Gaithersburg facility.

Services segment gross margin decreased \$60.1 million, or 54%, to \$(171.1) million in 2024. Services segment gross margin percentage decreased 22 percentage points to (163)% in 2024. The decrease was primarily due to the Settlement Agreement with Janssen and resulting revenue and write-down of related assets mentioned above, coupled with lower production at the Company's Canton facility. This decrease was partially offset by an increase in production at the Camden facility prior to the sale of the facility to Bora and a decrease in overhead costs at our other Maryland facilities. Services segment adjusted gross margin excludes the impact of the settlement charge, net of \$110.2 million and restructuring costs of \$0.2 million.

OTHER REVENUE

Year Ended December 31, 2024 Compared with Year Ended December 31, 2023

Contracts and Grants

Contract and grants revenue increased \$3.7 million, or 14%, to \$30.0 million in 2024. The increase was related to work under the Ebanga™ program, partially offset by the wind-down of our other funded development initiatives.

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

Consolidated and Segment Operating Results:

<i>(in millions, except %)</i>	Year Ended December 31,			
	2023	2022	\$ Change	% Change
Revenues:				
Commercial Product sales, net:				
NARCAN [®]	\$ 487.5	\$ 373.7	\$ 113.8	30 %
Other Commercial Products	9.8	12.9	(3.1)	(24)%
Total Commercial Product sales, net	497.3	386.6	110.7	29 %
MCM Product sales, net:				
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 %
Total MCM Product sales, net	447.2	579.6	(132.4)	(23)%
Services:				
Bioservices - Services	72.8	105.0	(32.2)	(31)%
Bioservices - Leases	5.7	4.9	0.8	16 %
Total Services revenues	78.5	109.9	(31.4)	(29)%
Contracts and grants	26.3	41.4	(15.1)	(36)%
Total revenues	<u>\$ 1,049.3</u>	<u>\$ 1,117.5</u>	<u>\$ (68.2)</u>	<u>(6)%</u>
Operating expenses:				
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)%
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 %
Goodwill impairment	218.2	6.7	211.5	NM
Impairment of long-lived assets	306.7	—	306.7	NM
Total operating expenses	<u>1,775.7</u>	<u>1,287.5</u>	<u>488.2</u>	<u>38 %</u>
Loss from operations	(726.4)	(170.0)	(556.4)	NM
Other income (expense):				
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)%
Total other income (expense), net	<u>(4.8)</u>	<u>(49.0)</u>	<u>44.2</u>	<u>(90)%</u>
Loss before income taxes	(731.2)	(219.0)	(512.2)	NM
Income tax provision (benefit)	29.3	(7.4)	36.7	NM
Net loss	<u>\$ (760.5)</u>	<u>\$ (211.6)</u>	<u>\$ (548.9)</u>	<u>NM</u>

NM - Not meaningful

Revenues and gross margin

<i>(dollars in millions)</i>	Year Ended December 31,		% Change
	2023	2022	
Total revenues	\$ 1,049.3	\$ 1,117.5	(6)%
Contracts and grants	26.3	41.4	(36)%
Total segment revenues ⁽¹⁾	\$ 1,023.0	\$ 1,076.1	(5)%
Cost of sales or services			
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)%
Total cost of sales or services	\$ 705.4	\$ 693.1	2 %
Intangible asset amortization allocated to:			
Cost of Commercial Products	\$ 38.6	\$ 42.9	(10)%
Cost of MCM Products	27.0	16.9	60 %
Cost of Services	—	0.1	(100)%
Total intangible asset amortization	\$ 65.6	\$ 59.9	10 %
Total segment gross margin ⁽¹⁾	\$ 252.0	\$ 323.1	(22)%
Total segment gross margin % ⁽¹⁾	25 %	30 %	

⁽¹⁾ We define total segment revenues, which is a non-GAAP financial measure, as our total revenues, less contracts and grants revenue. 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 and intangible asset amortization. We define total segment gross margin percentage, which is a non-GAAP financial measure, as total segment gross margin as a percentage of total segment revenues. 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.

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

Total segment gross margin decreased \$71.1 million, or 22%, to \$252.0 million in 2023. Total segment gross margin percentage decreased 5 percentage points to 25%. The decrease was primarily due to a decrease in the MCM Products segment gross margin of \$183.8 million, partially offset by increases in the Commercial Products segment gross margin and Bioservices segment gross margin of \$65.0 million and \$47.7 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

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.

SG&A 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 OTC NARCAN[®]. 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.

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.

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, 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 was \$8.9 million in income in 2023 compared to \$11.7 million in expense in 2022. The change of \$20.6 million, or 176%, 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 tax provision (benefit)

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 SEGMENT

<i>(dollars in millions)</i>	Year Ended December 31,		
	2023	2022	% Change
Revenues	\$ 497.3	\$ 386.6	29 %
Cost of sales	210.3	160.3	31 %
Intangible asset amortization	38.6	42.9	(10)%
Gross margin ⁽¹⁾	<u>\$ 248.4</u>	<u>\$ 183.4</u>	35 %
Gross margin % ⁽¹⁾	50 %	47 %	
Add back:			
Intangible asset amortization	38.6	42.9	(10)%
Segment adjusted gross margin ⁽²⁾	<u>\$ 287.0</u>	<u>\$ 226.3</u>	27 %
Segment adjusted gross margin % ⁽²⁾	58 %	59 %	

⁽¹⁾ Gross margin is calculated as revenues less cost of sales and intangible asset amortization. Gross margin percentage is calculated as gross margin divided by revenues.

⁽²⁾ Segment adjusted gross margin, which is a non-GAAP financial measure, for our Commercial Products segment, is calculated as gross margin plus intangible asset amortization. Segment adjusted gross margin percentage, 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 percentage 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[®]

NARCAN[®] sales increased \$113.8 million, or 30%, to \$487.5 million in 2023. The increase was primarily driven by higher sales of OTC NARCAN[®] and branded NARCAN[®] to U.S. public interest channels and Canadian retail, partially offset by the cessation of authorized generic NARCAN[®] 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[®], partially offset by higher sales of Vaxchora[®]. During the second quarter of 2023, we sold Vivotif[®] and Vaxchora[®] to Bavarian Nordic as part of our travel health business.

Cost of Sales, Intangible Asset Amortization 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 OTC NARCAN[®] and higher branded NARCAN[®] sales.

Intangible asset amortization allocated to Commercial Products decreased \$4.3 million, or 10%, to \$38.6 million in 2023. The decrease was due to lower amortization expense resulting from the intangibles sold as part of our travel health business to Bavarian Nordic.

Commercial Products segment gross margin increased \$65.0 million, or 35%, to \$248.4 million in 2023. Commercial Products segment gross margin percentage increased 3 percentage points to 50% in 2023. The increase was largely due to a decrease in royalty expense, partially offset by a decrease in the per unit selling price in response to increased competition for generic NARCAN[®]. Commercial Products segment adjusted gross margin excludes the impact of intangible asset amortization of \$38.6 million.

MCM PRODUCTS SEGMENT

<i>(dollars in millions)</i>	Year Ended December 31,		
	2023	2022	% Change
Revenues	\$ 447.2	\$ 579.6	(23)%
Cost of sales	305.6	264.3	16 %
Intangible asset amortization	27.0	16.9	60 %
Gross margin ⁽¹⁾	<u>\$ 114.6</u>	<u>\$ 298.4</u>	(62)%
Gross margin % ⁽¹⁾	26 %	51 %	
Add back:			
Intangible asset amortization	27.0	16.9	60 %
Changes in fair value of financial instruments	0.2	2.6	(92)%
Restructuring costs	5.6	—	NM
Inventory step-up provision	3.9	51.4	(92)%
Segment adjusted gross margin ⁽²⁾	<u>\$ 151.3</u>	<u>\$ 369.3</u>	(59)%
Segment adjusted gross margin % ⁽²⁾	34 %	64 %	

⁽¹⁾ Gross margin is calculated as revenues less cost of sales and intangible asset amortization. Gross margin percentage is calculated as gross margin divided by revenues.

⁽²⁾ Segment adjusted gross margin, which is a non-GAAP financial measure, for our MCM Products segment, is calculated as gross margin plus intangible asset amortization, restructuring costs and non-cash items related to changes in fair value of financial instruments and inventory step-up provision. Segment adjusted gross margin percentage, 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 percentage 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[®] and BioThrax[®], partially offset by an increase in Anthrasil[®] 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[®], 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[®]. 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[®] product sales, partially offset by lower RSDL[®] and Trobigard[®] product sales due to timing.

Cost of Sales, Intangible Asset Amortization 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[®], BAT[®] and Anthrasil[®], partially offset by lower sales of CYFENDUS[®], coupled with higher allocations to MCM Product COGS at our Bayview facility, shutdown costs and inventory write-offs.

Intangible asset amortization allocated to MCM Product segment increased \$10.1 million, or 60%, to \$27.0 million in 2023. The increase was due to higher amortization expense for intangible assets related to TEMBEXA[®], NARCAN[®], and Ebanga[™] which were acquired during the second half of 2022.

MCM Products segment gross margin decreased \$183.8 million, or 62%, to \$114.6 million in 2023. MCM Products segment gross margin percentage decreased 25 percentage points to 26% 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 Products segment adjusted gross margin excludes the impact of intangible asset amortization of \$27.0 million, 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 SEGMENT

<i>(dollars in millions)</i>	Year Ended December 31,		
	2023	2022	% Change
Revenues	\$ 78.5	\$ 109.9	(29)%
Cost of services	189.5	268.5	(29)%
Intangible asset amortization	—	0.1	(100)%
Gross margin ⁽¹⁾	<u>\$ (111.0)</u>	<u>\$ (158.7)</u>	30 %
Gross margin % ⁽¹⁾	(141)%	(144)%	
Add back:			
Intangible asset amortization	—	0.1	(100)%
Restructuring costs	8.4	—	NM
Segment adjusted gross margin ⁽²⁾	<u>\$ (102.6)</u>	<u>\$ (158.6)</u>	35 %
Segment adjusted gross margin % ⁽²⁾	(131)%	(144)%	

⁽¹⁾ Gross margin is calculated as revenues less cost of sales and intangible asset amortization. Gross margin percentage is calculated as gross margin divided by revenues.

⁽²⁾ Segment adjusted gross margin, which is a non-GAAP financial measure, for our Services segment, is calculated as gross margin plus intangible asset amortization and restructuring costs. Segment adjusted gross margin percentage, 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 percentage 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, Intangible Asset Amortization 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.

Intangible asset amortization allocated to Services decreased \$0.1 million, or 100%, to no amortization in 2023. The decrease was due to the completion of the amortization of intangible assets acquired from Cangene.

Services segment gross margin increased \$47.7 million, or 30%, to \$(111.0) million in 2023. Services segment 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 EbangaTM, which was awarded in the current period, and TEMBEXA[®].

Financial Condition, Liquidity and Capital Resources

Our financial condition is summarized as follows:

<i>(dollars in millions)</i>	December 31,		Change %
	2024	2023	
Financial assets:			
Cash and cash equivalents	\$ 99.5	\$ 111.7	(11)%
Restricted cash	6.1	—	NM
Total cash, cash equivalents and restricted cash	\$ 105.6	\$ 111.7	(5)%
Borrowings:			
Debt, current portion	\$ —	\$ 413.7	(100)%
Debt, net of current portion	663.7	446.5	49 %
Total borrowings	\$ 663.7	\$ 860.2	(23)%
Working capital:			
Current assets	\$ 598.7	\$ 679.5	(12)%
Current liabilities	162.4	651.3	(75)%
Total working capital	\$ 436.3	\$ 28.2	NM

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 various credit agreements, including our Term Loan Agreement and other lines of credit we have established from time to time. We also occasionally obtain financing from the sale of our common stock upon exercise of stock options. As of December 31, 2024, we had unrestricted cash and cash equivalents of \$99.5 million and available borrowing capacity of up to \$100.0 million under the Revolving Credit Agreement.

Going Concern Considerations

During the second quarter of 2024, in evaluating the Company's ability to continue as a going concern, the Company took into account the potential mitigating effects of management's previously disclosed plans to mitigate the substantial doubt about the Company's ability to continue as a going concern, which plans had not yet been fully implemented. During the third quarter of 2024, the Company made significant progress implementing these plans, which progress is described below. As a result, the Company concluded that as of September 30, 2024, it alleviated substantial doubt about the Company's ability to continue as a going concern within one year after the date that the third quarter financial statements were issued.

During the third quarter of 2024, the Company entered into the Term Loan Agreement, which provides for a Term Loan of \$250.0 million, and the Revolving Credit Agreement, which provides for Revolving Loans of up to \$100.0 million, which have maturity dates that can extend through the second quarter of 2029. Also during the third quarter of 2024, the Company repaid all amounts outstanding under its Prior Credit Agreement. As of December 31, 2024, there was \$250.0 million outstanding under the Term Loan Agreement and no outstanding Revolving Loans. For more information about the new Senior Secured Credit Facilities, see Note 10, "Debt" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K.

During the year ended December 31, 2024, the Company generated cash through the sale of certain assets, including the RSDL[®] Transaction, which provided for a cash purchase price of approximately \$75.0 million; and the Camden Transaction, which provided for a cash purchase price of approximately \$35.0 million. Additionally, the Company received funds of \$50.0 million in connection with the Settlement Agreement with Janssen related to the 2022 termination of the Janssen Agreement. See Note 3, "Divestitures" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Form 10-K for additional information related to RSDL[®] Transaction and Camden Transaction and Note 19, "Litigation" in the Notes to Consolidated Financial Statements in Part II, Item 8, of this Form 10-K for additional information related to the accounting treatment and settlement of the arbitration with Janssen.

Additionally, the Company has realized positive operational impacts of its restructuring and cost savings initiatives, including the closure of certain Bioservices facilities and reductions in force.

As of December 31, 2024, the Company had unrestricted cash and cash equivalents of \$99.5 million and available borrowing capacity of up to \$100.0 million under the Revolving Credit Agreement. The Company believes that its sources of liquidity, including debt and cash flows from operating activities, are adequate to fund its operations for at least the next twelve months from the issuance of these consolidated financial statements.

At-the-Market Equity Offering Facility

In May 2023, the Company established an at-the-market equity offering program (the "ATM Program") pursuant to which the Company may, from time to time, sell up to \$150.0 million aggregate gross sales price of shares of its common stock through Evercore Group L.L.C. and RBC Capital Markets, LLC, as sales agents. There were no sales of the Company's common stock under the ATM Program during the year ended December 31, 2024. Our Registration Statement on Form S-3 related to the ATM Program expired on August 9, 2024. The Company cannot sell any shares under the ATM Program until a new Registration Statement on Form S-3 is filed and becomes effective. During the second quarter of 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, 2024, \$140.9 million aggregate gross sales price of shares of the Company's common stock remains available for issuance under the ATM Program.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2024 and 2023.

<i>(dollars in millions)</i>	Year Ended December 31,	
	2024	2023
Net cash provided by (used in):		
Operating activities	\$ 58.7	\$ (206.3)
Investing activities	125.2	212.3
Financing activities	(190.0)	(535.7)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	—	(1.2)
Net change in cash, cash equivalents and restricted cash	<u>\$ (6.1)</u>	<u>\$ (530.9)</u>

Operating Activities:

Net cash provided by operating activities increased \$265.0 million in 2024. The increase in net cash provided by operating activities was primarily due to positive changes in operating assets and liabilities of \$159.0 million, driven largely by a decrease to Prepaid and other assets related to the write-down to net realizable values of the assets classified within "Other long term assets" related to the Janssen Agreement and Settlement Agreement. Additionally, net loss decreased by \$569.9 million, offset by a positive change in Goodwill impairment and Impairment of long lived assets of \$218.2 million and \$279.5 million, respectively.

Investing Activities:

Net cash provided by investing activities decreased \$87.1 million in 2024. The decrease 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, partially offset by proceeds received in 2024 related to the RSDL[®] Transaction and the sale of the Baltimore-Camden facility of \$110.2 million, milestone payments received in 2024 related to an asset divestiture of \$30.0 million, and a lower capital expenditures of \$28.7 million.

Financing Activities:

Net cash used in financing activities decreased \$345.7 million in 2024. The decrease in cash used in financing activities was primarily due to proceeds from the Company's new Term Loan Agreement and a reduction in principal payments and proceeds on the revolving credit facility under the Prior Credit Agreement, partially offset by an increase in payments related to the prior Term Loan Facility and an increase in debt issuance costs associated with entry into the Term Loan Agreement and Revolving Credit Agreement.

Debt

As of December 31, 2024, the Company has \$700.0 million of fixed and variable rate debt with varying maturities, with no payable amounts 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 potential asset sales; and
- our Term Loan Agreement and Revolving Loans.

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, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our Senior Unsecured Notes and our Senior Secured Credit Facilities, which could limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities, buying back shares or declaring dividends. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

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 Unsecured Notes or our Senior Secured Credit Facilities. 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 Loans as of December 31, 2024 and the revolver under the Prior Credit Agreement as of December 31, 2023 was:

<i>(in millions)</i>	December 31,	
	2024	2023
Total Capacity	\$ 100.0	\$ 300.0
Less:		
Outstanding Letters of Credit ⁽¹⁾	—	0.5
Outstanding Indebtedness	—	219.2
Unused Capacity	<u>\$ 100.0</u>	<u>\$ 80.3</u>

⁽¹⁾ As a result of entering into the Revolving Credit Agreement during the third quarter of 2024, our outstanding letters of credit were moved to cash collateral. The full amount of these letters of credit is reflected in "Restricted Cash" on the Consolidated Balance Sheets as of December 31, 2024.

Contractual Obligations

As of December 31, 2024, 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, 2024, the Company had fixed lease payment obligations of \$15.3 million, with \$3.6 million due within 12 months. The Company has non-cancelable purchase commitments of \$632.4 million, with an estimated \$195.6 million being due within 12 months.

Critical Accounting Policies and Estimates

Our consolidated financial statements and related disclosures are prepared in accordance with U.S. 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's contracts for the sale of MCM products include certain acceptance criteria before title passes to the customer. 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.

The Company's NARCAN[®] customer contracts, including OTC NARCAN[®] customer contracts, are fixed price contracts. For the majority of the Company's OTC NARCAN[®] contracts, the Company invoices and records revenue when the customers 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 OTC NARCAN[®] 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 under direct retailer contracts, specialty distributor fees, wholesaler fees, prompt payment discounts and government rebates. OTC NARCAN[®] 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 and administrative expenses" and "Cost of Commercial Product Sales", respectively, in the Consolidated Statement of Operations. Revenues from OTC NARCAN[®] 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. For contracts with direct retailers, the Company considers several factors in the estimation process for the allowance for returns of OTC NARCAN[®], 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. As 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

The Company's acquisitions accounted for as asset acquisitions may 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.

Long-lived assets

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 2024, due to the decision to close the Company's Baltimore-Bayview Drug Substance manufacturing facility and Rockville, Maryland Drug Product facility, the Company determined there were sufficient indicators of impairment for the Bayview and Rockville asset groups within the Bioservices reporting unit to require an impairment analysis. As a result, the Company performed recoverability tests on those asset groups and concluded that the Bayview and Rockville asset groups were not recoverable as the undiscounted expected cash flows did not exceed their carrying values. Based on these analyses, the Company allocated and recognized a non-cash impairment charge of \$27.2 million during 2024.

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. For internally manufactured inventory, the Company determines normal capacity for each production facility and allocates fixed production-overhead costs on that basis. The Company records inventory acquired in business combinations utilizing the comparative sales method, which estimates the expected sales price reduced for all costs expected to be incurred to complete/dispose of the inventory with a profit on those costs. The Company analyzes its inventory each reporting period and records a reserve to reduce the cost basis to net realizable value for inventory that has become obsolete, expired, slow-moving or short-dated based on customer requirements. Reserves for excess and obsolete inventory are relieved when the related inventory is disposed of through scrap or sale.

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 2024 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 secured overnight financing rate ("SOFR"), as defined in our Term Loan Agreement, 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 SOFR rate as of December 31, 2024 would increase our interest expense by approximately \$2.5 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, Singapore dollar and British pound. We manage our foreign currency exchange rate risk primarily by either entering into foreign currency hedging transactions or incurring operating expenses in the local currency in the countries in which we operate, to the extent practicable. We currently do not hedge all of our foreign currency exchange exposure and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Emergent BioSolutions Inc. and Subsidiaries

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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, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, 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, 2024, 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 3, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matter

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

Reserve for Excess and Obsolete Inventories

Description of the Matter The Company had total inventories, net of \$311.7 million as of December 31, 2024. As discussed in Note 2 of the consolidated financial statements, inventories are stated at the lower of cost or net realizable value. The company evaluates its inventories each reporting period and records a reserve to account for inventory that has become obsolete, expired, slow-moving, or short-dated based on customer requirements.

Auditing the Company's assessment for excess and obsolete inventories was subjective and involved auditor judgment as the estimate relies on factors that are outside of the Company's control. In particular, the analysis is dependent on assumptions such as the expected timing of delivery for customer orders and the shelf-life requirements of customers.

How We Addressed the Matter in Our Audit We obtained an understanding, evaluated the design, and tested the operating effectiveness of the Company's control over the inventory reserve process, which included management's review of the assumptions, and the completeness and accuracy of the data underlying the inventory reserve analysis.

Our audit procedures included, among others, assessing the appropriateness of the Company's methodology and the significant assumptions used in the analysis for reserve of excess and obsolete inventory. We tested the mathematical accuracy of the calculations and audited the completeness and accuracy of the underlying inputs used, such as expiration dates, and customer shelf-life requirements. In addition, we performed inquiries of management and inspected documentation, such as customer contracts to evaluate the reasonableness of the Company's estimate.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2004.
Tysons, Virginia
March 3, 2025

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

	December 31,	
	2024	2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 99.5	\$ 111.7
Restricted cash	6.1	—
Accounts receivable, net	154.5	191.0
Inventories, net	311.7	328.9
Prepaid expenses and other current assets	26.9	47.9
Total current assets	598.7	679.5
Property, plant and equipment, net	270.6	382.8
Intangible assets, net	501.5	566.6
Other assets	18.9	194.3
Total assets	\$ 1,389.7	\$ 1,823.2
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 60.9	\$ 112.2
Accrued expenses	17.7	18.6
Accrued compensation	56.1	74.1
Debt, current portion	—	413.7
Other current liabilities	27.7	32.7
Total current liabilities	162.4	651.3
Debt, net of current portion	663.7	446.5
Deferred tax liability	41.7	47.2
Other liabilities	39.1	28.9
Total liabilities	906.9	1,173.9
Stockholders' equity:		
Preferred stock, \$0.001 par value per share; 15.0 shares authorized, no shares issued and outstanding	—	—
Common stock, \$0.001 par value per share; 200.0 shares authorized, 59.9 and 57.8 shares issued; 54.3 and 52.2 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	928.0	904.4
Accumulated other comprehensive loss, net	(5.2)	(5.7)
Accumulated deficit	(212.4)	(21.8)
Total stockholders' equity	482.8	649.3
Total liabilities and stockholders' equity	\$ 1,389.7	\$ 1,823.2

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

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

	Year Ended December 31,		
	2024	2023	2022
Revenues:			
Commercial Product sales	\$ 398.9	\$ 497.3	\$ 386.6
MCM Product sales	509.8	447.2	579.6
Total Product sales, net	908.7	944.5	966.2
Bioservices:			
Services	103.5	72.8	105.0
Leases	1.4	5.7	4.9
Total Bioservices revenues	104.9	78.5	109.9
Contracts and grants	30.0	26.3	41.4
Total revenues	1,043.6	1,049.3	1,117.5
Operating expenses:			
Cost of Commercial Product sales ⁽¹⁾	185.9	210.3	160.3
Cost of MCM Product sales ⁽¹⁾	219.4	305.6	264.3
Cost of Bioservices ⁽¹⁾	276.0	189.5	268.5
Research and development	70.7	111.4	188.3
Selling, general and administrative	308.0	368.4	339.5
Amortization of intangible assets	65.1	65.6	59.9
Goodwill impairment	—	218.2	6.7
Impairment of long-lived assets	27.2	306.7	—
Total operating expenses	1,152.3	1,775.7	1,287.5
Loss from operations	(108.7)	(726.4)	(170.0)
Other income (expense):			
Interest expense	(71.0)	(87.9)	(37.3)
Gain on sale of business	24.3	74.2	—
Other, net	12.5	8.9	(11.7)
Total other income (expense), net	(34.2)	(4.8)	(49.0)
Loss before income taxes	(142.9)	(731.2)	(219.0)
Income tax provision (benefit)	47.7	29.3	(7.4)
Net loss	\$ (190.6)	\$ (760.5)	\$ (211.6)
Loss per common share			
Basic	\$ (3.60)	\$ (14.85)	\$ (4.22)
Diluted	\$ (3.60)	\$ (14.85)	\$ (4.22)
Weighted average shares outstanding			
Basic	53.0	51.2	50.1
Diluted	53.0	51.2	50.1

⁽¹⁾ Exclusive of intangible assets amortization

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

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

	Year Ended December 31,		
	2024	2023	2022
Net loss	\$ (190.6)	\$ (760.5)	\$ (211.6)
Other comprehensive income (loss), net of tax:			
Foreign currency translation adjustments, net	0.5	0.9	1.0
Unrealized gains on hedging activities	—	2.7	10.8
Reclassification adjustment for gains on hedging activities	—	(8.9)	(0.1)
Reclassification adjustment for (gains) losses on pension benefit obligation	—	(3.5)	7.5
Total other comprehensive income (loss), net of tax	0.5	(8.8)	19.2
Comprehensive loss, net of tax	<u>\$ (190.1)</u>	<u>\$ (769.3)</u>	<u>\$ (192.4)</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,		
	2024	2023	2022
Operating Activities			
Net loss	\$ (190.6)	\$ (760.5)	\$ (211.6)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Share-based compensation expense	18.0	23.1	45.1
Depreciation and amortization	108.8	125.1	143.3
Change in fair value of contingent obligations, net	0.6	0.2	2.6
Amortization of deferred financing costs	7.4	21.3	4.1
Deferred income taxes	(5.5)	(8.9)	(28.6)
Noncash gain on sale of business	(32.2)	(74.2)	—
Change in fair value of warrant and forward liabilities	1.1	—	—
Goodwill impairment	—	218.2	6.7
Impairment of long-lived assets	27.2	306.7	—
Loss on disposal of assets	28.7	21.1	3.6
Other	6.5	(8.1)	2.8
Changes in operating assets and liabilities:			
Accounts receivable	(24.4)	(21.6)	118.1
Inventories	(24.5)	0.6	(57.1)
Prepaid expenses and other assets	169.9	11.7	(19.9)
Accounts payable	(33.0)	10.6	(14.0)
Accrued expenses and other liabilities	12.3	(55.7)	(66.7)
Long-term incentive plan accrual	3.6	4.8	—
Accrued compensation	(18.2)	(10.4)	(0.8)
Income taxes receivable and payable, net	23.3	(16.2)	28.7
Contract liabilities	(20.3)	5.9	9.6
Net cash provided by (used in) operating activities	58.7	(206.3)	(34.1)
Investing Activities			
Purchases of property, plant and equipment	(22.9)	(51.6)	(115.8)
Proceeds from sale of property, plant and equipment	7.9	—	—
Royalty settlement payment	—	—	(21.8)
Milestone payments from prior asset divestiture (acquisition)	30.0	(6.3)	—
Asset acquisitions	—	—	(243.7)
Proceeds from sale of business	110.2	270.2	—
Net cash provided by (used in) investing activities	125.2	212.3	(381.3)
Financing Activities			
Proceeds from the issuance of debt, net of lender fees	219.0	—	—
Proceeds allocated to warrants issued in conjunction with debt	13.4	—	—
Proceeds allocated to common stock issued in conjunction with debt	9.3	—	—
Purchases of treasury stock	—	—	(82.1)
Proceeds from revolving credit facility	65.0	20.0	598.0
Principal payments on revolving credit facility	(284.2)	(398.8)	—
Principal payments on term loan facility	(198.2)	(164.6)	(33.8)
Debt issuance costs	(14.6)	—	—
Proceeds from share-based compensation activity	1.5	1.8	5.0
Taxes paid for share-based compensation activity	(1.2)	(2.5)	(5.9)
Proceeds from at-the-market sale of stock, net of commissions and expenses	—	8.4	—
Net cash provided by (used in) financing activities:	(190.0)	(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	(6.1)	(530.9)	66.3
Cash, cash equivalents and restricted cash, beginning of period	111.7	642.6	576.3
Cash, cash equivalents and restricted cash, end of period	\$ 105.6	\$ 111.7	\$ 642.6
Supplemental cash flow disclosures:			
Cash paid for interest	\$ 64.0	\$ 68.3	\$ 33.0
Cash paid for income taxes, net of refunds	\$ 26.5	\$ 52.8	\$ 6.2
Non-cash investing and financing activities:			
Purchases of property, plant and equipment unpaid at period end	\$ 1.9	\$ 5.7	\$ 9.4
Gain on extinguishments of debt	\$ 0.6	\$ 2.5	\$ —
Issuance of common stock in conjunction with debt	\$ 7.7	\$ —	\$ —
Reconciliation of cash and cash equivalents and restricted cash:			
Cash and cash equivalents	\$ 99.5	\$ 111.7	\$ 642.6
Restricted cash	6.1	—	—
Total	\$ 105.6	\$ 111.7	\$ 642.6

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

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

	\$0.001 Par Value Common Stock		Treasury Stock		Additional Paid- In Capital		Accumulated Other Comprehensive Income (Loss)		Retained Earnings (Accumulated Deficit)		Total Stockholders' Equity	
	Shares	Amount	Shares	Amount								
Balance at December 31, 2021	55.1	\$ 0.1	(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)	
Balance at December 31, 2022	55.7	\$ 0.1	(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	
Balance at December 31, 2023	57.8	\$ 0.1	(5.6)	\$ (227.7)	\$	\$	(5.7)	\$	(21.8)	\$	649.3	
Net loss	—	—	—	—	—	—	—	—	(190.6)	—	(190.6)	
Other comprehensive loss, net of tax	—	—	—	—	—	—	0.5	—	—	—	0.5	
Share-based compensation activity	1.0	—	—	15.9	—	—	—	—	—	—	15.9	
Issuance of common stock	1.1	—	—	7.7	—	—	—	—	—	—	7.7	
Balance at December 31, 2024	59.9	\$ 0.1	(5.6)	\$ (227.7)	\$	\$	(5.2)	\$	(212.4)	\$	482.8	

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 10 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”).

The Company manages the business with a focus on three operating segments: (1) a Commercial Products segment consisting of NARCAN[®] Nasal Spray and other commercial products that were sold as part of our travel health business in the second quarter of 2023 (see Note 3, “Divestitures” 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 is an intranasal formulation of naloxone approved by the United States Food and Drug Administration (“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 Vivotif[®], 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, “Divestitures”.

MCM Products Segment:

Anthrax - MCM Products

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

Trobigard Revocation

On April 2, 2024, the Belgium Federal Agency for Medicines and Health Products acknowledged and confirmed Emergent’s request to revoke the Market Authorization for the Trobigard Auto-Injector.

Sale of RSDL[®]

On July 31, 2024, the Company entered into the Stock and Asset Purchase Agreement (the “RSDL[®] Agreement”) with SERB Pharmaceuticals, through its wholly owned subsidiary BTG International Inc. (collectively, “SERB”), pursuant to which, among other things, the Company sold its worldwide rights to RSDL[®] to SERB (the “RSDL[®] Transaction”). See Note 3, “Divestitures” for more information on the RSDL[®] Transaction.

Services Segment:

Bioservices - CDMO

The Company’s 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 the Company refers to as “molecule-to-market” offerings, employ diverse technology platforms (mammalian, microbial, viral and plasma) across a network of development and manufacturing sites operated by the Company for its internal products and pipeline candidates and third-party bioservices. The Company services 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. In May 2024, the Company initiated a further organizational restructuring plan (the “May 2024 Plan”) announcing the closure of the Company’s Baltimore-Bayview Drug Substance manufacturing facility and Rockville, Maryland Drug Product facility. Additionally, on August 20, 2024, pursuant to the previously announced Asset Purchase Agreement (the “Asset Purchase Agreement”), the Company completed the sale of its Drug Product facility in Baltimore-Camden (the “Camden Transaction”) to Bora Pharmaceuticals Injectables Inc., a subsidiary of Bora Pharmaceuticals Co., Ltd. (“Bora”). See Note 3, “Divestitures” and Note 4, “Impairment and restructuring charges” for more information related to these announcements.

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. For presentation purposes, reclassifications of certain items have been made for comparability.

Liquidity and capital resources

The Company has historically financed its operating and capital expenditures through existing cash and cash equivalents, cash from operations, development contracts and grant funding and borrowings under various credit agreements, including the Term Loan Agreement (as defined below) and other lines of credit it has established from time to time.

In evaluating the Company’s ability to continue as a going concern in prior periods including through the second quarter of 2024, the Company took into account the potential mitigating effects of management’s previously disclosed plans to mitigate the substantial doubt about the Company’s ability to continue as a going concern, which plans had not yet been fully implemented. During the third quarter of 2024, the Company made significant progress implementing these plans, which progress is described below. As a result, the Company concluded that as of September 30, 2024, it alleviated substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the 2024 third quarter financial statements were issued.

During the third quarter of 2024, the Company entered into a credit agreement which provides for a term loan (the “Term Loan”) of \$250.0 million (the “Term Loan Agreement”) and a credit agreement for asset-based revolving loans (the “Revolving Credit Agreement” and together with the Term Loan Agreement, the “Senior Secured Credit Facilities”) with maturity dates that can extend through the second quarter of 2029. Also during the third quarter, the Company repaid all amounts outstanding under its Amended and Restated Credit Agreement, dated October 15, 2018, by and among the Company, the lenders party thereto from time to time, and Wells Fargo Bank, National Association, as the Administrative Agent (the “Prior Credit Agreement”). As of December 31, 2024, there was \$250.0 million outstanding under the Term Loan Agreement. The Revolving Credit Agreement provides for commitments with respect to asset-based revolver loans (the “Revolving Loans”) of up to the lesser of (x) \$100.0 million, which may be increased (but not above \$125.0 million, or the “Maximum Revolver Amount”) or decreased (but not below \$50.0 million) by the Borrowers in accordance with the terms of the Revolving Credit Agreement and (y) the Borrowing Base (as defined in the Revolving Credit Agreement). Once reduced, the facility may not be increased. As of December 31, 2024, there were no outstanding Revolving Loans. For more information about the Senior Secured Credit Facilities, see Note 10, “Debt” for a discussion of the material terms and financial covenants. As of December 31, 2024, the Company was in compliance with all the covenants under the Senior Secured Credit Facilities.

During the year ended December 31, 2024, the Company generated cash through the sale of certain assets, including the RSDL[®] Transaction, which provided for a cash purchase price of approximately \$75.0 million; and the Camden Transaction, which provided for a cash purchase price of approximately \$35.0 million, which includes customary closing adjustments for working capital and transaction expenses of the business at closing. Additionally, the Company received funds of \$50.0 million in connection with the confidential arbitration settlement (the “Settlement Agreement”) with Janssen Pharmaceuticals, Inc. (“Janssen”), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, related to the 2022 termination of the Company’s manufacturing services agreement with Janssen (the “Janssen Agreement”). See Note 3, “Divestitures” for additional information related to RSDL[®] Transaction and Camden Transaction, and Note 19, “Litigation” for additional information related to the accounting treatment and settlement of the arbitration with Janssen. Additionally, the Company has realized positive operational impacts of its restructuring and cost savings initiatives, including the closure of certain Bioservices facilities and reductions in force.

As of December 31, 2024, the Company had unrestricted cash and cash equivalents of \$99.5 million and available borrowing capacity of up to \$100.0 million under the Revolving Credit Agreement. The Company believes that its sources of liquidity, including debt and cash flows from operating activities, are adequate to fund its operations for at least the next twelve months from the issuance of these consolidated financial statements.

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 definite lived intangible assets and other long-lived assets. Other estimates include allowances for expected credit losses, inventory, depreciation and amortization, contingent consideration, share-based compensation, warrants, 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 and restricted cash

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

Warrants

The Company accounts for Warrants as either equity instruments, liabilities or derivative liabilities in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and/or ASC 815, *Derivatives and Hedging* ("ASC 815"), depending on the specific terms of the applicable warrant agreement.

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, includes:

- Level 1 — Observable inputs for identical assets or liabilities such as quoted prices in active markets;
- Level 2 — Inputs other than quoted prices in active markets that are either directly or indirectly observable; and
- Level 3 — Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

On a recurring basis, the Company measures and records money market funds (Level 1), contingent purchase consideration (Level 3) and value of Warrants (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.

Significant customers and accounts receivable

Billed accounts receivable are stated at invoice amounts and consist of amounts due from the United States Government ("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[®] 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 2025 through 2036. The Company has derived a significant portion of its revenue from sales of our Government - MCM products under contracts with the USG. The Company's current USG contracts do not necessarily increase the likelihood that it will secure future comparable contracts with the USG. The Company expects that a significant portion of the business will continue to be under government contracts that present a number of risks that are not typically present in the commercial contracting process. USG contracts for ACAM2000[®] and Anthrax Vaccines and other medical countermeasures products are subject to unilateral termination or modification by the government. The Company may fail to achieve significant sales of its medical countermeasures products, including ACAM2000[®] and Anthrax Vaccines to customers in addition to the USG, which would harm their growth opportunities. The Company's commercial product sales, largely NARCAN[®] 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 39%, 38% and 43% of total revenues for 2024, 2023 and 2022, respectively. The Company's accounts receivable as of December 31, 2024 and 2023, 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 Agreement and any derivative instruments that the Company may utilize from time to time. There is risk that the Company's Revolving Credit Agreement investors and derivative counterparties will not be available to fund as obligated. If funding under the Revolving Credit Agreement 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 Agreement and any derivative instruments that the Company may utilize from time to time by contracting with experienced large financial institutions and monitoring the credit quality of its lenders. As of December 31, 2024, 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. For internally manufactured inventory, the Company determines normal capacity for each production facility and allocates fixed production-overhead costs on that basis. The Company records inventory acquired in business combinations utilizing the comparative sales method, which estimates the expected sales price reduced for all costs expected to be incurred to complete/dispose of the inventory with a profit on those costs. The Company analyzes its inventory each reporting period and records a reserve to reduce the cost basis to net realizable value for inventory that has become obsolete, expired, slow-moving or short-dated based on customer requirements. Reserves for excess and obsolete inventory are relieved when the related inventory is disposed of through scrap or sale.

Pre-launch inventory

Within the Company's Commercial Product 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 include federal, state, local and international taxes. Income taxes are accounted for using the asset and liability method. Deferred tax assets/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/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 not more likely than not 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/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 not more likely than not that some portion or all of the deferred tax assets will be realized. 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 credits that are available. Historically, 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/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 times 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"). Upon successful completion of each project, the asset is classified as a definite-lived intangible and the Company will decide as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated and begin amortization.

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

The Company's acquisitions accounted for as asset acquisitions may 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 are included in right-of-use ("ROU") assets and liabilities. The Company has elected to record expense as incurred for leases with minimum lease payments of 12 months or less.

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 MCM 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, 2024.

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.

The Company's NARCAN[®] customer contracts, including OTC NARCAN[®] customer contracts, are fixed price contracts. For the majority of the Company's OTC NARCAN[®] contracts, the Company invoices and records revenue when the customers 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[®] 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 under our direct retailer contracts, specialty distributor fees, wholesaler fees, prompt payment discounts and government rebates. OTC NARCAN[®] 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 and administrative expenses" and Cost of commercial product sale", respectively, in the Consolidated Statement of Operations. Revenues from OTC NARCAN[®] 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. For contracts with direct retailers, the Company considers several factors in the estimation process for the allowance for returns of OTC NARCAN[®] 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. As 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 associated with technology transfer and scale up activities throughout the development stage, including internally and through third party contract manufacturers;
- costs of Bioservices for clinical trial material; and
- costs of materials intended for use and used in clinical trials and R&D.

Comprehensive loss

Comprehensive loss is comprised of net loss and other changes in equity that are excluded from net 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 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.

Earnings (loss) per common share

Basic earnings (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.

Advertising Costs

Advertising costs are expensed as incurred and are included as an element of "Selling, general and administrative" ("SG&A") expense in the Consolidated Statement of Operations. Advertising costs were \$23.0 million, \$26.9 million and \$8.6 million for the years ended December 31, 2024, 2023 and 2022, respectively.

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, performance 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 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.

The Company uses a Monte Carlo valuation model for estimating performance stock options and liability classified awards granted that vest based on market conditions. The Monte Carlo model incorporates more complex variables than closed-form models such as the Black-Scholes valuation model used for stock option grants. The Monte Carlo valuation model simulates a distribution of stock prices to yield an expected distribution of stock prices over the performance period. The stock-paths are simulated using volatilities calculated with historical information using data from a look-back period that is equal to the term of the award. The model assumes a risk-free interest rate with a term equal to the expected term of the award. The simulations are repeated multiple times and the mean of the discounted values is calculated as the grant date fair value for the award. The final payout of the award as calculated by the model is then discounted back to the grant date using the risk-free interest rate.

New Accounting Standards

Recently Adopted Accounting Standards

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 Company adopted ASU 2023-07 during the year ended December 31, 2024 with no material impact to the Company's consolidated financial statements.

Accounting Standards Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires a public business entity 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.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40) Disaggregation of Income Statement Expenses*, which requires a public business entity to disclose additional information about specific expense categories in the notes to financial statements on an annual and interim basis. The amendments are effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. A public entity should apply the amendments either prospectively to financial statements issued for reporting periods after the effective date of this ASU or retrospectively to any or all prior periods presented in the financial statements. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements.

3. Divestitures

Sale of Travel Health Business

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[®], 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.

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. On July 18, 2024, Bavarian Nordic announced that the European Medicines Agency had validated the marketing authorization application for CHIKV VLP, which triggered a development milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$10.0 million. On August 13, 2024, Bavarian Nordic announced that the FDA has accepted and granted Priority Review for the Biologics License Application for CHIKV VLP, which triggered a milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$20.0 million. The Company received both development milestone payments during the year ended December 31, 2024. On February 14, 2025, Bavarian Nordic

announced that the FDA approved CHIKV VLP under the Priority Review, which triggered a development milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$30.0 million. On February 28, 2025, Bavarian Nordic announced that the European Commission approved CHIKV VLP, which triggered a development milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$20.0 million. Both payments are expected to be received in the first half of 2025.

As a result of the divestiture, 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 for the year ended December 31, 2023.

In connection with the divestiture, the Company entered into a Transition Services Agreement (the "Bavarian Nordic TSA") with Bavarian Nordic to help support its ongoing operations. Under the Bavarian Nordic TSA, the Company provided 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 Bavarian Nordic TSA was recorded within "Other, net" on the Consolidated Statements of Operations. While the services under the Bavarian Nordic TSA were substantially completed in the third quarter of 2024, certain services continue to be provided as of December 31, 2024. The Bavarian Nordic TSA services income was \$0.5 million and \$3.2 million for the year ended December 31, 2024 and 2023, respectively. The Company determined that the disposal of the Company's travel health business did not qualify for reporting as a discontinued operation since it does not represent a strategic shift that had or will have a major effect on the Company's operations and financial results.

Sale of RSDL[®]

On July 31, 2024, the Company, through its wholly owned subsidiary Emergent BioSolutions Canada Inc., entered into the RSDL[®] Agreement with SERB pursuant to which, among other things, the Company sold its worldwide rights to RSDL[®] to SERB. The RSDL[®] Transaction also included the sale to SERB of all the outstanding capital stock of Emergent Protective Products USA Inc. ("EPPU"), a wholly owned subsidiary of the Company, which leases a manufacturing facility in Hattiesburg, Mississippi, as well as certain assets related to RSDL[®], including intellectual property rights, contract rights, inventory and marketing authorizations. In addition, the employees of EPPU joined SERB in connection with the RSDL[®] Transaction.

Pursuant to the RSDL[®] Transaction, SERB assumed certain government contracts related to RSDL[®] decontamination lotion, including the Company's existing contract to supply RSDL[®] to the U.S. Department of Defense, through a new contract award to the Canadian Commercial Corporation.

At the closing, SERB paid a cash purchase price of \$75.0 million, exclusive of customary closing adjustments related to inventory. In addition, SERB will owe the Company a \$5.0 million payment upon achievement of a milestone relating to sourcing of a certain component of RSDL[®] decontamination lotion. In connection with the RSDL[®] Transaction, the Company recognized a pre-tax gain of \$60.8 million, net of transaction costs of \$4.1 million, recorded within "Gain (loss) on sale of business" on the Consolidated Statements of Operations for the year ended December 31, 2024. The Company determined that the disposal of RSDL[®] 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 the Company's operations and financial results.

The Company and SERB entered into a transition services agreement (the "SERB TSA") to ensure the orderly transition of RSDL[®] decontamination lotion and the related assets to SERB, and a supply agreement (the "SERB Supply Agreement") pursuant to which SERB has a suite reservation at the Company's Winnipeg facility where the Company will perform Bioservices activities to manufacture and supply bulk lotion to SERB. The Company and SERB also entered into a reverse supply agreement (together with the SERB TSA and the SERB Supply Agreement, the "SERB Agreements") pursuant to which SERB supplies to the Company finished RSDL[®] for the purposes of the Company's performance of certain transitional distribution services under customer contracts that have not yet transferred to SERB. Under the SERB Agreements, the Company will retain a portion of net sales received upon delivery of RSDL[®] to the delayed transfer customers.

The Company accounted for this transaction as a multi-element arrangement and separated the discrete deliverables into different units of account. While there are multiple agreements, the Company determined that the agreements were agreed upon with a single commercial objective and accounted for all of the agreements on a combined basis. The discrete deliverables identified were the sale of the RSDL Transaction disposal group, the obligations under the supply agreement for the suite reservation at Winnipeg and the manufacture and supply of bulk lotion, and the transition services agreement and reverse supply agreement services. All of the deliverables within the agreements were priced at market and according to their relative standalone selling prices. Income from performing services under the SERB TSA is recorded within "Services" revenues on the Consolidated Statements of Operations and was \$2.0 million for the year ended December 31, 2024.

Sale of Baltimore-Camden Facility

On August 20, 2024, pursuant to the Asset Purchase Agreement, the Company completed the sale of its Drug Product facility in Baltimore-Camden to an affiliate of Bora. The Baltimore-Camden facility, which was part of the Company's Bioservices segment, had clinical and commercial non-viral aseptic fill/finish services on four fill lines, including lyophilization, formulation development, and support services. Alongside the facility, approximately 350 Emergent employees joined Bora as part of the transaction. At closing, Bora paid a cash purchase price of approximately \$35.0 million, which includes customary closing adjustments to date for working capital and transaction expenses of the business at closing.

As a result of the divestiture, the Company recognized a pre-tax loss of \$36.5 million, net of transaction costs of \$3.8 million, during the year ended December 31, 2024 recorded within "Gain (loss) on sale of business" on the Consolidated Statements of Operations. The Company determined that the disposal of the Camden Site 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 the Company's operations and financial results.

In connection with the divestiture, the Company entered into a Transition Services Agreement (the "Bora TSA") with Bora to help support its ongoing operations. Under the Bora TSA, the Company is providing certain transition services to Bora, including information technology, finance and enterprise resource planning, human resources, employee benefits and other limited services. Income from performing services under the Bora TSA is recorded within "Other, net" on the Consolidated Statements of Operations and was \$0.5 million for the year ended December 31, 2024.

4. Impairment and restructuring charges

2024 Impairment of long-lived assets

During the preparation of the Company's financial statements for the three months ended June 30, 2024, due to the decision to close the Company's Baltimore-Bayview Drug Substance manufacturing facility and the Rockville, Maryland Drug Product facility, the Company determined there were sufficient indicators of impairment for the Bayview and Rockville asset groups within the Bioservices reporting unit. As a result, the Company performed recoverability tests on those asset groups and concluded that the Bayview and Rockville 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, each representing Level 3 non-recurring fair value measurements. Based on these analyses, the Company allocated and recognized a non-cash impairment charge of \$27.2 million during the second quarter of 2024.

2023 Impairment of long-lived assets

During the preparation of the Company's financial statements for the three months ended June 30, 2023, due to deterioration in performance and resulting downward revisions to the Company's internal Bioservices forecast made during the second quarter, including future expected cash flows, the Company determined there were sufficient indicators of impairment on the Camden, Bayview and Rockville 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, each representing Level 3 non-recurring fair value measurements. Based on these analyses, the Company allocated and recognized a non-cash impairment charge of \$306.7 million during the second quarter of 2023.

The table below presents the total impairment charge by asset class for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
Buildings, building improvements and leasehold improvements	\$ 7.8	\$ 81.5
Furniture and equipment	14.1	117.5
Software	0.2	0.3
Construction-in-progress	5.1	107.4
Total impairment of long-lived assets	<u>\$ 27.2</u>	<u>\$ 306.7</u>

Restructuring Charges

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 charges related to the January 2023 Plan consisted primarily of charges related to employee transition, severance payments and employee benefits. The cumulative amount of restructuring charge related to the January 2023 Plan since inception is \$9.3 million. 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, which was intended to strengthen its core business and financial position by reducing investment in and de-emphasizing focus on its CDMO services business for future growth. As part of the August 2023 Plan, the Company reduced its workforce by approximately 400 employees. The charges related to the August 2023 Plan consisted primarily of employee transition, severance payment and employee benefit charges. The cumulative amount of restructuring charge related to the August 2023 Plan since inception is \$19.4 million. 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.

May 2024 Organizational Restructuring Plan

In May 2024, the Company initiated the May 2024 Plan. These strategic actions led to a reduction of the Company's workforce by approximately 300 employees across all areas of the Company and the elimination of approximately 85 positions that were vacant, as well as the closure of the Company's Baltimore-Bayview Drug Substance manufacturing facility and Rockville, Maryland Drug Product facility. Decisions regarding the elimination of positions and the closure of manufacturing facilities were subject to local law and consultation requirements in certain countries, as well as the Company's business needs. The cumulative amount of restructuring charge related to the May 2024 Plan since inception is \$19.8 million. All activities related to the May 2024 Plan were substantially completed during the third quarter of 2024. 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 2024 Organizational Restructuring Plan

In August 2024, the Company initiated an organizational restructuring plan ("the August 2024 Plan") at the Company's Lansing facility, which reduced the Company's workforce by approximately 70 employees, as well as eliminated several open positions. The Company also implemented non-labor optimization efforts, such as reducing the Company's external and vendor spend. The cumulative amount of restructuring charges related to the August 2024 Plan since inception is \$3.3 million. All activities related to the August 2024 Plan were substantially completed during the fourth quarter of 2024. 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 related to the January 2023 Plan, August 2023 Plan, May 2024 Plan and August 2024 Plan by reportable segment as well as amounts included within unallocated corporate SG&A expense and R&D expense:

	Year Ended December 31,	
	2024	2023
Commercial Products	\$ —	\$ —
MCM Products	7.2	5.6
Services	0.2	8.4
Total restructuring costs by segment	7.4	14.0
Corporate	9.3	11.7
R&D	5.8	3.6
Total restructuring costs	<u>\$ 22.5</u>	<u>\$ 29.3</u>

The following table presents the total restructuring costs, by function, for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
Employee transition	\$ 0.3	\$ 0.6
Severance payments	19.3	27.0
Employee benefits	2.9	1.7
Total restructuring costs	<u>\$ 22.5</u>	<u>\$ 29.3</u>

The following table provides the components of and changes in the Company's restructuring accrual for the January 2023 Plan during the years ended December 31, 2024 and 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	<u>\$ —</u>	<u>\$ 1.4</u>	<u>\$ —</u>	<u>\$ 1.4</u>
Accruals	—	—	—	—
Cash payments	—	(1.4)	—	(1.4)
Balance at December 31, 2024	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

The following table provides the components of and changes in the Company's restructuring accrual for the August 2023 Plan during the years ended December 31, 2024 and 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
Accruals	—	(0.6)	—	(0.6)
Cash payments	—	(4.7)	(0.1)	(4.8)
Balance at December 31, 2024	\$ —	\$ —	\$ —	\$ —

The following table provides the components of and changes in the Company's restructuring accrual for the May 2024 Plan during the year ended December 31, 2024:

	Employee Transition	Severance Payments	Employee Benefits	Total
Balance at December 31, 2023	\$ —	\$ —	\$ —	\$ —
Accruals	0.2	17.2	2.4	19.8
Cash payments	(0.2)	(12.7)	(1.6)	(14.5)
Balance at December 31, 2024	\$ —	\$ 4.5	\$ 0.8	\$ 5.3

The following table provides the components of and changes in the Company's restructuring accrual for the August 2024 Plan during the year ended December 31, 2024:

	Employee Transition	Severance Payments	Employee Benefits	Total
Balance at December 31, 2023	\$ —	\$ —	\$ —	\$ —
Accruals	0.1	2.6	0.6	3.3
Cash payments	(0.1)	(0.7)	(0.1)	(0.9)
Balance at December 31, 2024	\$ —	\$ 1.9	\$ 0.5	\$ 2.4

5. Inventories, net

Inventories, net consist of the following:

	December 31,	
	2024	2023
Raw materials and supplies	\$ 95.9	\$ 128.7
Work-in-process	86.3	113.3
Finished goods	129.5	86.9
Total inventories, net	\$ 311.7	\$ 328.9

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,	
	2024 ⁽¹⁾	2023 ⁽¹⁾
Land and improvements	\$ 25.8	\$ 30.0
Buildings, building improvements and leasehold improvements	196.1	229.9
Furniture and equipment	368.3	433.6
Software	67.2	64.0
Construction-in-progress	10.3	36.7
Property, plant and equipment, gross	\$ 667.7	\$ 794.2
Less: Accumulated depreciation and amortization	(397.1)	(411.4)
Total property, plant and equipment, net	\$ 270.6	\$ 382.8

⁽¹⁾ During the years ended December 31, 2024 and 2023, the Company recorded non-cash impairment charges of \$27.2 million and \$306.7 million, respectively, related to certain Bioservices long-lived assets. See Note 4, "Impairment and restructuring charges" for more details regarding the impairment charge.

For the years ended December 31, 2024 and 2023, construction-in-progress primarily included costs incurred to advance the Company's MCM Product 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 \$43.7 million, \$59.5 million and \$83.4 million for the years ended December 31, 2024, 2023, and 2022, 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 Janssen Agreement. For additional information related to the termination of the Janssen Agreement, refer to Note 19, "Litigation".

7. Intangible assets and goodwill

Intangible Assets

The Company's finite-lived intangible assets consist of products acquired via business combinations or asset acquisitions. The following table summarizes the Company's finite-lived intangible assets:

	Weighted Average Useful Life in Years	December 31, 2024			December 31, 2023		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Products	13.5	\$ 855.4	\$ 353.9	\$ 501.5	\$ 855.4	\$ 288.8	\$ 566.6
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	0.0	\$ 889.5	\$ 388.0	\$ 501.5	\$ 889.5	\$ 322.9	\$ 566.6

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

	Year Ended December 31,		
	2024	2023	2022
Amortization expense	\$ 65.1	\$ 65.6	\$ 59.9

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

Year	As of December 31, 2024	
2025	\$	65.1
2026		63.9
2027		60.6
2028		51.7
2029		51.7
Thereafter		208.5
Total remaining amortization	\$	501.5

Goodwill

The Company had no remaining goodwill as of December 31, 2024 and 2023. During 2023 and in prior periods, the Company performed its goodwill impairment evaluation annually, during the fourth quarter, or sooner if triggering events were 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 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 indicates the level within the fair value hierarchy of the valuation techniques the Company utilized to determine fair value:

	December 31, 2024				December 31, 2023			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Assets:								
Money market accounts	\$ 45.7	\$ 45.7	\$ —	\$ —	\$ 40.5	\$ 40.5	\$ —	\$ —
Total	\$ 45.7	\$ 45.7	\$ —	\$ —	\$ 40.5	\$ 40.5	\$ —	\$ —
Liabilities:								
Contingent consideration	\$ —	\$ —	\$ —	\$ —	\$ 5.6	\$ —	\$ —	\$ 5.6
Warrant liability	16.2	—	—	16.2	—	—	—	—
Total	\$ 16.2	\$ —	\$ —	\$ 16.2	\$ 5.6	\$ —	\$ —	\$ 5.6

2024 Warrant liability

In connection with the Term Loan Agreement, the Company issued to the lenders warrants to purchase 1.0 million shares of the Company’s common stock at an exercise price of \$9.8802 per share (the “Series I Warrants”) and warrants to purchase 1.5 million shares at an exercise price of \$15.7185 per share (the “Series II Warrants”) and, together with the Series I Warrants, the “Warrants”). The Warrants are currently exercisable and will expire on August 30, 2029. Because the Warrants could be cash settled based on events that are outside the control of the Company, it precludes the Warrants from applying the equity contract scope exception, and so are classified as a liability. As a result, the fair value of the Warrants will be remeasured each period with the gain or loss on the warrant liability included in “Other, net” on the Consolidated Statement of Operations. The fair value of the liability at issuance was \$13.4 million and, as of December 31, 2024, was remeasured to \$16.2 million as determined using the Black-Scholes method and is included within “Other Liabilities” on the Consolidated Balance Sheet.

The Company uses the Black-Scholes option pricing model to calculate the fair value of the Warrants at each reporting period. Assumptions used in the Black-Scholes option pricing model take into account the agreement terms as well as the quoted price of the Company's common stock in an active market. The volatility is based on the average historical volatility of the common stock. The expected life is based on the remaining contractual term of the Warrants, and the risk free interest rate is based on the implied yield available on U.S. Treasury securities with a maturity equivalent to the Warrants' expected life.

The table below is a reconciliation of the beginning and ending balance of the Company's Level 3 warrant liability as of December 31, 2024:

	Warrant Liability
Balance at December 31, 2023	\$ —
Issuance of Warrants	13.4
Change in fair value	2.8
Balance at December 31, 2024	\$ 16.2

The recurring Level 3 fair value measurement for the Company's warrant liability used the following significant unobservable inputs:

Warrant Liability	Valuation Technique	Unobservable Input	Range
2024 Warrants	Black-Scholes Method	Term (in years)	4.7
		Risk free interest rate	4.4%
		Volatility	95%

Contingent consideration

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 liabilities associated with business combinations are measured at fair value. The 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 change in fair value for the contingent consideration liabilities related to the Company's products is classified on the Company's Consolidated Statements of Operations as "Cost of MCM Product sales."

The following table is a reconciliation of the beginning and ending balance of the Company's Level 3 contingent consideration liability measured at fair value during the years ended December 31, 2024, 2023 and 2022:

	Contingent Consideration
Balance at December 31, 2022	\$ 8.0
Change in fair value	0.2
Settlements	(2.6)
Balance at December 31, 2023	\$ 5.6
Change in fair value	0.6
Settlements	(2.3)
Sales ⁽¹⁾	(3.9)
Balance at December 31, 2024	\$ —

⁽¹⁾ On July 31, 2024, the Company sold the worldwide rights to RSDL[®] to SERB. In connection with the RSDL[®] Transaction, the Company conveyed the contingent consideration liability related to RSDL[®] to SERB. See Note 3, "Divestitures" for more information regarding the RSDL[®] Transaction.

As of December 31, 2024, there was no liability related to contingent consideration. As of December 31, 2023, the current portion of the contingent consideration liability was \$2.7 million and was included in "Other current liabilities" on the Consolidated Balance Sheet. The non-current portion of the contingent consideration liability was \$2.9 million and was included in "Other liabilities" on the Consolidated Balance Sheet as of December 31, 2023.

Non-variable rate debt

As of December 31, 2024 and 2023, the fair value of the Company's 3.875% Senior Unsecured Notes (the "Senior Unsecured Notes") was \$369.1 million and \$184.3 million, respectively. The fair value was determined through market sources, which are Level 2 inputs and directly observable. The carrying amounts of the Company's other long-term variable interest rate debt arrangements approximate their fair values (see Note 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, 2024 and December 31, 2023, 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, 2024 and 2023, there was no remaining accumulated other comprehensive income associated with the terminated interest rate swaps.

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 falls 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, 2024 and 2023:

	Classification	Year Ended December 31,	
		2024	2023
Interest rate swaps gain (loss)	Interest expense	\$ —	\$ 8.9

10. Debt

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

	December 31,	
	2024	2023
Senior secured credit agreement - Term loan due 2029	\$ 250.0	\$ —
3.875% Senior Unsecured Notes due 2028	450.0	450.0
Senior secured credit agreement - Term loan due 2025	—	198.2
Senior secured credit agreement - Revolver loan due 2025	—	219.2
Other	—	1.0
Total debt	\$ 700.0	\$ 868.4
Current portion of long-term debt, net of debt issuance costs	—	(413.7)
Unamortized debt issuance costs	(36.3)	(8.2)
Non-current portion of debt	\$ 663.7	\$ 446.5

There were \$35.0 million of unamortized debt issuance costs recorded in connection with the execution of the Term Loan Agreement within a contra account to directly offset the Term Loan balance.

Debt issuance costs associated with the Company's Revolving Loans, as described in further detail below, were recorded as an asset within "Other long-term assets" on the Company's Consolidated Balance Sheets. As of December 31, 2024, the Company has \$3.9 million in unamortized debt issuance costs associated with the Revolving Loans. If the Company draws on the capacity available under the Revolving Loans, the debt issuance costs would be reclassified to a contra account to directly offset the Revolving Loans balance.

During the year ended December 31, 2023, the Company reclassified the debt issuance costs associated with the Company's revolver loan due 2025 under the Prior Credit Agreement to a contra account to directly offset the loan balance in "Debt, current portion" on the Company's Consolidated Balance Sheets. As of December 31, 2024, the Company had no debt issuance costs associated with the revolver loan due 2025. As of December 31, 2023, the Company had \$5.3 million of debt issuance costs associated with the revolver loan due 2025.

During the year ended December 31, 2024, the Company entered into a bilateral agreement with a bank in the amount of \$5.1 million that is fully collateralized by cash, which is classified within "Restricted cash" in the Company's Consolidated Balance Sheet as of December 31, 2024.

The Company recorded a gain on extinguishments of debt of \$0.6 million during the year ended December 31, 2024, respectively in "Other, net" on the Consolidated Statements of Operations related to the Prior Credit Agreement and other loan forgiveness.

3.875% Senior Unsecured Notes due 2028

On August 7, 2020, the Company completed its offering of \$450.0 million aggregate principal amount of its Senior Unsecured Notes. Interest on the Senior Unsecured Notes is payable on February 15 and August 15 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 all or a portion of the Senior Unsecured Notes at a redemption price equal to 100% of the principal amount of the Senior Unsecured Notes plus a "make-whole" premium and accrued and unpaid interest as set forth in the related indenture. Upon the occurrence of a change of control, the Company must offer to repurchase the Senior Unsecured Notes at a purchase price of 101% of the principal amount of such 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.

Term Loan Agreement

On August 30, 2024, the Company entered into the Term Loan Agreement which provides for a Term Loan of \$250.0 million. The Term Loan was drawn in full on the date of entry into the Term Loan Agreement (the "Closing Date"). The Term Loan was issued with an original issue discount of 3.00%.

The Term Loan will accrue interest at the Company's option at (i) the Base Rate (as defined in the Term Loan Agreement) (subject to a floor of 1.00%) plus 7.25% per annum, referred to as "Term Base Rate Loans" or (ii) Adjusted Term Secured Overnight Financing Rate ("SOFR") (as defined in the Term Loan Agreement) (subject to a floor of 2.00% until the second anniversary of the Closing Date, and thereafter, 3.00%) plus 8.25% per annum, referred to as "Term SOFR Loans"). A default interest rate of an additional 2.00% per annum would apply on all outstanding obligations that are not paid when due. If any defaulted obligations are Term SOFR Loans, then such loans would, at the end of the applicable interest period, automatically be converted to Term Base Rate Loans that would continue to be subject to the default interest rate.

The Term Loan will mature on the first to occur (such date, the "Term Loan Maturity Date") of (i) August 30, 2029, (ii) the date of acceleration of the Term Loan upon the occurrence and during the continuance of an event of default and (iii) solely to the extent the aggregate principal amount of Senior Unsecured Notes outstanding exceeds \$25.0 million, May 15, 2028, which is three months prior to the August 15, 2028 maturity date of the Senior Unsecured Notes. The Term Loan Agreement contains certain customary default and cross-default provisions, representations and warranties and affirmative and negative covenants, including (a) restrictions on prepayments and repurchases of indebtedness, including the Senior Unsecured Notes, subject to further customary permitted debt payments (b) a minimum liquidity requirement of \$75.0 million commencing on September 30, 2024 and tested every two weeks, and (c) a consolidated gross leverage ratio tested every fiscal quarter commencing with the fiscal quarter ending December 31, 2025, initially at 5.10:1.00 with step-downs as set forth in the Term Loan Agreement. As of December 31, 2024, the Company was in compliance with all covenants under the Term Loan Agreement.

All indebtedness outstanding under the Term Loan Agreement is guaranteed by certain of the Company's direct and indirect subsidiaries, other than certain subsidiaries that are not material, are excluded pursuant to the terms of the Term Loan Agreement, or will become guarantors on a post-closing basis (the Company and the guarantors, collectively, the Credit Parties"). The indebtedness under the Term Loan Agreement is secured by a first-priority security interest in and lien on substantially all assets of the Company and the other Credit Parties.

The Company may elect to prepay the Term Loan, in whole or in part, subject to (i) through and including the first anniversary of the Closing Date, a make-whole premium plus 4.00% of the aggregate principal amount of the Term Loan subject to prepayment and (ii) after the first anniversary of the Closing Date, a 4.00% prepayment premium, which percentage shall be reduced by 0.25% as set forth on a schedule attached to the Term Loan Agreement. The Term Loan Agreement requires mandatory prepayments of the Term Loan in an amount equal to (a) 100% of the aggregate net cash proceeds from the incurrence of certain indebtedness by the Term Loan Credit Parties and (b) (subject to certain reinvestment rights) 100% of the aggregate net cash proceeds from (1) subject to certain specified exceptions, dispositions of property by the Credit Parties (provided that with respect to any dispositions occurring on or after the Closing Date, prepayment will not be required unless the net cash proceeds exceed \$10.0 million in the aggregate per fiscal year or \$5.0 million on a per-transaction basis) and (2) insurance proceeds received by any Credit Party or their subsidiaries resulting from theft, loss, physical destruction or damage of property.

On the Closing Date, the Company used a portion of the proceeds of the Term Loan to repay all amounts outstanding and terminate commitments under the senior term loan facility under the Prior Credit Agreement, plus accrued interest and fees. The Company previously repaid all amounts outstanding under the revolving credit facility under the Prior Credit Agreement.

Revolving Loan Agreement

On September 30, 2024, the Company entered into the Revolving Credit Agreement with certain subsidiary borrowers (together with the Company, the "Borrowers"), the lenders from time to time party thereto, and Wells Fargo Bank, National Association, as agent (the "Agent"). The Credit Agreement provides for commitments with respect to Revolving Loans of up to the lesser of (x) \$100.0 million, which may be increased (but not above \$125.0 million, or the "Maximum Revolver Amount") or decreased (but not below \$50.0 million) by the Borrowers in accordance with the terms of the Revolving Credit Agreement and (y) the Borrowing Base (as defined in the Revolving Credit Agreement). Once reduced, the facility may not be increased. Up to \$5.0 million of capacity under the Revolving Loans may be used for swing loans and up to \$10.0 million may be used for the issuance of letters of credit.

The Revolving Loans will accrue interest at the Base Rate (as defined in the Revolving Credit Agreement) plus a margin of 1.25% (such loans, "Revolving Base Rate Loans") or, at the Company's election, at a rate equal to Adjusted Term SOFR (as defined in the Revolving Credit Agreement and subject to a floor of 0.00%) plus a margin of 2.25% (such loans, "Revolving SOFR Loans"), in each case until September 30, 2025. After September 30, 2025, the applicable margin may be reduced to 0.75% in the case of Revolving Base Rate Loans, or 1.75% in the case of Revolving SOFR Loans, provided the Borrowers' total leverage ratio is less than 4.00 to 1.00 for the most recently completed fiscal quarter and an event of default is not continuing. A default interest rate of an additional 2.00% per annum would apply on all outstanding obligations that are not paid when due.

The Revolving Loans will mature on the first to occur of (i) September 30, 2029; (ii) to the extent there remain outstanding any portion of the term loans extended under the Term Loan Agreement, the date that is 90 days prior to the maturity date under the Term Loan Agreement; and (iii) to the extent any of the Senior Unsecured Notes remain outstanding, May 17, 2028, which is 90 days prior to the August 15, 2028 maturity date of the Senior Unsecured Notes. The Revolving Credit Agreement contains certain customary default and cross-default provisions (including with respect to defaults under the Term Loan Agreement), representations and warranties and affirmative and negative covenants, including (a) restrictions on prepayments and repurchases of indebtedness, including the Senior Unsecured Notes, (b) restrictions on dispositions of material intellectual property, (c) a minimum liquidity requirement of \$50.0 million through the day prior to the first date following September 30, 2025 on which the Company's total leverage ratio measured as of the preceding 12-month period is less than 5.25 to 1.00 (the "Covenant Conversion Date") and (d) from the Covenant Conversion Date, a fixed charge coverage ratio requirement of at least 1.00 to 1.00. As of December 31, 2024, the Company was in compliance with all covenants under the Revolving Credit Agreement.

All indebtedness outstanding under the Revolving Credit Agreement is guaranteed by certain of the Borrowers' material direct and indirect subsidiaries, subject to customary exclusions. The indebtedness under the Credit Agreement is secured by a first-priority security interest in and lien on the ABL Priority Collateral and a second-priority security interest and lien on the Term Loan Priority Collateral (in each case as defined in the Revolving Credit Agreement).

The Borrowers may elect to prepay any Revolving Loans, in whole or in part, without premium or penalty. If at any time outstanding Revolving Loans and letters of credit exceed the lesser of (i) the Borrowing Base, as adjusted for reserves established by the Agent, and (ii) the Maximum Revolver Amount, the Borrowers will be required to prepay outstanding obligations in the amount of such excess. The Agent may establish, increase or decrease reserves at its discretion.

Debt Maturity

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

Year	As of December 31, 2024
2025	\$ —
2026	—
2027	—
2028	700.0
2029	—
Thereafter	—
Total debt	\$ 700.0

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, performance stock options, restricted stock units, performance stock units and liability classified long-term incentive awards.

As of December 31, 2024, an aggregate of 31.2 million shares of common stock were authorized for issuance under the Emergent Plan, of which a total of approximately 6.7 million shares of common stock remain available for future awards to be made to plan participants. As of December 31, 2024, an aggregate of 5.0 million shares of common stock were authorized for issuance under the Inducement Plan and 4.0 million shares remain available for future awards to be made under the Inducement Plan. Additionally, during the year ended December 31, 2024, the Company granted an \$8.0 million liability-classified long-term incentive award subject to performance based market conditions with the option to settle the award in any combination of cash or shares. The fair value of the liability-classified long-term incentive award was valued at grant using a Monte Carlo valuation model and will be revalued at each reporting period until the award is earned or expires. The long-term incentive award has a performance period of five years to vest based on the Company's stock price performance.

Stock options and performance stock options

The Company utilizes the Black-Scholes valuation model for estimating the fair value of stock options granted. 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. Set forth below are the assumptions used in valuing the stock options granted:

	Year Ended December 31,		
	2024	2023	2022
Expected dividend yield	0 %	0 %	0 %
Expected volatility	78%-96%	63%-69%	54%-62%
Risk-free interest rate	3.43%-4.67%	4.00%-4.46%	1.54%-4.31%
Expected average life of stock options	4.8 years	4.5 years	4.5 years

During the year ended December 31, 2024, the Company granted performance stock options. These awards vest the later of one year after the grant date or the achievement of the market based performance condition. The performance period is five years after the grant date and the awards expire seven years after the grant date. The related stock-based compensation is recognized over the requisite service period, taking into account the probability that the market based performance condition will be achieved. The Company utilized the Monte Carlo valuation model for estimating the fair value of performance stock options granted. Set forth below are the assumptions used in valuing the performance stock options granted:

	Year Ended December 31,		
	2024	2023	2022
Expected dividend yield	0 %	—	—
Expected volatility	67.1 %	—	—
Risk-free interest rate	4.20%	—	—
Expected average life of performance stock options	4.7 years	—	—

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

	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Stock options outstanding at December 31, 2023	1.1	\$ 34.44		
Stock options granted ⁽¹⁾	5.0	\$ 2.67		
Stock options exercised	(0.1)	\$ 8.43		
Stock options forfeited	(1.0)	\$ 4.44		
Stock options expired	(0.2)	\$ 50.57		
Stock options outstanding at December 31, 2024	4.8	\$ 7.61	5.9	\$ 28.3
Stock options exercisable at December 31, 2024	0.5	\$ 45.12	3.2	\$ 0.1

⁽¹⁾ Includes 0.8 million performance stock options that were granted in 2024 with a weighted average exercise price of \$2.33 and are not exercisable as of December 31, 2024.

There was \$0.3 million cash received from option exercises for the years ended December 31, 2024. There was no cash received from option exercises for the year ended December 31, 2023 and \$0.5 million for the year ended December 31, 2022. There were no performance options exercised during the years ended December 31, 2024, 2023 and 2022.

The weighted average grant date fair value of options granted during the years ended December 31, 2024, 2023 and 2022 was \$1.80, \$5.35 and \$17.85 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 an immaterial intrinsic value of options exercised during the year ended December 31, 2024 and no intrinsic value of options exercised during the year ended December 31, 2023. There was \$0.3 million of intrinsic value of options exercised during the year ended December 31, 2022.

The weighted average grant date fair value of performance options granted during the year ended December 31, 2024 was \$1.13. There were no performance options granted during the years ended December 31, 2023 and 2022.

As of December 31, 2024, there was \$5.5 million of unrecognized compensation cost related to stock options and \$0.5 million of unrecognized compensation costs related to performance stock options. These costs are expected to be recognized over the weighted average periods of 2.0 years for stock options and 1.6 years for performance 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 and the Inducement Plan:

	Number of Shares	Weighted-Average Grant Date Fair Value	Aggregate Intrinsic Value
Stock awards outstanding at December 31, 2023	2.6	\$ 16.57	\$ 6.20
Stock awards granted	0.2	\$ 6.46	
Stock awards released	(1.0)	\$ 20.62	
Stock awards forfeited ⁽¹⁾	(0.6)	\$ 14.45	
Stock awards outstanding at December 31, 2024	1.2	\$ 12.01	\$ 11.60

⁽¹⁾ Performance stock units forfeited during the year ended December 31, 2024 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, 2024, 2023 and 2022 was \$21.6 million, \$31.8 million and \$30.9 million, respectively. As of December 31, 2024, there was \$5.6 million of unrecognized compensation cost related to unvested restricted stock units. This cost is expected to be recognized straight-line over a weighted average period of 1.1 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. There were no performance unit awards released during year ended December 31, 2024. The total fair value of performance unit awards released during the years ended December 31, 2023 and 2022 was \$2.4 million and \$2.5 million, respectively. As of December 31, 2024, there was \$0.5 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 1.0 year.

Share-based compensation expense

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

	Year Ended December 31,		
	2024	2023	2022
Cost of Commercial Product sales	\$ —	\$ 0.1	\$ 0.8
Cost of MCM Product sales	1.8	3.8	6.5
Cost of Bioservices	0.2	1.0	1.8
R&D	1.1	2.0	5.4
Selling, general and administrative	14.9	16.2	30.6
Total share-based compensation expense	\$ 18.0	\$ 23.1	\$ 45.1

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.

2024 Issuance of Common Stock

In connection with the Term Loan Agreement, the Company entered into a Subscription Agreement, dated as of August 30, 2024 (the "Subscription Agreement") with the lenders under the Term Loan Agreement, under which on September 17, 2024, the Company issued to the lenders 1.1 million shares of common stock with an aggregate value of \$10.0 million, at a price per share of \$8.98, which was based on the volume weighted average price per share of common stock for the 30 consecutive trading days ending on, but excluding, the tenth business day of the Term Loan Agreement. At inception, the Subscription Agreement represented a forward sale of the Company's common stock (the "Forward").

Since the number of shares issued under the Forward was determined based on a fixed monetary value established on August 30, 2024, which necessitated issuing a variable number of shares, the Forward was initially classified and recorded as a liability. As it was classified as a liability, the Forward had to be remeasured to its fair value upon settlement on September 17, 2024. Consequently, the Company recognized a gain of \$1.6 million, which was recorded under "Other, net" in the Consolidated Statement of Operations for the year ended December 31, 2024. This gain resulted from a drop in stock price between the execution date of the Subscription Agreement and the actual issuance date of the shares. As of December 31, 2024, there was no remaining liability related to the Forward on the Consolidated Balance Sheets.

2024 Warrant Issuance

In connection with the Term Loan Agreement, the Company issued to the lenders Series I Warrants to purchase 1.0 million shares of common stock and Series II Warrants to purchase 1.5 million shares of common stock. The Warrants are currently exercisable and will expire on August 30, 2029. Because the Warrants could be cash settled based on events that are outside the control of the Company, it precludes the Warrants from applying the equity contract scope exception, and so are classified as a liability. As of December 31, 2024, the fair value of the Warrants was \$16.2 million. See Note 8, "Fair value measurements," for more information on the accounting treatment and valuation of the Warrants.

As of December 31, 2024, the Company had the following Warrants outstanding to acquire shares of its common stock:

	Warrants Outstanding	Range of Exercise Price per Share	Expiration Date
Warrants issued related to the Term Loan Agreement	2.5	\$9.88 - \$15.72	August 2029
Total	<u>2.5</u>		

During the year ended December 31, 2024, no Warrants expired or were exercised.

At-the-Market Equity Offering Facility

In May 2023, the Company established an "at-the-market" equity offering program (the "ATM Program") pursuant to which the Company may, from time to time, sell up to \$150.0 million aggregate gross sales price of shares of its common stock through Evercore Group L.L.C. and RBC Capital Markets, LLC, as sales agents. There were no sales of the Company's common stock under the ATM Program during the year ended December 31, 2024. Our Registration Statement on Form S-3 related to the ATM Program expired on August 9, 2024. The Company cannot sell any shares under the ATM Program until a new Registration Statement on Form S-3 is filed and becomes effective. During the second quarter of 2023, the Company sold 1.1 million shares of the Company's 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, 2024, \$140.9 million aggregate gross sales price of shares of the Company's common stock remains available for issuance under the ATM Program.

12. Loss per common share

Basic loss per common share is calculated using the treasury method by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted 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, as well as shares issuable upon exercises of the Warrants. Diluted loss per share excludes anti-dilutive securities, which represent the number of potential common shares related to shares issuable under our equity compensation plan and pursuant to exercises of the Warrants that were excluded from diluted loss per common share because their effect would have been antidilutive.

The following table presents the calculation of basic and diluted loss per common share:

	Year Ended December 31,		
	2024	2023	2022
Numerator:			
Net loss	\$ (190.6)	\$ (760.5)	\$ (211.6)
Denominator:			
Weighted-average number of shares-basic	53.0	51.2	50.1
Dilutive securities - equity awards	—	—	—
Weighted-average number of shares-diluted	53.0	51.2	50.1
Net loss per common share - basic	\$ (3.60)	\$ (14.85)	\$ (4.22)
Net loss per common share - diluted	\$ (3.60)	\$ (14.85)	\$ (4.22)

The following table presents the securities and equity awards that are not considered in the diluted 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, 2024, 2023 and 2022 or the period resulted in a net loss, thus making the awards anti-dilutive. 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,		
	2024	2023	2022
Anti-dilutive stock awards	4.9	3.6	2.8

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,								
	2024			2023			2022		
	USG	Non-USG	Total	USG	Non-USG	Total	USG	Non-USG	Total
Commercial Product sales	\$ 0.8	\$ 398.1	\$ 398.9	\$ 0.8	\$ 496.5	\$ 497.3	\$ 0.8	\$ 385.8	\$ 386.6
MCM Product sales	381.3	128.5	509.8	373.5	73.7	447.2	444.6	135.0	579.6
Bioservices:									
Services ⁽¹⁾	—	103.5	103.5	—	72.8	72.8	—	105.0	105.0
Leases	—	1.4	1.4	—	5.7	5.7	—	4.9	4.9
Total Bioservices	\$ —	\$ 104.9	\$ 104.9	\$ —	\$ 78.5	\$ 78.5	\$ —	\$ 109.9	\$ 109.9
Contracts and grants	28.4	1.6	30.0	20.4	5.9	26.3	37.2	4.2	41.4
Total revenues	<u>\$ 410.5</u>	<u>\$ 633.1</u>	<u>\$ 1,043.6</u>	<u>\$ 394.7</u>	<u>\$ 654.6</u>	<u>\$ 1,049.3</u>	<u>\$ 482.6</u>	<u>\$ 634.9</u>	<u>\$ 1,117.5</u>

⁽¹⁾ Bioservices Services revenues for the year ended December 31, 2024 include \$50.0 million attributable to the Settlement Agreement with Janssen related to the 2022 termination of the Janssen Agreement. The revenue is related to raw materials purchased for the Janssen Agreement which Janssen had not reimbursed. See Note 19, “Litigation” for additional information related to the accounting treatment and settlement of the arbitration with Janssen.

For the years ended December 31, 2024, 2023 and 2022, 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,		
	2024	2023	2022
% of product sales:			
Commercial Products:			
NARCAN [®]	44 %	51 %	39 %
Other Commercial products	— %	1 %	1 %
MCM Products:			
Anthrax MCM	15 %	20 %	30 %
Smallpox MCM	31 %	18 %	24 %
Other Products	10 %	10 %	6 %

For the years ended December 31, 2024 and 2023, 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, USG for 43% and the second customer for 10% of total revenues, both primarily attributable to the MCM Products segment. For the years ended December 31, 2024, 2023, and 2022, the Company’s revenues from customers within the United States comprised 79%, 58% and 79%, respectively, of total revenues.

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 2.1 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, 2024, the Company’s non-USG lease revenues were \$1.4 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 \$2.2 million in 2025, \$2.3 million in 2026, \$0.9 million in 2027, \$0.9 million in 2028, no lease revenue in 2029 and no lease revenue in 2030 and beyond.

Transaction price allocated to remaining performance obligations

As of December 31, 2024, the Company has future contract value on unsatisfied performance obligations of approximately \$393.2 million associated with all arrangements entered into by the Company. The Company expects to recognize \$348.2 million of unsatisfied performance obligations within the next 24 months. The amount and timing of revenue recognition for unsatisfied performance obligations can change. The future revenues associated with unsatisfied performance obligations exclude the value of unexercised option periods in the Company's revenue arrangements. Often the timing of manufacturing activities changes based on customer needs and resource availability. Government funding appropriations can impact the timing of product deliveries. The success of the Company's development activities that receive development funding support from the USG under development contracts can also impact the timing of revenue recognition.

Contract assets

The Company considers accounts receivable and deferred costs associated with revenue generating contracts, which are not included in inventory or property, plant and equipment and the Company does not currently have a contractual right to bill, to be contract assets. As of December 31, 2024 and December 31, 2023, the Company had \$9.7 million and \$21.9 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, 2023	\$	29.9
Balance at December 31, 2024	\$	9.3
Revenue recognized in the period from amounts included in contract liability at the beginning of the period:	\$	26.2

As of December 31, 2024 and 2023, the current portion of contract liabilities was \$4.8 million and \$27.2 million, respectively, and was included in "Other current liabilities" on the Consolidated Balance Sheet.

Accounts receivable and allowance for expected credit losses

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

	December 31,	
	2024	2023
Accounts receivable:		
Billed	\$ 135.4	\$ 141.8
Unbilled	19.6	51.4
Allowance for expected credit losses	(0.5)	(2.2)
Accounts receivable, net	\$ 154.5	\$ 191.0

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. 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. The Company's provisions for expected credit losses for the years ended December 31, 2024, 2023 and 2022 were \$5.3 million, \$2.1 million and \$0.3 million, respectively.

14. Leases

The Company is the lessee for operating leases for offices, R&D facilities and manufacturing facilities. The Company determines if an arrangement is a lease at inception. Operating leases are included in right-of-use 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,		
	2024	2023	2022
Operating lease cost:			
Amortization of right-of-use assets	\$ 3.2	\$ 4.0	\$ 5.6
Interest on lease liabilities	0.8	0.8	1.1
Total operating lease cost	\$ 4.0	\$ 4.8	\$ 6.7

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 "SG&A" expense on the Company's Consolidated Statements of Operations.

Supplemental balance sheet information related to leases was as follows:

Leases	Classification	December 31,	
		2024	2023
Operating lease right-of-use assets	Other assets	\$ 11.7	\$ 16.2
Operating lease liabilities, current portion	Other current liabilities	\$ 2.7	\$ 3.5
Operating lease liabilities	Other liabilities	9.7	13.8
Total operating lease liabilities		\$ 12.4	\$ 17.3

Operating leases:

Weighted average remaining lease term (years)	5.8	6.2
Weighted average discount rate	5.5 %	5.3 %

The maturity analysis below summarizes future undiscounted cash flows for our operating leases as of December 31, 2024:

Year	As of December 31, 2024
2025	\$ 3.6
2026	2.8
2027	2.2
2028	1.8
2029	1.8
Thereafter	3.1
Total undiscounted lease liabilities	15.3
Less: Imputed interest	2.9
Total lease liabilities	\$ 12.4

15. Income taxes

The Company uses the asset/liability method of accounting for income taxes. Under this method, deferred tax assets/liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets/liabilities and their respective tax basis. Deferred tax assets/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 not more likely than not 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, 2024, the Company reassessed the valuation allowance and considered negative evidence, including its significant losses in the current year and prior years, 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 \$80.2 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 amounts of GILTI in its consolidated financial statements for the years ended December 31, 2024, 2023 and 2022.

For the year ended December 31, 2024, the Company has re-evaluated its historical indefinite reinvestment assertion and determined it remains appropriate to record a deferred withholding tax liability for only the undistributed earnings of a certain subsidiary. 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 \$1.2 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,		
	2024	2023	2022
Current			
Federal	\$ 4.4	\$ (0.6)	\$ (9.4)
State	1.4	0.5	1.9
International	47.4	36.7	33.8
Total current	<u>53.2</u>	<u>36.6</u>	<u>26.3</u>
Deferred			
Federal	(4.4)	(2.0)	(37.7)
State	—	(1.2)	(3.2)
International	(1.1)	(4.1)	7.2
Total deferred	<u>(5.5)</u>	<u>(7.3)</u>	<u>(33.7)</u>
Income tax (benefit) provision	<u>\$ 47.7</u>	<u>\$ 29.3</u>	<u>\$ (7.4)</u>

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

	December 31,	
	2024	2023
Deferred tax assets		
Federal losses carryforward	\$ 108.7	\$ 58.7
State losses carryforward	67.1	38.9
R&D carryforward	22.6	21.9
Stock compensation	4.6	6.8
Foreign losses carryforward	14.4	13.9
Inventory reserves	10.1	12.6
Lease liability	3.3	4.3
IRC 263A capitalized costs	1.3	2.8
Capitalized R&D	38.2	35.3
IRC 163(j) Interest Limitation	44.6	26.2
Fixed assets	14.2	26.7
Intangible assets	13.4	13.8
Accrued compensation	0.3	2.8
Other	3.4	4.8
Gross deferred tax assets	346.2	269.5
Valuation allowance	(339.0)	(257.8)
Total deferred tax assets	7.2	11.7
Deferred tax liabilities		
Fixed assets	(1.8)	(2.6)
Intangible assets	(38.1)	(40.4)
Right-of-use asset	(3.1)	(4.0)
Foreign Withholding Tax	(1.2)	(5.5)
Prepaid expenses	(4.1)	(4.2)
Other	(0.6)	(2.2)
Total deferred tax liabilities	(48.9)	(58.9)
Net deferred tax liabilities	\$ (41.7)	\$ (47.2)

As of December 31, 2024, the Company has approximately \$517.6 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 \$481.6 million which will carryforward indefinitely, although, limited to eighty percent of taxable income annually. The Company has U.S. federal R&D tax credit carryforwards of \$17.6 million which will expire in 2027 through 2042.

As of December 31, 2024, the Company had post-apportionment state NOLs totaling approximately \$1.2 billion 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 \$57.7 million in net operating losses from foreign jurisdictions as of December 31, 2024, which will carryforward indefinitely.

The Company's valuation allowance increased by \$80.2 million due to the Company's generation of significant losses in 2024.

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,		
	2024	2023	2022
U.S.	\$ (355.5)	\$ (805.1)	\$ (442.6)
International	212.6	73.9	224.0
Loss before income taxes	<u>(142.9)</u>	<u>(731.2)</u>	<u>(218.6)</u>
Federal tax at statutory rates	\$ (30.0)	\$ (153.6)	\$ (46.0)
State taxes, net of federal benefit	(28.6)	(52.7)	(13.5)
Impact of foreign operations	1.5	(8.5)	(7.2)
Change in valuation allowance	80.2	193.6	37.8
Tax credits	(0.2)	(0.9)	(3.5)
Pillar Two tax	6.8	—	—
Stock compensation	4.1	6.8	4.7
Goodwill Impairments	—	23.3	1.8
Adjustment of prior year taxes	0.4	1.3	(1.8)
Compensation limitation	1.7	0.3	0.7
Unrecognized tax benefit	(3.5)	(0.6)	(9.0)
Impact of divestitures	(3.9)	1.0	—
GILTI, net	15.8	17.8	20.7
Foreign withholding tax	3.5	0.8	4.7
Permanent differences	(0.1)	0.7	3.2
Income tax (benefit) provision	<u>\$ 47.7</u>	<u>\$ 29.3</u>	<u>\$ (7.4)</u>

The effective annual tax rate for the years ended December 31, 2024, 2023, and 2022 was (33)%, (4)% and 3%, respectively.

The effective annual tax rate of (33)% in 2024 is significantly different than the statutory rate primarily due to the impact of reduced U.S. losses, valuation allowance charge in the U.S., jurisdictional mix of income, GILTI, and other permanent differences.

The effective annual tax rate of (4)% in 2023 is significantly different 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 significantly different 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 total unrecognized tax benefits recorded at December 31, 2024 and 2023 of \$1.7 million and \$6.6 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, 2024, 2023 and 2022:

	Year Ended December 31,		
	2024	2023	2022
Gross unrecognized tax benefits, beginning of period	\$ 6.6	\$ 6.8	\$ 12.7
Increases (decreases) for tax positions for prior years	—	0.4	(1.5)
Increases for tax positions for current year	—	0.1	0.7
Settlements	(2.3)	—	—
Lapse of statute of limitations	(2.6)	(0.7)	(5.1)
Gross unrecognized tax benefits, end of period	<u>\$ 1.7</u>	<u>\$ 6.6</u>	<u>\$ 6.8</u>

The current year change includes the reversal of a \$2.6 million liability due to a lapse of the statute of limitations during the year as well as partial cash payment of \$2.3 million.

The Company includes interest and potential penalties related to unrecognized tax benefits in income tax expense. As of December 31, 2024 and 2023, the total amount of interest and penalties accrued was \$0.8 million and \$1.6 million, respectively. The Company recognized interest and penalty expense (benefit) in 2024, 2023 and 2022 of \$(0.8) million, \$0.2 million and \$(2.1) 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, 2024 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 2021 and onwards remain open to examination. The Company's tax returns for Canada remain open to examination for the tax years 2016 and onward. The Company's Irish tax returns remain open to examination for the tax years 2018 and onward.

As of December 31, 2024, 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. In addition, the Company's 2021 Texas Franchise tax returns and 2022 Quebec Income tax returns are under audit.

16. Defined benefit and 401(k) savings plan

Defined benefit pension plan

Prior to 2024, the Company 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, and the sale is described further in Note 3, “Divestitures”. 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 were required 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 no pension expense related to the Swiss Plan for the year ended December 31, 2024. The Company recognized pension expense related to the Swiss Plan of \$0.6 million and \$0.8 million, reflected as a component of selling, general and administrative expenses, for the years ended December 31, 2023 and 2022, respectively.

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

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

⁽¹⁾ The Swiss Plan was sold as part of our travel health business to Bavarian Nordic, as described further in Note 3, “Divestitures”.

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, 2024, 2023 and 2022, the Company made matching contributions of approximately \$5.7 million, \$8.3 million and \$8.8 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, 2024, the Company has approximately \$632.4 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 \$195.6 million will be purchased within the next year. For the years ended December 31, 2024, 2023, and 2022, the Company purchased \$96.1 million, \$107.8 million and \$199.6 million, respectively, of materials and services under these commitments.

18. Segment information

The Company manages its business with a focus on three reportable segments. The Commercial Product segment, which includes NARCAN[®] products and other commercial products that were sold as part of the travel health business in the second quarter of 2023 (see Note 3, "Divestitures" for more information on the sale of the travel health business); the MCM Products segment, which includes the Anthrax - MCM products, Smallpox - MCM products and Other Products; and the Services segment, consisting of the Company's Bioservices offerings.

The Company's CODM is its President, Chief Executive Officer and Director. The CODM evaluates the performance of the Company's reportable segments based on segment adjusted gross margin. The Company defines segment adjusted gross margin as sales less cost of sales excluding restructuring costs, changes in fair value of financial instruments, settlement charges, net and inventory step-up provision for each reportable segment. The Company does not allocate amortization of intangible assets, research and development expenses, selling, general and administrative costs, interest and other income (expense) or taxes to each reportable segment in the operating results that are regularly reviewed by the CODM. The CODM uses these reported measures to assess segment performance, allocate resources and monitor budget and guidance versus actual results. These metrics are used by the CODM to make key operating decisions, such as decisions about allocating capital and other resources to each segment. The accounting policies for segment reporting are the same as those described in Note 2, "Summary of significant accounting policies". Intersegment revenue, cost of sales, and profit are eliminated in the segment measures regularly reviewed by the CODM as these activities are eliminated in consolidation and thus are not included in management's evaluation of performance for each segment.

The Company manages its assets on a total company basis, not by segment, as the Company's assets are shared or commingled. Therefore, the Company's CODM does not regularly review any asset information by segment and, accordingly, the Company does not report asset information by segment. The measure of segment assets is reported on the Consolidated Balance Sheet as "Total assets".

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 information provided to the CODM, along with a reconciliation of segment adjusted gross margin to loss before income taxes as reported in the Consolidated Statement of Operation for the years ended December 31, 2024, 2023, and 2022:

	Year Ended December 31,		
	2024	2023	2022
Revenues:			
Commercial Product sales	\$ 398.9	\$ 497.3	\$ 386.6
MCM Product sales	509.8	447.2	579.6
Services	104.9	78.5	109.9
Reconciliation of revenue:			
Contracts and grants revenue	30.0	26.3	41.4
Total consolidated revenues	\$ 1,043.6	\$ 1,049.3	\$ 1,117.5
Less:			
Cost of Commercial Product sales	\$ 185.9	\$ 210.3	\$ 160.3
Cost of MCM Product sales ⁽¹⁾	205.4	295.9	210.3
Cost of Services ⁽²⁾	165.6	181.1	268.5
Segment adjusted gross margin			
Commercial Product	\$ 213.0	\$ 287.0	\$ 226.3
MCM Products	304.4	151.3	369.3
Services	(60.7)	(102.6)	(158.6)
Total segment adjusted gross margin	\$ 456.7	\$ 335.7	\$ 437.0
Reconciliation to loss before income tax:			
Contracts and grants revenue	\$ 30.0	\$ 26.3	\$ 41.4
Amortization of intangible assets	(65.1)	(65.6)	(59.9)
Restructuring costs	(7.4)	(14.0)	—
Inventory step-up provision	(6.2)	(3.9)	(51.4)
Changes in fair value of financial instruments	(0.6)	(0.2)	(2.6)
Settlement charge, net	(110.2)	—	—
Goodwill impairment	—	(218.2)	(6.7)
Impairment of long-lived assets	(27.2)	(306.7)	—
Research and development	(70.7)	(111.4)	(188.3)
Selling, general and administrative	(308.0)	(368.4)	(339.5)
Interest expense	(71.0)	(87.9)	(37.3)
Gain on sale of business	24.3	74.2	—
Other, net	12.5	8.9	(11.7)
Loss before income taxes	\$ (142.9)	\$ (731.2)	\$ (219.0)

⁽¹⁾ Excludes \$0.6 million, \$0.2 million and \$2.6 million of changes in fair value of financial instruments, \$7.2 million, \$5.6 million, and no restructuring costs, and \$6.2 million, \$3.9 million and \$51.4 million of inventory step-up provision during the years ended December 31, 2024, 2023, and 2022, respectively.

⁽²⁾ Excludes \$0.2 million, \$8.4 million, and no restructuring costs during the years ended December 31, 2024, 2023, and 2022, respectively, and \$110.2 million settlement charge, net during the year ended December 31, 2024.

The following table includes depreciation expense for each reportable segment:

	Year Ended December 31,		
	2024	2023	2022
Depreciation:			
Commercial Products	\$ —	\$ 0.3	\$ 3.2
MCM Products	20.3	22.8	29.7
Services	9.9	22.5	43.2
Other	13.5	13.9	7.3
Total	\$ 43.7	\$ 59.5	\$ 83.4

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

	Year Ended December 31,		
	2024	2023	2022
Revenue:			
United States	\$ 822.6	\$ 607.2	\$ 886.1
Canada	140.4	224.2	148.6
Other	80.6	217.9	82.8
Total revenues	\$ 1,043.6	\$ 1,049.3	\$ 1,117.5

The following table includes 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,	
	2024	2023
Long-lived assets, net:		
United States	\$ 238.0	\$ 352.3
Canada	34.5	37.2
Other	2.7	2.9
Total Long-lived assets, net	\$ 275.2	\$ 392.4

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 Exchange Act. 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. An order granting the Lead Plaintiff's motion for class certification and appointment of class representatives was entered on June 18, 2024.

On September 12, 2024, the Company and the Lead Plaintiffs entered into an agreement in principle to settle the claims against the Company and each of the Company's current and former officers and directors. On October 4, 2024, the Court granted preliminary approval of the proposed settlement, ordered notice to the settlement class and scheduled a final fairness hearing for February 27, 2025. On February 6, 2025, the Lead Plaintiffs filed a Motion for Final Approval of Class Action Settlement, Certification of the Settlement Class and Approval of Plan of Allocation and Motion for Award of Attorneys' Fees, Reimbursement of Expenses and Compensatory Awards for Lead Plaintiffs. Under the proposed settlement, the claims against the Company and its officers and

directors will be dismissed with prejudice and released in exchange for a payment from the Company of \$40.0 million, \$30.0 million of which was paid from insurance proceeds, and was funded in the fourth quarter of 2024. At the scheduled fairness hearing on February 27, 2025, the Court granted final approval of the settlement. The Company recorded the settlement and insurance recoverable amounts as pre-tax operating expense and income, respectively, within "Selling, general and administrative" expenses on the Consolidated Statement of Operations for the year ended December 31, 2024.

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 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 documents as required in response and will continue to cooperate with these government inquiries should further requests be made. 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 and the Select Subcommittee released its final report related to the coronavirus crisis on December 9, 2022.

SEC Enforcement Proceeding

As previously disclosed, in the second quarter of 2021, the Company received subpoenas from the SEC related to certain disclosures regarding the incidents described above under the heading "Securities Litigation." The Company has been cooperating with the SEC's investigation. During the first quarter of 2025, the Company determined that a loss resulting from the investigation was probable and that the amount of loss could be reasonably estimated. As a result, the Company recorded an accrual within "Selling, general and administrative" expenses in the Consolidated Statement of Operations for the year ended December 31, 2024 of \$1.5 million, and the related liability is included in "Other current liabilities" in our Consolidated Balance Sheet as of December 31, 2024.

2022 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, 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. 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 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. On June 14, 2022, Janssen filed a Demand for Arbitration and on July 29, 2022 the Company filed its Answering Statement and counterclaims. On July 3, 2024, the Company and Janssen entered into the Settlement Agreement to resolve all claims among the parties arising from the Janssen Agreement and the activities referenced above. Pursuant to the terms of the Settlement Agreement, Janssen paid the Company \$50.0 million on July 31, 2024.

Beginning in the fourth quarter of 2022, because the arbitration process with Janssen was 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" prior to announcing the Settlement Agreement was \$158.7 million. The Company recorded \$50.0 million in "Services revenue" and "Cost of Services" on the Consolidated Statement of Operations during the year ended December 31, 2024 to reflect the settlement receivable as a change in the transaction price for the Janssen Agreement. Additionally, the Company recorded \$110.2 million for the year ended December 31, 2024 within "Cost of Services" on the Consolidated Statement of Operations to write down the remaining inventory to its net realizable value and for estimated disposal costs. The receivable for the settlement amount was collected during the third quarter of 2024 and there was no long-term asset balance remaining within "Other Assets" related to the Janssen Agreement as of December 31, 2024.

20. Subsequent events

Development milestone payments for CHIKV VLP

On February 14, 2025, Bavarian Nordic announced that the FDA approved CHIKV VLP under the Priority Review, which triggered a development milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$30.0 million. On February 28, 2025, Bavarian Nordic announced that the European Commission approved CHIKV VLP, which triggered a development milestone payment receivable under the Purchase and Sale Agreement to the Company in the amount of \$20.0 million. Both payments are expected to be received in the first half of 2025.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. 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, 2024, our 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, 2024. 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, 2024, 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, 2024, a copy of which is included in this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There have been no changes in 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, 2024 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, 2024, 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, 2024, 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, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes and financial statement schedule listed in the Index at Item 15 and our report dated March 3, 2025, expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

Tysons, Virginia

March 3, 2025

ITEM 9B. OTHER INFORMATION

During the three months ended December 31, 2024, directors and officers (as defined in Exchange Act Rule 16a-1(f)) of the Company adopted written plans for the sale of the Company's common stock intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5-1(c) ("Rule 10b5-1 trading arrangements") as set forth in the table below.

Name	Position	Action	Adoption date	Rule 10b5-1 Trading Plan Provides for Purchase/Sale ⁽¹⁾	Total Shares of Common Stock to be Sold	Expiration Date ⁽²⁾
Keith Katkin	Director	Adoption	November 8, 2024	Sale	7,844	November 8, 2025
Coleen Glessner	Chief Quality and Compliance Officer	Adoption	December 2, 2024	Sale	30,608	December 31, 2025

⁽¹⁾ Sales may begin on the third business day following the filing of this Annual Report on 10-K.

⁽²⁾ Subject to early termination in accordance with the terms of the Rule 10b5-1 trading arrangements.

Each of the above-named directors and officers is currently and is expected to remain in compliance with his or her share ownership guidelines following the sale of any common shares pursuant to his or her Rule 10b5-1 trading arrangement.

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

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Code of Ethics

We have adopted a code of business conduct and ethics that applies to our directors, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), as well as our other employees. A copy of our code of business conduct and ethics is available on our website at www.emergentbiosolutions.com. We intend to post on our website all disclosures that are required by applicable law, the rules of the SEC or the New York Stock Exchange concerning any amendment to, or waiver of, our code of business conduct and ethics. The reference to our website is intended to be an inactive textual reference only. Neither the information on 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 2025 Annual Meeting of Stockholders, which we expect to file 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 2025 Annual Meeting of Stockholders, which we expect to file 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 2025 Annual Meeting of Stockholders, which we expect to file 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 2025 Annual Meeting of Stockholders, which we expect to file 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 2025 Annual Meeting of Stockholders, which we expect to file 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, 2024 and 2023
- Consolidated Statements of Operations for the years ended December 31, 2024, 2023 and 2022
- Consolidated Statements of Comprehensive Loss for the years ended December 31, 2024, 2023 and 2022
- Consolidated Statements of Cash Flows for the years ended December 31, 2024, 2023 and 2022
- Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2024, 2023 and 2022
- Notes to Consolidated Financial Statements

Financial Statement Schedules

Schedule II - Valuation and Qualifying Accounts for the years ended December 31, 2024, 2023 and 2022 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
Year Ended December 31, 2024				
Prepaid expenses and other current assets allowance	\$ 7.5	0.7	(1.0)	\$ 7.2
Year Ended December 31, 2023				
Prepaid expenses and other current assets allowance	\$ 7.1	0.8	(0.4)	\$ 7.5
Year Ended December 31, 2022				
Prepaid expenses and other current assets allowance	\$ 3.7	3.9	(0.5)	\$ 7.1

Exhibit Index

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

Exhibit Number	Exhibit Description
3.1	Third Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3 to the Company's Quarterly Report on Form 10-Q filed on August 5, 2016).
3.2	Amended and Restated By-laws of the Company (incorporated by reference to Exhibit 3 to the Company's Current Report on Form 8-K filed on August 16, 2012).
4.1	# Description of the Company's Securities.
4.2	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 3 to the Company's Registration Statement on Form S-1 filed on October 20, 2006) (Registration No. 333-136622).
4.3	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).
4.4	First Supplemental Indenture, dated as of August 30, 2024, by and among Emergent BioSolutions Inc., the subsidiary guarantors party thereto and U.S. Bank Trust Company, National Association, as trustee (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed on September 3, 2024).
4.5	Form of 3.875% Senior Unsecured Note due 2028 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed on August 7, 2020.) (incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
4.6	Form of Warrant (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on September 3, 2024).
10.1	Equity Distribution Agreement, dated May 17, 2023 (incorporated by reference to Exhibit 10.2 to the 8-K filed on May 18, 2023).
10.2	†† Credit Agreement, dated as of August 30, 2024, by and among Emergent BioSolutions Inc., the lenders from time to time party thereto and OHA Agency LLC, as administrative agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on September 3, 2024).
10.3	††# Credit Agreement, dated as of September 30, 2024, by and among Emergent BioSolutions Inc., certain of its subsidiaries, as borrowers, the lenders party thereto from time to time, and Wells Fargo Bank, National Association, as the agent.
10.4	Form of Subscription Agreement, dated August 30, 2024, between Emergent BioSolutions Inc. and the Subscribing Entities (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed on September 3, 2024).
10.5	Warrant Agreement between Emergent BioSolutions Inc. and Broadridge Corporate Issuer Solutions LLC, as Warrant Agent, dated August 30, 2024 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on September 3, 2024).
10.6	† Stock and Asset Purchase Agreement, dated July 31, 2024, between Emergent BioSolutions Canada Inc., a wholly owned subsidiary of the Company, and BTG International Inc., a wholly owned subsidiary of SERB Pharmaceuticals (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, filed on November 6, 2024).
10.7	* Emergent BioSolutions Inc. Amended and Restated Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on May 29, 2024).
10.8	* Emergent BioSolutions Inc. Inducement Plan (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed on December 11, 2023).
10.9	* Emergent BioSolutions Inc. Amended Employee Stock Purchase Plan (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form S-8, filed on June 5, 2023).
10.10	* Executive Agreement, dated February 19, 2024 between Emergent BioSolutions Inc. and Joseph Papa (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 21, 2024).
10.11	* Form of Letter Agreement, dated July 26, 2023 (incorporated by reference to Exhibit 99.1 to the 8-K filed on July 27, 2023).
10.12	* Form of Amendment to Letter Agreement, dated April 23, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on April 26, 2024).
10.13	* Form of Director Nonstatutory Stock Option Agreement (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K filed on February 22, 2019).

Exhibit Number	Exhibit Description
10.14	* Form of Director Restricted Stock Unit Agreement (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.15	* Global Form of Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.16	* Global Form of Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.17	††* Form of 2022-2024 Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to Current Report on Form 8-K filed on February 22, 2022).
10.18	††* Form of 2023-2025 Performance Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to Current Report on Form 8-K filed on March 23, 2023).
10.19	* Form of Indemnity Agreement for Directors and Senior Officers (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on January 18, 2013).
10.20	* Annual Bonus Plan for Executive Officers (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on March 5, 2010).
10.21	* Second Amended and Restated Senior Management Severance Plan (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on July 16, 2015).
10.22	† Solicitation/Contract/Order for Commercial Items (the CDC BioThrax Procurement Contract), effective December 8, 2016, from the Centers for Disease Control and Prevention to Emergent Biodefense Operations Lansing LLC (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K, filed on February 28, 2017).
10.23	Modification No. 1, effective January 27, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.24	† Modification No. 2, effective February 23, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.25	Modification No. 3, effective March 22, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.26	† Modification No. 4, effective April 5, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.27	† Modification No. 5, effective September 8, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 3, 2017).
10.28	† Modification No. 6, effective September 21, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.27 the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.29	† Modification No. 7, effective February 26, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 4, 2018).
10.30	Modification No. 8, effective March 6, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 4, 2018).
10.31	† Modification No. 9, effective June 6, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.32	† Modification No. 10, effective June 18, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.33	† Modification No. 11, effective June 20, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.34	† Modification No. 12, effective June 21, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.35	† Modification No. 13, effective September 21, 2018 to the CDC BioThrax Procurement (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 2, 2018).
10.36	† Modification No. 14, effective October 1, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.45 the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.37	† Modification No. 15, effective December 7, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.46 the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.38	† Modification No. 16, effective January 14, 2019, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.47 the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.39	†† Modification No. 17, effective June 13, 2019, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 2, 2019).

Exhibit Number	Exhibit Description
10.40	†† Modification No. 18, effective September 11, 2019, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.39 the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.41	†† Modification No. 19, effective January 6, 2020, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.40 the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.42	†† Modification No. 20, effective January 7, 2020, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.41 the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.43	†† Modification No. 21, effective January 7, 2020, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.45 the Company's Annual Report on Form 10-K filed on February 19, 2021)
10.44	†† Modification No. 22 to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.46 the Company's Annual Report on Form 10-K filed on February 19, 2021)
10.45	†† Modification No. 23, effective September 30, 2020, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.47 the Company's Annual Report on Form 10-K filed on February 19, 2021)
10.46	†† Modification No. 24, effective February 2, 2021, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021).
10.47	†† Modification No. 25, effective September 29, 2021, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021).
10.48	†† Modification No. 26, effective November 1, 2021, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.48 the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.49	† Modification No. 27, effective March 31, 2022, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on April 29, 2022).
10.50	† Modification No. 28, effective April 14, 2022, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 2, 2022).
10.51	† Modification No. 29, effective June 16, 2022, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 2, 2022).
10.52	Award/Contract, effective January 9, 2024 (BioThrax IDIQ Contract), from the United States Department of Defense to Emergent Biodefense Operations Lansing LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 2, 2024).
10.53	Delivery Order 1, effective January 22, 2024 to the BioThrax IDIQ Contract (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on May 2, 2024).
10.54	Modification No. 1, effective February 13, 2024 to the BioThrax IDIQ Contract (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on May 2, 2024).
10.55	Modification No. 2, effective March 21, 2024 to the BioThrax IDIQ Contract (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on May 2, 2024).
10.56	Modification No. 3, effective December 13, 2024, to the BioThrax IDIQ Contract (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 8, 2025).
10.57	† Award/Contract (the BARDA AV7909 Contract), effective September 30, 2016, from the BioMedical Advanced Research and Development Authority to Emergent Product Development Gaithersburg Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2016).
10.58	† Modification No. 1, effective March 16, 2017, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021)
10.59	† Modification No. 2, effective August 29, 2018, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021).
10.60	†† Modification No. 3, effective July 30, 2019, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2019).
10.61	†† Modification No. 4, effective March 3, 2020, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 1, 2020).
10.62	†† Modification No. 5, effective April 10, 2020, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 1, 2020).
10.63	†† Modification No. 6, effective July 13, 2020, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.64	†† Modification No. 7, effective December 2, 2020, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).

Exhibit Number	Exhibit Description
10.65	†† Modification No. 8, effective March 22, 2021, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.66	†† Modification No. 9, effective April 21, 2021, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.67	†† Modification No. 10, effective June 10, 2021 to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.68	†† Modification No. 11, effective September 30, 2021, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on November 5, 2021).
10.69	†† Modification No. 12, effective December 2, 2021, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.61 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.70	†† Modification No. 13, effective March 30, 2023, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2023).
10.71	†† Modification No. 14, effective March 30, 2023, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2023).
10.72	† Modification No. 15, effective October 6, 2023, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.80 to the Company's Annual Report on Form 10-K filed on March 8, 2024).
10.73	† Modification No. 16, effective November 21, 2023, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.81 to the Company's Annual Report on Form 10-K filed on March 8, 2024).
10.74	†† Modification No. 17, effective June 26, 2024, to the BARDA AV7909 Contract (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on July 2, 2024).
10.75	†† Modification No. 18, effective December 12, 2024, to the BARDA AV909 Contract (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 8, 2025).
10.76	†# 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.
10.77	† Amendment No. 1 to License Agreement, dated as of December 13, 2016, by and between Opiant Pharmaceuticals, Inc. and Adapt Pharma Operations Limited. (incorporated by reference to Exhibit 10.52 the Company's Annual Report on Form 10-K filed on February 22, 2019).
10.78	Amendment No. 2 to License Agreement, dated December 15, 2014, by and between Opiant Pharmaceuticals, Inc. and Adapt Pharma Operations Limited, effective March 18, 2019 (incorporated by reference to Exhibit 10.1 the Company's Quarterly Report on Form 10-Q filed on May 8, 2019).
10.79	†† Award/Contract, effective August 30, 2019 (ACAM2000 Contract), from the Assistant Secretary, U.S. Department of Health and Human Services (ASPR/OPM) to Emergent Product Development Gaithersburg Inc. (incorporated by reference to Exhibit 10.48 the Company's Annual Report on Form 10-K filed on February 25, 2020).
10.80	†† Modification No. 1, effective, May 28, 2020 to the ACAM2000 Contract (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on July 31, 2020).
10.81	†† Modification No. 2, effective, October 28, 2020 to the ACAM2000 Contract (incorporated by reference to Exhibit 10.60 the Company's Annual Report on Form 10-K filed on February 19, 2021).
10.82	†† Modification No. 3, effective, April 1, 2021 to the ACAM2000 Contract (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.83	†† Modification No. 4, effective, July 13, 2021 to the ACAM2000 Contract (incorporated by reference to Exhibit 10.69 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.84	†† Modification No. 5, effective, September 29, 2021 to the ACAM2000 Contract (incorporated by reference to Exhibit 10.70 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.85	†† Modification No. 6, effective, November 1, 2021 to the ACAM2000 Contract (incorporated by reference to Exhibit 10.71 to the Company's Annual Report on Form 10-K filed on February 25, 2022).
10.86	†† Modification No. 7, effective October 6, 2022, to the ACAM2000 Contract (incorporated by reference to Exhibit 10.92 to the Company's Annual Report on Form 10-K filed on March 8, 2024).
10.87	† Modification No. 8, effective November 21, 2022, to the ACAM2000 Contract (incorporated by reference to Exhibit 10.93 to the Company's Annual Report on Form 10-K filed on March 8, 2024).
10.88	† Modification No. 9, effective May 24, 2023, to the ACAM2000 Contract (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2023).
10.89	† Modification No. 10, effective May 26, 2023, to the ACAM2000 Contract (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2023).
10.90	†† Modification No. 11, effective April 29, 2024, to the ACAM2000 Contract (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on May 1, 2024).
10.91	†† Modification No. 12, effective June 28, 2024, to the ACAM2000 Contract (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on July 2, 2024).

Exhibit Number	Exhibit Description
10.92	†† Work Order to Manufacturing Services Agreement, dated June 10, 2020, between Emergent Manufacturing Operations Baltimore, LLC and AstraZeneca Pharmaceuticals LP (included as part of AZ MSA) (incorporated by reference to Exhibit 10.14 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.93	†† Amendment No. 1, effective September 30, 2020, to AZ MSA (incorporated by reference to Exhibit 10.15 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2020).
10.94	†† Amendment No. 2, effective October 30, 2020, to AZ MSA (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.95	†† Amendment No. 3, effective November 25, 2020, to AZ MSA (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.96	†† Amendment No. 4, effective January 21, 2021, to AZ MSA (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on April 30, 2021).
10.97	†† Change Order No. 1 to Work Order #5997-01, effective July 31, 2020, to AZ MSA (incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.98	†† Change Order No. 2 to Work Order #5997-01, effective August 04, 2020, to AZ MSA (incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.99	†† Change Order No. 4 to Work Order #5997-01, effective November 17, 2020, to AZ MSA (incorporated by reference to Exhibit 10.13 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.100	†† Change Order No. 5 to Work Order #5997-01, effective September 16, 2020, to AZ MSA (incorporated by reference to Exhibit 10.14 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.101	†† Change Order No. 6 to Work Order #5997-01, effective October 13, 2020, to AZ MSA (incorporated by reference to Exhibit 10.15 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.102	†† Change Order No. 10 to Work Order #5997-01, effective March 10, 2021, to AZ MSA (incorporated by reference to Exhibit 10.16 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
10.103	†† Change Order No. 13 to Work Order #5997-01, effective April 23, 2021, to AZ MSA (incorporated by reference to Exhibit 10.17 to the Company's Quarterly Report on Form 10-Q filed on July 30, 2021).
19	# Insider Trading Policy.
21	# Subsidiaries of the Company.
23	# Consent of Independent Registered Public Accounting Firm.
31.1	# Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).
31.2	# Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).
32.1	# Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	# Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Emergent BioSolutions Compensation Recovery Policy, effective October 26, 2023 (incorporated by reference to Exhibit 10.224 to the Company's Annual Report on Form 10-K filed on March 8, 2024).
101	# The following financial information related to the Company's Annual Report on Form 10-K for the year ended December 31, 2024, 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 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.
104	# Cover Page Interactive Data File, formatted in iXBRL and contained in Exhibit 101.
	# Filed herewith
	† Confidential treatment granted by the SEC as to certain portions. Confidential materials omitted and filed separately with the SEC.
	†† Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.
	* Management contract or compensatory plan or arrangement filed herewith in response to Item 15(a) of Form 10-K.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

By: /s/RICHARD S. LINDAHL

Richard S. Lindahl

Executive Vice President, Chief Financial Officer and
Treasurer

Date: March 3, 2025

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 3, 2025
<u>/s/Richard S. Lindahl</u> Richard S. Lindahl	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 3, 2025
<u>/s/Zsolt Harsanyi, Ph.D.</u> Zsolt Harsanyi, Ph.D.	Director	March 3, 2025
<u>/s/Sujata Dayal</u> Sujata Dayal	Director	March 3, 2025
<u>/s/Donald DeGolyer</u> Donald DeGolyer	Director	March 3, 2025
<u>/s/Neal Fowler</u> Neal Fowler	Director	March 3, 2025
<u>/s/Keith Katkin</u> Keith Katkin	Director	March 3, 2025
<u>/s/Ronald B. Richard</u> Ronald B. Richard	Director	March 3, 2025
<u>/s/Louis W. Sullivan, M.D.</u> Louis W. Sullivan, M.D.	Director	March 3, 2025
<u>/s/Marvin White</u> Marvin White	Director	March 3, 2025
<u>/s/Kathryn Zoon, Ph.D.</u> Kathryn Zoon, Ph.D.	Director	March 3, 2025

BOARD OF DIRECTORS

Zsolt Harsanyi, Ph.D.

Independent Director, Chairman of the Board
Former Chief Executive Officer and Chairman of the Board, Exponential Biotherapies Inc.

- Audit and Finance Committee Member
- Quality, Compliance, Manufacturing and Risk Management Committee Member
- Scientific Review Committee Member

Sujata Dayal

Independent Director
Former Vice President and Global Chief Compliance Officer, Medline Industries, Inc.

- Chair, Quality, Compliance, Manufacturing and Risk Management Committee
- Special Transactions Committee Member

Donald DeGolyer

Independent Director
Founder, and Former Chief Executive Officer and Director of Vertice Pharma (a Warburg Pincus company)

- Compensation Committee Member
- Special Transactions Committee Member

Neal Fowler

Independent Director
Chief Executive Officer of Pathalys Pharma, Inc.

- Audit and Finance Committee Member
- Scientific Review Committee Member

Keith Katkin

Independent Director
Former Chief Executive Officer, Urovant Sciences Ltd.

- Chair, Special Transactions Committee
- Compensation Committee Member
- Nominating and Corporate Governance Committee Member

Ronald B. Richard

Independent Director
Former President and Chief Executive Officer, The Cleveland Foundation

- Chair, Nominating and Corporate Governance Committee
- Compensation Committee Member

Louis W. Sullivan, M.D.

Independent Director
President Emeritus, Morehouse School of Medicine; Former Secretary, Department of Health and Human Services

- Chair, Compensation Committee
- Nominating and Corporate Governance Committee Member

Marvin White

Independent Director
President and Chief Executive Officer, Aptevo Therapeutics Inc.

- Chair, Audit and Finance Committee
- Scientific Review Committee Member
- Special Transactions Committee Member

Kathryn C. Zoon, Ph.D.

Independent Director
Scientist Emeritus, National Institute of Allergy and Infectious Diseases at the National Institutes of Health

- Chair, Scientific Review Committee
- Nominating and Corporate Governance Committee Member
- Quality, Compliance, Manufacturing and Risk Management Committee Member

**All titles are as of 3/21/2025*

EXECUTIVE OFFICERS

Joseph Papa

President, CEO and Director

Richard Lindahl

Executive Vice President, Chief Financial Officer and Treasurer

Coleen Glessner

Executive Vice President, Quality and Ethics and Compliance

Paul Williams

Senior Vice President, Products Business

William Hartzel

Senior Vice President, Manufacturing and Bioservices

Jessica Perl

Senior Vice President, General Counsel and Corporate Secretary

Simon Lowry

Senior Vice President, Chief Medical Officer, Head of Research and Development

Stephanie Duatschek

Senior Vice President and Chief Strategy and Transformation Officer

Michelle Pepin

Senior Vice President and Chief Human Resources Officer

CORPORATE HEADQUARTERS

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

Additional copies of the company's Form 10-K for the year ended December 31, 2024 of the exhibits thereto, are available without charge upon written request to Investor Relations, Emergent BioSolutions Inc., 300 Professional Drive, Gaithersburg, MD 20879, or by calling (240) 631-3200, or accessing the company's website at www.emergentbiosolutions.com.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young LLP, McLean, VA, United States

STOCK TRANSFER AGENT AND REGISTRAR

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

Broadridge Corporate Issuer Solutions, Inc.

P.O. Box 1342
Brentwood, NY 11717
1-877-830-4936 or 1-720-378-5591
Shareholder@broadridge.com

INVESTOR RELATIONS

Richard Lindahl
Executive Vice President, Chief Financial Officer
(240) 631-3360
Lindahlr@ebis.com

MARKET INFORMATION

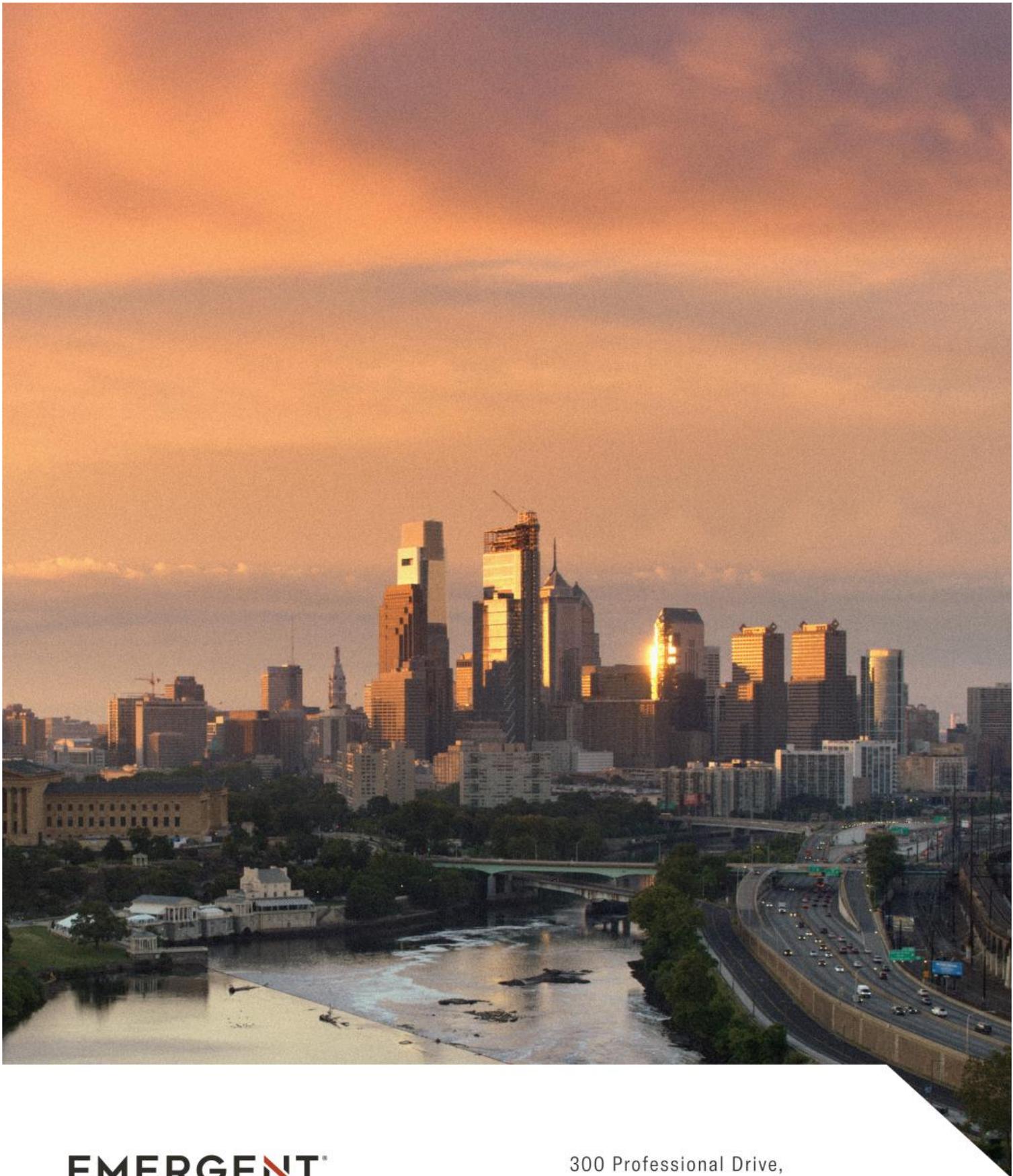
Emergent BioSolutions Inc.'s common stock trades on the New York Stock Exchange under the trading symbol "EBS."

ANNUAL MEETING

The annual meeting of Emergent BioSolutions Inc. will be held in virtual format via live audio webcast on April 30, 2025 at 9:00 a.m. Eastern Time. Stockholders can attend the meeting online at www.virtualshareholdermeeting.com/EBS2025

CORPORATE GOVERNANCE

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



EMERGENT

300 Professional Drive,
Gaithersburg, Maryland 20879 USA

emergentbiosolutions.com

