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

FORM 10-Q

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

For the quarterly period ended June 30, 2023

OR

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

For the transition period from to

Commission file number: **001-33137**

EMERGENT

EMERGENT BIOSOLUTIONS INC.

(Exact Name of Registrant as Specified in Its Charter)

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

400 Professional Drive Suite 400

Gaithersburg, MD 20879

(Address and zip code of Principal Executive Offices)

(240) 631-3200

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Trading Symbol*	*Name of each exchange on which registered*
Common Stock, par Value $0.001 per share	**EBS**	**New York Stock Exchange**

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 to 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," "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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 1, 2023, the registrant had 51,807,027 shares of common stock outstanding.

Emergent BioSolutions Inc. and Subsidiaries
Form 10-Q
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PART I. FINANCIAL INFORMATION

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes 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 our future performance, business strategy, operations, financial position, revenues and earnings, projected costs, prospects, plans and objectives of management are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "predict," "should," "will," "would," and similar expressions or variations thereof, the negative thereof, but these terms are not the exclusive means of identifying such statements. Forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. You should realize that if underlying assumptions prove inaccurate or if known or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. You are therefore cautioned not to place undue reliance on any forward-looking statement contained herein. Any forward-looking statement speaks only as of the date on which such statement is made and, except as required by law, we do not undertake any obligation to update any forward-looking statement to reflect new information, events or circumstances.

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

- the availability of U.S. Government ("USG") funding for contracts related to procurement of our medical countermeasures, including CYFENDUS™ (Anthrax Vaccine Adsorbed (AVA), Adjuvanted), previously known as AV7909, BioThrax® (Anthrax Vaccine Adsorbed) and ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) among others, as well as contracts related to development of medical countermeasures;
- our ability to meet our commitments to quality and compliance in all of our manufacturing operations;
- our ability to negotiate additional USG procurement or follow-on contracts for our medical countermeasures ("MCM") products that have expired or will be expiring;
- the commercial availability, including the timing of availability, of over-the-counter NARCAN® (naloxone HCl) Nasal Spray;
- the impact of a generic marketplace on NARCAN® (naloxone HCl) Nasal Spray and future NARCAN sales;
- our ability to perform under our contracts with the USG, including the timing of and specifications relating to deliveries;
- our ability to provide contract development and manufacturing ("CDMO") services for the development and/or manufacture of product and/or product candidates of our customers at required levels and on required timelines;
- the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices and other regulatory obligations;
- our ability to negotiate new CDMO contracts and the negotiation of further commitments related to the collaboration and deployment of capacity toward future commercial manufacturing under our existing CDMO contracts;
- our ability to collect reimbursement for raw materials and payment of service fees from our CDMO customers;
- the results of pending stockholder litigation and government investigations and their potential impact on our business;
- our ability to comply with the operating and financial covenants required by our revolving credit facility (the "Revolving Credit Facility") and our term loan facility (the "Term Loan Facility" and, together with the Revolving Credit Facility, the "Senior Secured Credit Facilities"), as well as our 3.875% Senior Unsecured Notes due 2028 ("Senior Unsecured Notes");
- our ability to resolve the going concern qualification in our consolidated financial statements and otherwise successfully manage our liquidity in order to continue as a going concern;
- the procurement of our product candidates by USG entities under regulatory authorities that permit government procurement of certain medical products prior to United States Food and Drug Administration (“FDA”) marketing authorization, and corresponding procurement by government entities outside of the U.S.;
- our ability to realize the expected benefits of the sale of our travel health business to Bavarian Nordic;
- the impact of the organizational changes we announced in January 2023;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;

- the impact of cyber security incidents, including the risks from the interruption, failure or compromise of our information systems or those of our business partners, collaborators or other third parties;
- the success of our commercialization, marketing and manufacturing capabilities and strategy; and
- the accuracy of our estimates regarding future revenues, expenses, capital requirements and needs for additional financing.

The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. When evaluating our forward-looking statements, you should consider this cautionary statement along with the risk factors identified elsewhere in this document, including in the sections entitled "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for our fiscal year ended December 31, 2022, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Quantitative and Qualitative Disclosures about Market Risk" in this Quarterly Report on Form 10-Q, 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®, CYFENDUS™, BioThrax®, BaciThrax®, RSDL®, BAT®, Trobigard®, Anthrasil®, CNJ-016®, ACAM2000®, NARCAN®, TEMBEXA® and any and all Emergent BioSolutions Inc. brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent BioSolutions Inc. or its subsidiaries in the United States or other countries. All other brands, products, services and feature names or trademarks are the property of their respective owners.

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 88.6	$ 642.6
Accounts receivable, net	290.1	158.4
Inventories, net	354.3	351.8
Prepaid expenses and other current assets	44.7	57.9
Total current assets	777.7	1,210.7
Property, plant and equipment, net	395.5	817.6
Intangible assets, net	592.8	728.8
Goodwill	218.2	218.2
Other assets	194.6	191.3
Total assets	$ 2,178.8	$ 3,166.6
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 108.3	$ 103.5
Accrued expenses	31.2	34.9
Accrued compensation	69.6	88.3
Debt, current portion	455.2	957.3
Other current liabilities	28.9	45.9
Total current liabilities	693.2	1,229.9
Debt, net of current portion	448.0	448.5
Deferred tax liability	57.9	71.8
Other liabilities	23.4	33.4
Total liabilities	1,222.5	1,783.6
Stockholders' equity:		
Preferred stock, par value $0.001 per share; 15.0 shares authorized, no shares issued or outstanding	—	—
Common stock, par value $0.001 per share; 200.0 shares authorized, 57.4 and 55.7 shares issued; 51.8 and 50.1 shares outstanding, respectively	0.1	0.1
Treasury stock, at cost, 5.6 and 5.6 common shares, respectively	(227.7)	(227.7)
Additional paid-in capital	895.8	873.5
Accumulated other comprehensive income (loss), net	(1.6)	3.1
Retained earnings	289.7	734.0
Total stockholders’ equity	956.3	1,383.0
Total liabilities and stockholders’ equity	$ 2,178.8	$ 3,166.6

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Product sales, net	$ 302.2	$ 237.2	$ 445.6	$ 474.3
Contract development and manufacturing ("CDMO"):				
Services	26.4	2.7	39.8	54.5
Leases	2.7	(4.5)	4.5	4.5
Total CDMO revenues	29.1	(1.8)	44.3	59.0
Contracts and grants	6.6	7.3	13.1	16.9
Total revenues	337.9	242.7	503.0	550.2
Operating expenses:				
Cost of product sales	134.9	91.0	237.8	171.3
Cost of CDMO	55.7	78.8	107.9	154.4
Impairment of long-lived assets	306.7	—	306.7	—
Research and development	26.0	49.8	66.6	96.2
Selling, general and administrative	91.4	81.1	191.9	165.9
Amortization of intangible assets	16.1	14.0	33.1	28.0
Total operating expenses	630.8	314.7	944.0	615.8
Loss from operations	(292.9)	(72.0)	(441.0)	(65.6)
Other income (expense):				
Interest expense	(28.6)	(7.8)	(46.5)	(16.0)
Gain on sale of business	74.9	—	74.9	—
Other, net	(3.6)	(3.0)	1.3	(5.0)
Total other income (expense), net	42.7	(10.8)	29.7	(21.0)
Loss before income taxes	(250.2)	(82.8)	(411.3)	(86.6)
Income tax provision (benefit)	11.1	(26.4)	33.0	(26.5)
Net loss	$ (261.3)	$ (56.4)	$ (444.3)	$ (60.1)
Net loss per common share				
Basic	$ (5.15)	$ (1.13)	$ (8.80)	$ (1.19)
Diluted	$ (5.15)	$ (1.13)	$ (8.80)	$ (1.19)
Weighted average shares outstanding				
Basic	50.7	50.0	50.5	50.3
Diluted	50.7	50.0	50.5	50.3

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (261.3)	$ (56.4)	$ (444.3)	$ (60.1)
Other comprehensive income (loss), net of tax:				
Foreign currency translation adjustments, net	2.6	0.4	2.5	0.9
Unrealized gains (losses) on hedging activities	1.2	1.9	(3.2)	6.8
Reclassification adjustment for gains on hedging activities	(2.9)	0.9	(0.5)	2.3
Reclassification adjustment for gains on pension benefit obligation	(3.5)	—	(3.5)	—
Total other comprehensive income (loss), net of tax	(2.6)	3.2	(4.7)	10.0
Comprehensive loss, net of tax	$ (263.9)	$ (53.2)	$ (449.0)	$ (50.1)

See accompanying notes to condensed consolidated financial statements.

Emergent BioSolutions Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(unaudited, in millions)

	Six Months Ended June 30,	
	2023	**2022**
Operating Activities		
Net loss	$ (444.3)	$ (60.1)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	15.1	22.2
Long-term incentive plan expense	2.4	—
Depreciation and amortization	67.5	75.4
Change in fair value of contingent obligations, net	1.9	1.8
Amortization of deferred financing costs	9.9	2.0
Deferred income taxes	(10.2)	2.6
Gain on sale of travel health business	(74.9)	—
Impairment of long-lived assets	306.7	—
Other	9.5	2.2
Changes in operating assets and liabilities:		
Accounts receivable	(130.6)	97.7
Inventories	(23.8)	(75.5)
Prepaid expenses and other assets	(17.8)	(19.4)
Accounts payable	10.9	(7.6)
Accrued expenses and other liabilities	(13.8)	(36.4)
Accrued compensation	(13.4)	(14.1)
Income taxes receivable and payable, net	14.2	(46.4)
Contract liabilities	(7.7)	2.7
Net cash used in operating activities	(298.4)	(52.9)
Investing Activities		
Purchases of property, plant and equipment	(27.6)	(64.3)
Proceeds from sale of travel health business, net	270.2	—
Net cash provided by (used in) investing activities	242.6	(64.3)
Financing Activities		
Purchases of treasury stock	—	(81.9)
Principal payments on revolving credit facility	(347.8)	—
Principal payments on term loan facility	(156.8)	(16.9)
Proceeds from stock-based compensation activity	1.3	3.0
Taxes paid for stock-based compensation activity	(2.3)	(5.4)
Proceeds from at-the-market sale of stock, net of commissions and expenses	8.2	—
Net cash used in financing activities:	(497.4)	(101.2)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(0.8)	0.4
Net change in cash, cash equivalents and restricted cash	(554.0)	(218.0)
Cash, cash equivalents and restricted cash, beginning of period	642.6	576.3
Cash, cash equivalents and restricted cash, end of period	$ 88.6	$ 358.3
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 38.8	$ 14.8
Cash paid for income taxes	$ 26.9	$ 20.0
Supplemental information on non-cash investing and financing activities:		
Purchases of property, plant and equipment unpaid at period end	$ 7.7	$ 7.3

See accompanying notes to condensed consolidated financial statements.

Emergent BioSolutions Inc. and Subsidiaries
Condensed Consolidated Statements of Changes in Stockholders' Equity
(unaudited, in millions)

	$0.001 Par Value Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	55.7	$ 0.1	(5.6)	$ (227.7)	$ 873.5	$ 3.1	$ 734.0	$ 1,383.0
Net loss	—	$ —	—	$ —	$ —	$ —	$ (183.0)	$ (183.0)
Share-based compensation activity	0.3	—	—	—	4.7	—	—	4.7
Other comprehensive loss, net of tax	—	—	—	—	—	(2.1)	—	(2.1)
Balance at March 31, 2023	56.0	$ 0.1	(5.6)	$ (227.7)	$ 878.2	$ 1.0	$ 551.0	$ 1,202.6
Net loss	—	$ —	—	$ —	$ —	$ —	$ (261.3)	$ (261.3)
Share-based compensation activity	0.3	—	—	—	9.4	—	—	9.4
At-the-market sale of stock, net of commissions and expenses	1.1	—	—	—	8.2	—	—	8.2
Other comprehensive loss, net of tax	—	—	—	—	—	(2.6)	—	(2.6)
Balance at June 30, 2023	57.4	$ 0.1	(5.6)	$ (227.7)	$ 895.8	$ (1.6)	$ 289.7	$ 956.3

	$0.001 Par Value Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	55.1	$ 0.1	(3.8)	$ (152.2)	$ 829.4	$ (16.1)	$ 957.8	$ 1,619.0
Net loss	—	$ —	—	$ —	$ —	$ —	$ (3.7)	$ (3.7)
Share-based compensation activity	0.2	—	—	—	5.4	—	—	5.4
Repurchases of common stock	—	—	(1.1)	(52.2)	—	—	—	(52.2)
Other comprehensive income, net of tax	—	—	—	—	—	6.8	—	6.8
Balance at March 31, 2022	55.3	$ 0.1	(4.9)	$ (204.4)	$ 834.8	$ (9.3)	$ 954.1	$ 1,575.3
Net loss	—	$ —	—	$ —	$ —	$ —	$ (56.4)	$ (56.4)
Share-based compensation activity	0.2	—	—	—	14.4	—	—	14.4
Repurchases of common stock	—	—	(0.7)	(23.3)	—	—	—	(23.3)
Other comprehensive income, net of tax	—	—	—	—	—	3.2	—	3.2
Balance at June 30, 2022	55.5	$ 0.1	(5.6)	$ (227.7)	$ 849.2	$ (6.1)	$ 897.7	$ 1,513.2

See accompanying notes to condensed consolidated financial statements.

1. Nature of the business and organization

Organization and business

Emergent BioSolutions Inc., including its consolidated subsidiaries (“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 care. The Company has a current product portfolio of 12 products (vaccines, therapeutics, and drug-device combination products). The revenue generated by the products comprises a substantial portion of the Company's revenue. The Company structures the business with a focus on markets and customers. As such, the key components of the business structure include the following four product and service categories: Anthrax - Medical Countermeasures ("MCM") Products, NARCAN, Smallpox - MCM Products and CDMO Services. The Company operates as two operating segments: (1) a products segment ("Products") consisting of the Anthrax - MCM products, NARCAN, Smallpox - MCM products and Other products and (2) a services segment ("Services") focused on CDMO services (Note 17, "Segment information").

The Company's products and services include:

Anthrax - MCM Products

- Anthrasil® (Anthrax Immune Globulin Intravenous (human)), the only polyclonal antibody therapeutic licensed by the United States Food and Drug Administration (“FDA”) and Health Canada for the treatment of inhalational anthrax in combination with appropriate antibacterial drugs;
- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the FDA for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- CYFENDUS™ (Anthrax vaccine adsorbed (AVA), adjuvanted), previously known as AV7909, which was recently approved by the FDA for post-exposure prophylaxis of disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs. CYFENDUS™ is procured by certain authorized government buyers for their use;
- Raxibacumab injection, the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax;

NARCAN

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

Smallpox - MCM Products

- ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live), the only single-dose smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection;
- CNJ-016® (Vaccinia Immune Globulin Intravenous (Human) (VIGIV)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination; and
- TEMBEXA®, an oral antiviral formulated as 100 mg tablets and 10 mg/mL oral suspension dosed once weekly for two weeks which has been approved by the FDA for the treatment of smallpox disease caused by variola virus in adult and pediatric patients, including neonates.

Other Products

- BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)), the only heptavalent antitoxin licensed by the FDA and Health Canada for the treatment of symptomatic botulism;
- Ebanga™ (ansuvimab-zykl), a monoclonal antibody with antiviral activity provided through a single IV infusion for the treatment of Ebola. Under the terms of a collaboration with Ridgeback Biotherapeutics ("Ridgeback"), Emergent will be responsible for the manufacturing, sale, and distribution of Ebanga™ in the U.S. and Canada, and Ridgeback will serve as the global access partner for Ebanga™;
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only medical device cleared by the FDA that is intended to remove or neutralize chemical warfare agents from the skin, including: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin; and
- Trobigard® atropine sulfate, obidoxime chloride auto-injector, a combination drug-device auto-injector procured product candidate that contains atropine sulfate and obidoxime chloride. It was approved in Belgium in 2021 but has not been approved by the FDA. Trobigard is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure outside of the U.S.

Sale of Travel Health Business

On May 15, 2023 the Company completed the sale of its 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, "Divestiture".

Services - Contract Development and Manufacturing

The Company's services line focused on CDMO offerings cover development services, drug substance manufacturing, drug product manufacturing, and when necessary, suite reservations, which depending on facts and circumstances could be considered a lease. These services are provided to customers from across the pharmaceutical and biotechnology industries as well as the U.S. Government (“USG”) and non-governmental organizations. The Company's technology platforms include mammalian, microbial, viral, plasma and advanced therapies utilizing the Company's core capabilities for manufacturing to third parties on a clinical and commercial (small and large) scale. Additional services include fill/finish formulation and analytical development services for injectable and other sterile products, inclusive of process design, technical transfer, manufacturing validations, aseptic filling, lyophilization, final packaging and stability studies, as well as manufacturing of vial and pre-filled syringe formats on multiple platforms.

2. Summary of significant accounting policies

Basis of presentation and consolidation

The accompanying unaudited condensed consolidated financial statements include the accounts of Emergent and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation. The unaudited condensed consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X issued by the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC.

All adjustments contained in the accompanying unaudited condensed consolidated financial statements are of a normal recurring nature and are necessary to present fairly the financial position of the Company as of June 30, 2023. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Going concern

As of June 30, 2023, there is $250.2 million outstanding on the Company's Revolving Credit Facility and $206.1 million on Term Loan Facility that matures in May 2025. The Company determined that there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation considered the mitigating effect of management's plans that have been implemented as of June 30, 2023. Management may evaluate the mitigating effect of its plans to determine if it is probable that (1) the plans will be effectively implemented within one year after the date the financial statements are issued, and (2) when implemented, the plans will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern. The Company's plans include (A) amending the agreement for the Senior Secured Credit Facilities which occurred on May 15, 2023 with the Fourth Amendment to Amended and Restated Credit Agreement, Waiver and First Amendment to Amended and Restated Collateral Agreement (the "Credit Agreement Amendment"), and (B) the execution of the capital raise requirement prescribed in the Credit Agreement Amendment, as further described below.

While the Company executed the Credit Agreement Amendment and extended the maturity date on the Senior Secured Credit Facilities to May 15, 2025, the Credit Agreement Amendment also requires the Company to raise at least $75.0 million through the issuance of equity and/or unsecured indebtedness by April 30, 2024. As a result of this provision, the Company has determined it is appropriate to continue to classify the debt as a current liability on the Condensed Consolidated Balance Sheets. While the Company expects to complete these actions, management cannot make the assumption that it is probable that the Company will be successful. As a result, the Company continues to evaluate a number of uncertain factors related to its assessment of its ability to satisfy the capital raise requirement, including its ability to comply with the terms and operating and financial covenants required by the Senior Secured Credit Facilities, other market conditions, economic conditions, particularly in the pharmaceutical and biotechnology industry, disruptions or volatility caused by factors such as lingering impacts of the COVID-19 pandemic, regional conflicts, inflation, and supply chain disruptions.

The Condensed Consolidated Financial Statements have been prepared assuming the Company will continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Pre-launch inventory

Within the Company's Products segment, 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 CDMO contract as CDMO pre-launch inventory may be capitalized if it has future economic benefit based on the terms of the contract.

Significant accounting policies

With the exception of the policy on pre-launch inventory discussed above, there have been no significant changes to the Company's summary of significant accounting policies during the six months ended June 30, 2023 contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, that have materially impacted the presentation of the Company's financial statements.

Fair value measurements

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

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

On a recurring basis, the Company measures and records money market funds (Level 1), interest-rate swap arrangements and time deposits (Level 2) and contingent purchase consideration (Level 3) using fair value measurements in the accompanying financial statements. The carrying amounts of the Company's short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable approximate their fair values due to their short maturities. The carrying amounts of the Company’s long-term variable interest rate debt arrangements (Level 2) approximate their fair values.

New accounting standards

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board that the Company adopts as of the pronouncement's specified effective date. There were no new accounting pronouncements that were issued or became effective since the issuance of the Company’s 2022 Annual Report on Form 10-K that had, or are expected to have, a material impact on its consolidated financial position, results of operations or cash flows.

3. Divestiture

On May 15, 2023, pursuant to the Purchase and Sale Agreement (the “Purchase and Sale Agreement”), by and between the Company, through its wholly owned subsidiaries Emergent International Inc. and Emergent Travel Health Inc. and Bavarian Nordic ("Bavarian Nordic”), the Company completed the previously announced sale of the Company’s travel health business, including rights to Vivotif®, 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 $270.0 million, exclusive of customary closing adjustments for cash, indebtedness, working capital and transaction expenses of the business at closing. Bavarian Nordic may also be required to pay milestone payments of up to $80.0 million related to the development of CHIKV VLP and receipt of marketing approval and authorization in the U.S. and Europe, and earn-out payments of up to $30.0 million based on aggregate net sales of Vaxchora and Vivotif in calendar year 2026.

As a result of the divestiture, during the three months ended June 30, 2023, the Company recognized a pre-tax gain of $74.9 million, net of transaction costs of $4.0 million, which was recorded within "Gain on sale of business" on the Condensed Consolidated Statements of Operations.

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

In connection with the divestiture, the Company entered into a Transition Services Agreement (“TSA”) with Bavarian Nordic to help support its ongoing operations. Under the TSA, the Company will provide certain transition services to Bavarian Nordic, including information technology, finance and enterprise resource planning, research and development, human resources, employee benefits and other limited services. Income from performing services under the TSA was recorded within "Other income (expense), net" on the Condensed Consolidated Statements of Operations and was $1.0 million for the three and six months ended June 30, 2023.

4. Restructuring and impairment charges

Impairment of long-lived assets

The Company tests its long-lived assets that are held and used for recoverability whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. During the preparation of our financial statements for the three months ended June 30, 2023, due to deterioration in performance and resulting downward revisions to our internal CDMO forecast made during the second quarter, including future expected cash flows, the Company determined there were sufficient indicators of impairment on certain asset groups within the CDMO reporting unit to require an impairment analysis. As a result, the Company performed recoverability tests on certain asset groups within the CDMO 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 this analysis, the Company allocated and recognized a non-cash impairment charge of $306.7 million during the three months ended June 30, 2023.

The table below presents the total impairment charge by asset class for the three months ended June 30, 2023:

	Three Months Ended June 30, 2023
Buildings, building improvements and leasehold improvements	$ 81.5
Furniture and equipment	117.5
Software	0.3
Construction-in-progress	107.4
Total impairment on long-lived assets	$ 306.7

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 eliminated approximately five percent of its total headcount. The Company made a $(0.1) million adjustment to the incurred charges in connection with the January 2023 Plan during the three months ended June 30, 2023 and incurred approximately $9.6 million in charges during the six months ended June 30, 2023. These charges consist primarily of charges related to employee transition, severance payments and employee benefits. All activities related to the January 2023 Plan were substantially completed during the first quarter of 2023. Restructuring costs are recognized as an operating expense within the Condensed Consolidated Statement of Operations and are classified based on the Company's classification policy for each category of operating expense.

The following table presents the total restructuring costs associated with the Company's segments as well as unallocated corporate and research and development ("R&D") charges for the three and six months ended June 30, 2023:

	Three Months Ended June 30, 2023	Six Months Ended June 30, 2023
Products	$ —	$ 2.0
Services	—	—
Total restructuring costs by segment	—	2.0
Corporate	0.1	5.1
R&D	$ (0.2)	2.5
Total restructuring costs	$ (0.1)	$ 9.6

The following table presents the total restructuring costs, by function, for the three and six months ended June 30, 2023:

	Three Months Ended June 30, 2023	Six Months Ended June 30, 2023
Employee transition	$ —	$ 0.3
Severance payments	0.1	8.8
Employee benefits	(0.2)	0.5
Total restructuring costs	$ (0.1)	$ 9.6

The following table provides the components of and changes in the Company's restructuring accrual during the three and six months ended June 30, 2023:

	Employee Transition	Severance Payments	Employee Benefits	Total
Balance at December 31, 2022	$ —	$ —	$ —	$ —
Accruals	0.3	8.7	0.7	9.7
Cash payments	(0.2)	(2.0)	(0.1)	(2.3)
Balance at March 31, 2023	$ 0.1	$ 6.7	$ 0.6	$ 7.4
Accruals	—	0.1	(0.2)	(0.1)
Cash payments	—	(3.6)	(0.1)	(3.7)
Balance at June 30, 2023	$ 0.1	$ 3.2	$ 0.3	$ 3.6

5. Inventories, net

Inventories, net consisted of the following:

	June 30, 2023	December 31, 2022
Raw materials and supplies	$ 140.3	$ 143.4
Work-in-process	149.3	116.2
Finished goods	64.7	92.2
Total inventories, net	$ 354.3	$ 351.8

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

6. Property, plant and equipment, net

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

	June 30, 2023 [1]	December 31, 2022
Land and improvements	$ 30.0	$ 54.9
Buildings, building improvements and leasehold improvements	226.4	327.9
Furniture and equipment	412.3	567.5
Software	64.7	65.6
Construction-in-progress	53.5	185.5
Property, plant and equipment, gross	$ 786.9	$ 1,201.4
Less: Accumulated depreciation & amortization	(391.4)	(383.8)
Total property, plant and equipment, net	$ 395.5	$ 817.6

[1] During the three months ended June 30, 2023, the Company recorded a non-cash impairment charge of $306.7 million related to certain CDMO long-lived assets. See Note 4, "Restructuring and impairment charges" for more details regarding the impairment charge.

As of June 30, 2023, construction-in-progress primarily included costs incurred to advance the Company's MCM Product capabilities. As of December 31, 2022, construction-in-progress primarily included costs incurred due to construction to advance the Company's CDMO capabilities.

Property, plant and equipment, net is stated at cost, less accumulated depreciation and amortization. During the year ended December 31, 2022, the Company recorded accelerated depreciation of $12.7 million reflecting a shortening of the useful life of certain property, plant and equipment which were to be used in the manufacturing process to fulfill the manufacturing services agreement with Janssen (the "Agreement"). For additional information related to the termination of the Agreement, refer to Note 13, "Revenue recognition".

7. Intangible assets and goodwill

The Company's intangible assets consist of products acquired via business combinations or asset acquisitions. The following table summarizes the Company's Intangible assets, net:

		June 30, 2023			December 31, 2022		
	Weighted Average Useful Life in Years	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount [1]	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Products	13.6	$ 849.1	$ 256.3	$ 592.8	$ 982.1	$ 253.3	$ 728.8
Customer relationships	0.0	28.6	28.6	—	28.6	28.6	—
CDMO	0.0	5.5	5.5	—	5.5	5.5	—
Total intangible assets		$ 883.2	$ 290.4	$ 592.8	$ 1,016.2	$ 287.4	$ 728.8

[1] During the six months ended June 30, 2023, the Company sold $102.9 million of intangible assets, net as part of the sale of its travel health business to Bavarian Nordic. See Note 3, "Divestiture" for more information on the sale of the business.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Amortization expense	$ 16.1	$ 14.0	$ 33.1	$ 28.0

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

	Products [1]	Services [2]	Total
Balance at December 31, 2022	$ 218.2	$ —	$ 218.2
Balance at June 30, 2023	$ 218.2	$ —	$ 218.2

[1] Amounts for the Company's Products segment include gross carrying values of $259.9 million as of June 30, 2023 and December 31, 2022 and accumulated impairment losses of $41.7 million.

[2] Amounts for the Company's Services segment include gross carrying values of $6.7 million as of June 30, 2023 and December 31, 2022, and accumulated impairment losses of $6.7 million.

The Company has $218.2 million of total goodwill which is attributable to its Products segment. Quantitative impairment assessments performed during the quarter ended June 30, 2023 indicated that the fair value of the reporting unit was approximately 14% in excess over its carrying value as of the assessment date. There is the risk of future impairments in our reporting unit as any further deterioration in their performance compared to forecast, changes in order volumes or delivery schedules for major customers, decline in our stock price, as well as any changes in economic forecasts and expected recovery in the biopharmaceutical industry, may require the Company to complete additional impairment tests in future quarters and could result in a reporting unit's fair value falling below carrying value in subsequent quarters. In the event the Company experiences factors that it believes indicate a decline in fair value, including negative changes to long-term growth rates or if discount rates increase, we may be required to record impairments of goodwill and other identified intangible assets. Further, if the composition of the Company's reporting units' assets and liabilities were to change and result in an increase in a reporting unit's carrying value, it could lead to additional impairment testing and further impairment losses.

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:

	June 30, 2023				December 31, 2022			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Assets:								
Money market accounts	$ 20.1	$ 20.1	$ —	$ —	$ 320.8	$ 320.8	$ —	$ —
Time deposits	—	—	—	—	170.7	—	170.7	—
Derivative instruments	—	—	—	—	8.5	—	8.5	—
Total	$ 20.1	$ 20.1	$ —	$ —	$ 500.0	$ 320.8	$ 179.2	$ —
Liabilities:								
Contingent consideration	$ 7.4	$ —	$ —	$ 7.4	$ 6.8	$ —	$ —	$ 6.8
Total	$ 7.4	$ —	$ —	$ 7.4	$ 6.8	$ —	$ —	$ 6.8

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

The table below is a reconciliation of the beginning and ending balance of the Company's contingent consideration liability:

	Contingent Consideration
Balance at December 31, 2022	$ 6.8
Change in fair value	1.5
Settlements	(0.7)
Balance at March 31, 2023	7.6
Change in fair value	0.4
Settlements	(0.6)
Balance at June 30, 2023	$ 7.4

As of June 30, 2023 and December 31, 2022, the current portion of the contingent consideration liability was $3.6 million and $3.1 million, respectively, and was included in "Other current liabilities" on the Condensed Consolidated Balance Sheets. The non-current portion of the contingent consideration liability is included in "Other liabilities" on the Condensed Consolidated Balance Sheets.

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

Contingent Consideration Liability	Fair Value as of June 30, 2023	Valuation Technique	Unobservable Input	Range
Royalty based	$7.4 million	Discounted cash flow	Discount rate	9.7%
			Probability of payment	0% - 75%
			Projected year of payment	2023 - 2028

Derivative instruments

Refer to Note 9, "Derivative instruments and hedging activities" for more information about the Company's derivative instruments.

Non-variable rate debt

As of June 30, 2023 and December 31, 2022, the fair value of the Company's 3.875% Senior Unsecured Notes was $252.9 million and $225.1 million, respectively. The fair value was determined through market sources, which are Level 2 inputs and directly observable. The carrying amounts of the Company’s other long-term variable interest rate debt arrangements approximate their fair values (see Note 10, "Debt").

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 quarter ended June 30, 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 June 30, 2023, the remaining accumulated other comprehensive income associated with the terminated interest rate swaps, before tax, was $3.5 million and will be amortized to earnings over the remaining term of the interest rate swaps prior to termination.

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

		Fair Value of Asset Derivatives	
	Classification	June 30, 2023	December 31, 2022
Interest Rate Swaps	Other Current Assets	$ —	$ 8.5

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

The following table summarizes the amount of gains or losses reclassified from "Accumulated other comprehensive income (loss), net" into "Interest expense" on the Condensed Consolidated Statement of Operations during the three and six months ended June 30, 2023 and 2022:

		Three Months Ended June 30,		Six Months Ended June 30,	
	Classification	2023	2022	2023	2022
Interest rate swaps gain (loss)	Interest expense	$ 2.9	$ (0.9)	$ 5.3	$ (2.3)

10. Debt

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

	June 30, 2023	December 31, 2022
Senior secured credit agreement - Term loan due 2025	$ 206.1	$ 362.8
Senior secured credit agreement - Revolver loan due 2025	250.2	598.0
3.875% Senior Unsecured Notes due 2028	450.0	450.0
Other	3.0	3.0
Total debt	$ 909.3	$ 1,413.8
Less: Unamortized debt issuance costs [1]	(6.1)	(8.0)
Less: Current portion of long-term debt, net	(455.2)	(957.3)
Non-current portion of debt, net	$ 448.0	$ 448.5

[1] As of June 30, 2023, excludes the unamortized debt issuance costs related to the revolver loan which are included within "Other current assets" on the accompanying Condensed Consolidated Balance Sheet.

During the quarter ended June 30, 2023, the Company reclassified the debt issuance costs associated with the revolver loan to "Other current assets." Prior to the second quarter of 2023, the debt issuance costs associated with the revolver loan were classified as a direct offset to the carrying value of the debt within "Other current liabilities." As of June 30, 2023 and December 31, 2022, the Company had $13.5 million and $1.3 million of debt issuance costs associated with the revolver loan, respectively.

3.875% Senior Unsecured Notes due 2028

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

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

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

Senior Secured Credit Facilities

On May 15, 2023, the Company entered into the Credit Agreement Amendment. The Credit Agreement Amendment amends the Existing Credit Agreement to, among other things, (a) extend the maturity date of the Senior Secured Credit Facilities from October 13, 2023 to May 15, 2025, (b) reduce the available commitments under the Revolving Credit Facility from $600.0 million to $300.0 million, (c) remove the Company's ability to incur incremental loans and (d) amend certain mandatory prepayment triggers, affirmative covenants, negative covenants and events of default thereunder. In connection with the Credit Agreement Amendment, the Company used the approximately $270.0 million of proceeds from the sale of its travel health business to Bavarian Nordic, which closed on May 15, 2023, together with approximately $217.2 million of cash on hand, to repay approximately $144.4 million in outstanding principal amount of loans under the Term Loan Facility and $342.8 million outstanding principal amount of loans under the Revolving Credit Facility.The Credit Agreement Amendment also requires that we make quarterly principal payments on the Term Loan Facility of approximately $3.9 million, which commenced on June 30, 2023 and will extend through March 31, 2025.

The Credit Agreement Amendment also (w) amends the consolidated debt service coverage ratio financial covenant to require the minimum level to be 2.25 to 1.00 for the fiscal quarters ending March 31, 2024, June 30, 2024, September 30, 2024 and December 31, 2024, and then 2.50 to 1.00 for each fiscal quarter ending thereafter, (x) amends the consolidated leverage ratio to require the maximum level to be 4.50 to 1.00 for the fiscal quarter ending March 31, 2024 and each fiscal quarter ending thereafter, (y) adds minimum Consolidated EBITDA requirements and maximum capital expenditure requirements for each of the months ending April 30, 2023 through February 29, 2024 and a minimum liquidity requirement as of the end of each calendar month and (z) requires the Company to increase its liquidity by April 30, 2024 by raising at least $75.0 million of equity or unsecured indebtedness.

In addition, the Credit Agreement Amendment replaces the interest rate benchmark such that borrowings under the Revolving Credit Facility and the outstanding principal amount of the Term Loan Facility shall bear interest at a rate per annum equal to (a) a rate based on SOFR, EURIBOR or CDOR plus a margin of 6.00% until March 31, 2024 and thereafter, a margin ranging from 2.75% to 4.00% depending on the Company’s consolidated leverage ratio, or (b) a base rate (which is the highest of the prime rate, the federal funds rate plus 0.50%, and a SOFR rate for an interest period of one month plus 1%) plus a margin of 5.00% until March 31, 2024 and thereafter, a margin ranging from 1.75% to 3.00% depending on the Company’s consolidated leverage ratio. In addition, the commitment fee the Company is required to pay in respect of the annual daily unused commitments under the Revolving Credit Facility shall be 0.15% to 0.40% per annum, depending on the Company’s consolidated leverage ratio.

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

11. Stock-based compensation and stockholders' equity

Stock-based compensation

During the six months ended June 30, 2023, the Company granted stock options to purchase 0.7 million shares of common stock, 1.4 million restricted stock units and 0.5 million performance stock units under the Emergent BioSolutions Inc. Stock Incentive Plan. Performance stock units are presented at the target payout percentage of 100% of target shares granted. Typically, the stock options and restricted stock unit grants vest over three equal annual installments beginning on the day prior to the anniversary of the grant date. The performance stock units settle in stock at the end of the three-year performance period based on the Company's results compared to the performance criteria. During the six months ended June 30, 2023, 0.6 million of stock options and 0.4 million shares of restricted stock units were forfeited prior to the completion of the applicable vesting requirements or expiration. Additionally, an immaterial amount of performance stock units were forfeited during the six months ended June 30, 2023, as the award targets or vesting requirements were not achieved.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Cost of product sales	$ 1.2	$ 1.9	$ 2.6	$ 3.6
Cost of CDMO	0.3	0.6	0.6	1.0
R&D	0.4	1.5	1.1	2.6
Selling, general and administrative	6.4	8.3	10.8	15.0
Total stock-based compensation expense	$ 8.3	$ 12.3	$ 15.1	$ 22.2

2021 Share Repurchase Program

On November 11, 2021, the Company announced that its Board of Directors authorized a stock repurchase program of up to an aggregate of $250.0 million of Common Stock (the "Share Repurchase Program"), of which $187.9 million was utilized to purchase approximately 4.4 million shares. The Share Repurchase Program expired on November 11, 2022. During the three and six months ended June 30, 2022, the Company utilized $23.3 million and $75.5 million to purchase approximately 0.7 million and 1.8 million shares, respectively. The Share Repurchase Program did not obligate the Company to acquire any specific number of shares. Repurchased shares are available for use in connection with the Company's stock plans and for other corporate purposes.

At-the-Market Equity Offering Facility

We may, from time to time, sell up to $150.0 million aggregate gross sales price of shares of our common stock through Evercore Group L.L.C. and RBC Capital Markets, LLC, as sales agents, under an “at-the-market” equity offering program (the “ATM Program”) that we entered into on May 18, 2023. During the three months ended June 30, 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 June 30, 2023, $140.9 million aggregate gross sales price of shares of our common stock remains available for issuance under the ATM Program. We intend to use proceeds obtained from the sale of shares under the ATM Program for general corporate purposes.

Accumulated other comprehensive income (loss), net of tax

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

	Defined Benefit Pension Plan	Derivative Instruments	Foreign Currency Translation Adjustments	Total
Balance at December 31, 2022	$ 3.5	$ 6.2	$ (6.6)	$ 3.1
Other comprehensive income (loss) before reclassifications	—	(4.4)	(0.1)	(4.5)
Amounts reclassified from accumulated other comprehensive income (loss)	—	2.4	—	2.4
Net current period other comprehensive income (loss)	—	(2.0)	(0.1)	(2.1)
Balance at March 31, 2023	$ 3.5	$ 4.2	$ (6.7)	$ 1.0
Other comprehensive income (loss) before reclassifications	—	1.2	2.6	3.8
Amounts reclassified from accumulated other comprehensive income (loss)	(3.5)	(2.9)	—	(6.4)
Net current period other comprehensive income (loss)	(3.5)	(1.7)	2.6	(2.6)
Balance at June 30, 2023	$ —	$ 2.5	$ (4.1)	$ (1.6)
Balance at December 31, 2021	$ (4.0)	$ (4.5)	$ (7.6)	$ (16.1)
Other comprehensive income (loss) before reclassifications	—	4.9	0.5	5.4
Amounts reclassified from accumulated other comprehensive income (loss)	—	1.4	—	1.4
Net current period other comprehensive income (loss)	—	6.3	0.5	6.8
Balance at March 31, 2022	$ (4.0)	$ 1.8	$ (7.1)	$ (9.3)
Other comprehensive income (loss) before reclassifications	—	1.9	0.4	2.3
Amounts reclassified from accumulated other comprehensive income (loss)	—	0.9	—	0.9
Net current period other comprehensive income (loss)	—	2.8	0.4	3.2
Balance at June 30, 2022	$ (4.0)	$ 4.6	$ (6.7)	$ (6.1)

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

	Three Months Ended June 30,					
	2023			2022		
	Pretax	Tax Expense	Net of tax	Pretax	Tax Expense	Net of tax
Defined benefit pension plan	$ (4.1)	$ 0.6	$ (3.5)	$ —	$ —	$ —
Derivative instruments	(2.4)	0.7	(1.7)	3.8	(1.0)	2.8
Foreign currency translation adjustments	2.1	0.5	2.6	1.3	(0.9)	0.4
Total adjustments	$ (4.4)	$ 1.8	$ (2.6)	$ 5.1	$ (1.9)	$ 3.2

	Six Months Ended June 30,					
	2023			2022		
	Pretax	Tax Expense	Net of tax	Pretax	Tax Expense	Net of tax
Defined benefit pension plan	$ (4.1)	$ 0.6	$ (3.5)	$ —	$ —	$ —
Derivative instruments	(5.0)	1.3	(3.7)	12.4	(3.3)	9.1
Foreign currency translation adjustments	2.0	0.5	2.5	2.0	(1.1)	0.9
Total adjustments	$ (7.1)	$ 2.4	$ (4.7)	$ 14.4	$ (4.4)	$ 10.0

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. 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 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 share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Numerator:				
Net loss	$ (261.3)	$ (56.4)	$ (444.3)	$ (60.1)
Denominator:				
Weighted-average number of shares outstanding-basic	50.7	50.0	50.5	50.3
Weighted-average number of shares outstanding-diluted	50.7	50.0	50.5	50.3
Net loss per common share - basic	$ (5.15)	$ (1.13)	$ (8.80)	$ (1.19)
Net loss per common share - diluted	$ (5.15)	$ (1.13)	$ (8.80)	$ (1.19)
Anti-dilutive securities	3.6	1.8	3.4	3.0

13. Revenue recognition

The Company operates as two operating segments (see Note 17, "Segment information"). The Company's revenues disaggregated by the major sources were as follows:

	Three Months Ended June 30, 2023			Three Months Ended June 30, 2022		
	USG	Non-USG	Total	USG	Non-USG	Total
Product sales, net	$ 150.5	$ 151.7	$ 302.2	$ 118.2	$ 119.0	$ 237.2
CDMO:						
Services	—	26.4	26.4	—	2.7	2.7
Leases	—	2.7	2.7	—	(4.5)	(4.5)
Total CDMO	$ —	$ 29.1	$ 29.1	$ —	$ (1.8)	$ (1.8)
Contracts and grants	4.6	2.0	6.6	6.2	1.1	7.3
Total revenues	$ 155.1	$ 182.8	$ 337.9	$ 124.4	$ 118.3	$ 242.7

	Six Months Ended June 30, 2023			Six Months Ended June 30, 2022		
	USG	Non-USG	Total	USG	Non-USG	Total
Product sales, net	$ 176.6	$ 269.0	$ 445.6	$ 221.6	$ 252.7	$ 474.3
CDMO:						
Services	—	39.8	39.8	—	54.5	54.5
Leases	—	4.5	4.5	—	4.5	4.5
Total CDMO	$ —	$ 44.3	$ 44.3	$ —	$ 59.0	$ 59.0
Contracts and grants	9.5	3.6	13.1	15.3	1.6	16.9
Total revenues	$ 186.1	$ 316.9	$ 503.0	$ 236.9	$ 313.3	$ 550.2

Termination of manufacturing services agreement with Janssen Pharmaceuticals, Inc.

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

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

During the three months ended June 30, 2023, there were no impacts on previously recognized revenue or depreciation related to the conclusion of the Agreement. As of June 30, 2023, the Company has no billed or unbilled net accounts receivable related to the Agreement.

Beginning in the fourth quarter of 2022, because the arbitration process is expected to extend longer than one year, the Company reclassified amounts related to the Janssen Agreement from "Inventories, net" and from "Prepaid expenses and other current assets" to "Other assets", resulting in $152.7 million in long-term assets related to the Janssen Agreement on the Condensed Consolidated Balance Sheet as of December 31, 2022. The long-term asset balance within "Other Assets" related to the Agreement as of June 30, 2023 was $154.0 million. These assets include termination penalties, certain inventory related items and raw materials inventory representing materials purchased for the Agreement which Janssen has not reimbursed. The Company evaluated the net realizable value of the inventory as of June 30, 2023, concluding that because the Agreement specifies the Company is entitled to, among other things, reimbursement of raw materials and non-cancelable orders in the event of a contract termination for any reason, the Company is entitled to payment from Janssen for these raw materials. Additionally, the Company has $5.2 million of non-cancelable orders as of June 30, 2023 which have not been received and Janssen has not reimbursed.

CDMO operating leases

Certain multi-year CDMO service arrangements with commercial 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 weighted average remaining term on the Company's operating lease components approximates 3.2 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. Excluding future amounts related to the Agreement as discussed above, the Company estimates future operating lease revenues to be $0.6 million in the remainder of 2023, $0.9 million in 2024, $0.9 million in 2025, $0.9 million in 2026, $0.9 million in 2027 and $0.9 million in years beyond 2027.

Transaction price allocated to remaining performance obligations

As of June 30, 2023, the Company has future contract value on unsatisfied performance obligations of approximately $452.0 million associated with all arrangements entered into by the Company. The Company expects to recognize $443.2 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 that the Company does not currently have a contractual right to bill, to be contract assets. As of June 30, 2023 and December 31, 2022, the Company had $30.3 million and $34.8 million, respectively, of contract assets recorded within "Accounts receivable, net" on the Condensed 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 Condensed 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 liability balances:

	Contract Liabilities
Balance at December 31, 2022	$ 31.7
Balance at June 30, 2023	$ 19.3
Revenue recognized in the period from amounts included in contract liability at the beginning of the period:	$ (6.8)

As of June 30, 2023 and December 31, 2022, the current portion of contract liabilities was $14.3 million and $26.4 million, respectively, and was included in "Other current liabilities" on the Condensed Consolidated Balance Sheets.

Accounts receivable and allowance for expected credit losses

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

	June 30, 2023	December 31, 2022
Accounts receivable:		
Billed	$ 238.5	$ 102.7
Unbilled	51.8	56.4
Allowance for expected credit losses	(0.2)	(0.7)
Accounts receivable, net	$ 290.1	$ 158.4

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.

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. For a discussion of lessor activities, see Note 13, "Revenue recognition."

The components of lease expense were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating lease cost:				
Amortization of right-of-use assets	$ 0.9	$ 1.4	$ 2.0	$ 2.8
Interest on lease liabilities	0.2	0.3	0.4	0.6
Total operating lease cost	$ 1.1	$ 1.7	$ 2.4	$ 3.4

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

Supplemental balance sheet information related to lessee activities is as follows:

Leases	Classification	June 30, 2023	December 31, 2022
Operating lease right-of-use assets	Other assets	$ 15.7	$ 19.4
Operating lease liabilities, current portion	Other current liabilities	$ 3.6	$ 5.8
Operating lease liabilities	Other liabilities	13.1	14.8
Total operating lease liabilities		$ 16.7	$ 20.6
Operating leases:			
Weighted average remaining lease term (years)		6.3	5.9
Weighted average discount rate		4.5 %	4.1 %

15. Income taxes

The estimated effective annual tax rate for the years ended December 31, 2023 and 2022, excluding the impact of discrete adjustments, was (8)% and 29%, respectively. The decrease in the estimated effective annual tax rate is primarily due to a valuation allowance charge. The Company recorded a discrete tax expense of $0.0 million and $0.0 million for the three and six months ended June 30, 2023, respectively, and $0.2 million and $0.6 million for the three and six months ended June 30, 2022, respectively. The discrete tax expense in 2023 was due to share-based compensation activity which was entirely offset by a valuation allowance charge. The discrete expense in 2022 was primarily due to share-based compensation activity offset by return to provision adjustments.

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. At each reporting period, the Company considers the scheduled reversal of deferred tax liabilities and assets, available taxes in carryback periods, tax planning strategies and projected future taxable income in making this assessment.

In 2022, the Company determined that it was more likely than not that certain deferred tax assets would not be realized due to reductions in estimates of future profitability and disclosure related to substantial doubt about the Company's ability to continue as a going concern. Accordingly, the Company recorded an additional valuation allowance charge of $127.5 million in calculating the estimated annual tax rate for the year ended December 31, 2023.

16. Litigation

Securities and shareholder litigation

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

On April 20, 2021, May 14, 2021, and June 2, 2021, putative class action lawsuits were filed against the Company and certain of its current and former senior officers in the United States District Court for the District of Maryland on behalf of purchasers of the Company's common stock, seeking to pursue remedies under the Securities Exchange Act of 1934. These complaints were filed by Palm Tran, Inc. – Amalgamated Transit Union Local 1577 Pension Plan; Alan I. Roth; and Stephen M. Weiss, respectively. The complaints allege, among other things, that the defendants made false and misleading statements about the Company's manufacturing capabilities with respect to COVID-19 vaccine bulk drug substance (referred to herein as "CDMO Manufacturing Capabilities"). These cases were consolidated on December 23, 2021, under the caption In re Emergent BioSolutions Inc. Securities Litigation, No. 8:21-cv-00955-PWG (the "Federal Securities Class Action"). The Lead Plaintiffs in the consolidated matter are Nova Scotia Health Employees' Pension Plan and The City of Fort Lauderdale Police & Firefighters' Retirement System. The defendants filed a motion to dismiss on May 19, 2022 and the Lead Plaintiff filed an opposition to that motion on July 19, 2022. A hearing on the motion to dismiss was conducted on April 19, 2023 and a decision on the motion is expected in the coming months. The defendants believe that the allegations in the complaints are without merit and intend to defend the matters vigorously. Given the uncertainty of litigation, the preliminary stage of the cases, and the legal standards that must be met for, among other things, class certification and success on the merits, the Company cannot reasonably estimate the possible loss or range of loss, if any, that may result from the consolidated action.

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

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

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

In addition to the above actions, the Company has received inquiries and subpoenas to produce documents related to these matters from the Department of Justice, the SEC, the Maryland Attorney General's Office, and the New York Attorney General's Office. The Company produced or is producing documents as required in response and will continue to cooperate with these government inquiries. The Company also received inquiries and subpoenas from Representative Carolyn Maloney and Representative Jim Clyburn, members of the House Committee on Oversight and Reform and the Select Subcommittee on the Coronavirus Crisis and Senator Murray of the Committee on Health, Education, Labor and Pensions. The Company produced documents and provided testimony and briefings as requested in response to these inquiries.

17. Segment information

The Company reports segment information based on the internal reporting used by management for making decisions and assessing performance. We manage our business with a focus on two reportable segments. Our Products segment, which includes the Anthrax - MCM products, NARCAN products, Smallpox - MCM products and Other products, and our Services segment consisting of our CDMO services. The Company evaluates the performance of these reportable segments based on revenue and Adjusted Gross Margin, which is a non-GAAP financial measure. Segment revenue includes external customer sales, but it does not include inter-segment services. The Company defines Adjusted Gross Margin as segment revenue less segment cost of sales reduced for significant restructuring events, inventory step-up provisions and changes in fair value of contingent consideration. The Company does not allocate research and development, selling, general and administrative costs, amortization of intangibles assets, interest and other income (expense) or taxes to operating segments in the management reporting reviewed by the chief operating decision maker ("CODM"). The accounting policies for segment reporting are the same as for the Company as a whole.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Products	$ 302.2	$ 237.2	$ 445.6	$ 474.3
Services	29.1	(1.8)	44.3	59.0
Total segment revenues	331.3	235.4	489.9	533.3
Contracts and grants revenues	6.6	7.3	13.1	16.9
Total revenues	$ 337.9	$ 242.7	$ 503.0	$ 550.2
Less: Cost of sales:				
Cost of Products	$ 134.9	$ 91.0	$ 237.8	171.3
Cost of Services	55.7	78.8	107.9	154.4
Total cost of sales	$ 190.6	$ 169.8	$ 345.7	$ 325.7
Products gross margin	$ 167.3	$ 146.2	$ 207.8	$ 303.0
Services gross margin	$ (26.6)	$ (80.6)	$ (63.6)	$ (95.4)
Consolidated gross margin[1]	$ 140.7	$ 65.6	$ 144.2	$ 207.6
Adjustments to gross margin:				
Products:				
Changes in fair value of contingent consideration	$ 0.4	$ 1.3	$ 1.9	$ 1.8
Restructuring costs	—	—	2.0	—
Inventory step-up provision	1.9	—	1.9	—
Products adjusted gross margin	$ 169.6	$ 147.5	$ 213.6	$ 304.8
Services adjusted gross margin	$ (26.6)	$ (80.6)	$ (63.6)	$ (95.4)
Consolidated adjusted gross margin[2]	$ 143.0	$ 66.9	$ 150.0	$ 209.4
Other reconciling items:				
Contracts and grants revenue	$ 6.6	$ 7.3	$ 13.1	$ 16.9
Adjustments to gross margin	(2.3)	(1.3)	(5.8)	(1.8)
Impairment of long-lived assets	(306.7)	—	(306.7)	—
Research and development	(26.0)	(49.8)	(66.6)	(96.2)
Selling, general and administrative	(91.4)	(81.1)	(191.9)	(165.9)
Amortization of intangible assets	(16.1)	(14.0)	(33.1)	(28.0)
Interest expense	(28.6)	(7.8)	(46.5)	(16.0)
Gain on sale of business	74.9	—	74.9	—
Other, net	(3.6)	(3.0)	1.3	(5.0)
Loss before income taxes	$ (250.2)	$ (82.8)	$ (411.3)	$ (86.6)

[1] Total segment revenues less total cost of sales.

[2] Consolidated gross margin plus adjustments to gross margin.

The following table includes depreciation expense for each segment:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Depreciation:				
Products	$ 7.5	$ 6.7	$ 15.5	$ 14.1
Services	8.4	20.8	16.3	28.6
Other	0.9	1.0	2.6	2.4
Total	$ 16.8	$ 28.5	$ 34.4	$ 45.1

18. Subsequent events

FDA Approval of CYFENDUS

On July 20, 2023, the FDA approved CYFENDUS™ for post-exposure prophylaxis of disease following suspected or confirmed exposure to Bacillus anthracis in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs. In December 2018, CYFENDUS vaccine was the subject of a pre-emergency use authorization package submitted to the FDA. The following year, the USG began procuring this product for national preparedness efforts.

Ebanga Procurement Contract

On July 31, 2023, the Company was awarded a 10-year contract by the Biomedical Advanced Research and Development Authority ("BARDA") for advanced development, manufacturing scale-up, and procurement of Ebanga™ treatment for Ebola. The contract consists of a base period of performance with two option periods valued at approximately $121 million, and five option periods for procurement of Ebanga™ over five years valued at up to $583 million. If all option periods are exercised, the total contract value will be valued at up to approximately $704 million.

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

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

August 2023 Organizational Restructuring Plan

On August 8, 2023, The Company announced an organizational restructuring plan (the “August 2023 Plan”) 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. The August 2023 Plan includes a reduction of the Company’s current workforce by approximately 400 employees. Decisions regarding the elimination of positions are subject to local law and consultation requirements in certain countries, as well as the Company’s business needs.

The Company estimates that it will incur approximately $19.0 million to $21.0 million in charges in connection with the August 2023 Plan, which it expects to incur in the third quarter of fiscal 2023. These charges consist primarily of cash charges related to severance (base bonus), transition services, and estimated benefits cost.

The estimates of the charges and expenditures that the Company expects to incur in connection with the August 2023 Plan, and the timing thereof, are subject to a number of assumptions, including local law requirements in various jurisdictions, and actual amounts may differ materially from estimates. In addition, the Company may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the August 2023 Plan.

ITEM 2. 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 unaudited condensed consolidated financial statements and accompanying notes and other financial information included elsewhere in this quarterly report on Form 10-Q and our audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, 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 "Special Note Regarding Forward-Looking Statements" section of this Quarterly Report on Form 10-Q and the "Risk Factor Summary" and "Risk Factors" sections in Part I, Item 1A of our Annual Report on Form 10-K for our fiscal year ended December 31, 2022 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

BUSINESS OVERVIEW

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

We are currently focused on the following four PHT categories: chemical, biological, radiological, nuclear and explosives ("CBRNE"); emerging infectious diseases ("EID"); public health crises; and acute, emergency and community care. We have a product portfolio of 12 products that contribute a substantial portion of our revenue and are sold to government and commercial customers. Additionally, we have a development pipeline consisting of a diversified mix of both pre-clinical and clinical stage product candidates. Finally, we have a fully integrated portfolio of CDMO services. Our CDMO service offerings cover development services, drug substance manufacturing and drug product manufacturing and packaging.

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

Products Segment:

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

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.

NARCAN

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

Smallpox - MCM Products

- ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live), the only single-dose smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection;
- CNJ-016® (Vaccinia Immune Globulin Intravenous (Human) (VIGIV)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination; and
- TEMBEXA®, an oral antiviral formulated as 100 mg tablets and 10 mg/mL oral suspension dosed once weekly for two weeks which has been approved by the FDA for the treatment of smallpox disease caused by variola virus in adult and pediatric patients, including neonates.

Other Products

- BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)), the only heptavalent antitoxin licensed by the FDA and Health Canada for the treatment of symptomatic botulism;
- Ebanga™ (ansuvimab-zykl), a monoclonal antibody with antiviral activity provided through a single IV infusion for the treatment of Ebola. Under the terms of a collaboration with Ridgeback Biotherapeutics ("Ridgeback"). Emergent will be responsible for the manufacturing, sale, and distribution of Ebanga™ in the U.S. and Canada, and Ridgeback will serve as the global access partner for Ebanga™;
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only medical device cleared by the FDA that is intended to remove or neutralize chemical warfare agents from the skin, including: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin; and
- Trobigard® atropine sulfate, obidoxime chloride auto-injector, a combination drug-device auto-injector procured product candidate that contains atropine sulfate and obidoxime chloride. It was approved in Belgium in 2021 but has not been approved by the FDA. Trobigard is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure outside of the U.S.

Services Segment:

Services - Contract Development and Manufacturing

Our services revenue consists of distinct but interrelated CDMO services: drug substance manufacturing; drug product manufacturing (also referred to as "fill/finish" services) and packaging; development services including technology transfer, process and analytical development services; and, when necessary, suite reservation obligations. These services, which we refer to as "molecule-to-market" offerings, employ diverse technology platforms (mammalian, microbial, viral and plasma) across a network of nine geographically distinct development and manufacturing sites operated by us for our internal products and pipeline candidates and third-party CDMO services. We service both clinical-stage and commercial-stage projects for a variety of third-party customers, including government agencies, innovative pharmaceutical companies, and non-government organizations.

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 eliminated approximately five percent of its total headcount. The Company incurred approximately $9.6 million in charges in connection with the January 2023 Plan during the six months ended June 30, 2023. These charges consist primarily of charges related to employee transition, severance payments and employee benefits. All activities related to the January 2023 Plan were substantially completed during the first quarter of 2023.

Sale of Travel Health Business to Bavarian Nordic

On May 15, 2023, pursuant to the Purchase and Sale Agreement (the "Purchase and Sale Agreement"), by and between the Company, through its wholly owned subsidiaries Emergent International Inc. and Emergent Travel Health Inc., and Bavarian Nordic, the Company completed the previously announced sale of the Company's travel health business, including rights to Vivotif®, 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 $270.0 million, exclusive of customary closing adjustments for cash, indebtedness, working capital and transaction expenses of the business at closing. Bavarian Nordic may also be required to pay milestone payments of up to $80.0 million related to the development of CHIKV VLP and receipt of marketing approval and authorization in the U.S. and Europe, and earn-out payments of up to $30.0 million based on aggregate net sales of Vaxchora and Vivotif in calendar year 2026.

As a result of the divestiture, the Company recognized a pre-tax gain of $74.9 million during the quarter, net of transaction costs of $4.0 million, which was recorded within "Gain on sale of business" on the Condensed Consolidated Statements of Operations.

FDA Approval of CYFENDUS

On July 20, 2023, the FDA approved CYFENDUS™ for post-exposure prophylaxis of disease following suspected or confirmed exposure to Bacillus anthracis in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs. In December 2018, CYFENDUS vaccine was the subject of a pre-emergency use authorization package submitted to the FDA. The following year, the USG began procuring this product for national preparedness efforts.

Ebanga Procurement Contract

On July 31, 2023, the Company was awarded a 10-year contract by the Biomedical Advanced Research and Development Authority ("BARDA") for advanced development, manufacturing scale-up, and procurement of Ebanga™ treatment for Ebola. The contract consists of a base period of performance with two option periods valued at approximately $121 million, and five option periods for procurement of Ebanga™ over five years valued at up to $583 million. If all option periods are exercised, the total contract value will be valued at up to approximately $704 million.

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

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

Impairment of long-lived assets

The Company tests its long-lived assets that are held and used for recoverability whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. During the preparation of our financial statements for the three months ended June 30, 2023, due to deterioration in performance and resulting downward revisions to our internal CDMO forecast made during the second quarter, including future expected cash flows, the Company determined there were sufficient indicators of impairment on certain asset groups within the CDMO reporting unit to require an impairment analysis. As a result, the Company performed recoverability tests on certain asset groups within the CDMO 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 this analysis, the Company allocated and recognized a non-cash impairment charge of $306.7 million during the three months ended June 30, 2023.

August 2023 Organizational Restructuring Plan

On August 8, 2023, The Company announced an organizational restructuring plan (the “August 2023 Plan”) 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. The August 2023 Plan includes a reduction of the Company’s current workforce by approximately 400 employees. Decisions regarding the elimination of positions are subject to local law and consultation requirements in certain countries, as well as the Company’s business needs.

The Company estimates that it will incur approximately $19.0 million to $21.0 million in charges in connection with the August 2023 Plan, which it expects to incur in the third quarter of fiscal 2023. These charges consist primarily of cash charges related to severance (base bonus), transition services, and estimated benefits cost.

The estimates of the charges and expenditures that the Company expects to incur in connection with the August 2023 Plan, and the timing thereof, are subject to a number of assumptions, including local law requirements in various jurisdictions, and actual amounts may differ materially from estimates. In addition, the Company may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the August 2023 Plan.

FINANCIAL OPERATIONS OVERVIEW

Revenues

We generate 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 ("SNS"), a national repository of medical countermeasures including critical antibiotics, vaccines, chemical antidotes, antitoxins, and other critical medical supplies. The USG primarily purchases our products under long-term, firm fixed-price procurement contracts, generally with annual options. Our opioid overdose treatment product, NARCAN® Nasal Spray, is sold commercially through wholesalers and distributors, physician-directed or standing order prescriptions at retail pharmacies and to state and local community healthcare agencies, practitioners and hospitals.

We also generate revenue from our CDMO services, which is based on our established development and manufacturing infrastructure, technology platforms and expertise. Our services include a fully integrated molecule-to-market CDMO services business offering across development services, drug substance and drug product for small to large pharmaceutical and biotechnology industry and government agencies/non-governmental organizations. From time to time, clients require suite reservations at our various manufacturing sites, which may be considered leases depending on the facts and circumstances.

We have received contracts and grant funding from the USG and other non-governmental organizations to perform research and development ("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 CDMO services

Products - The primary expenses that we incur to deliver our products consist of fixed and variable costs. We determine the cost of product sales for products sold during a reporting period based on the average manufacturing cost per unit in the period those units were manufactured. Fixed manufacturing costs include facilities and utilities costs. Variable manufacturing costs primarily consist of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff, contract manufacturing operations, sales-based royalties, shipping and logistics. In addition to the fixed and variable manufacturing costs described above, the cost of product sales depends on utilization of available manufacturing capacity. For our commercial sales, other associated expenses include sales-based royalties (which include fair value adjustments associated with contingent consideration), shipping, and logistics.

Services - The primary expenses that we incur to deliver our CDMO services consist of fixed and variable costs, including personnel, equipment, and facilities costs. Our manufacturing process includes the production of bulk material and performing drug product work for containment and distribution of biological products. For drug product customers, we receive work in process inventory to be prepared for distribution.

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 of CDMO services for our clinical trial material; and
- costs of materials intended for use and used in clinical trials and R&D.

In many cases, we seek funding for development activities from external sources and third parties, such as governments and non-governmental organizations, or through collaborative partnerships. We expect our R&D spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of R&D spending, the number of product

candidates under development, the size, structure and duration of any clinical programs that we may initiate, the costs associated with manufacturing and development of our product candidates on a large-scale basis for later stage clinical trials, and our ability to use or rely on data generated by government agencies.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of personnel-related costs and professional fees in support of our executives, sales and marketing, business development, government affairs, finance, accounting, information technology, legal, human resource functions and other corporate functions. Other costs include facility costs not otherwise included in cost of product sales and CDMO services or R&D expense.

Income taxes

Uncertainty in income taxes is accounted for using a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We recognize in our financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position.

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S., requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenues and expenses. Actual results may differ from these estimates. There have been no significant changes to our critical accounting policies and estimates contained in "Critical Accounting Policies and Estimates" in the Management's Discussion and Analysis, in Part II, Item 7, of our Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC.

New accounting standards

For a discussion of new accounting standards please see Note 2, "Summary of significant accounting policies", in Part I item 1, of this Quarterly Report on Form 10-Q.

RESULTS OF OPERATIONS

(in millions, except %)	Three Months Ended June 30, 2023	2022	$ Change	% Change	Six Months Ended June 30, 2023	2022	$ Change	% Change
Revenues								
Product sales, net:								
Anthrax MCM	$ 21.2	$ 95.8	$ (74.6)	(78) %	$ 43.1	$ 205.2	$ (162.1)	(79) %
NARCAN	133.9	101.6	32.3	32 %	234.3	194.6	39.7	20 %
Smallpox MCM	123.9	16.0	107.9	NM	131.1	39.4	91.7	NM
Other Products sales	23.2	23.8	(0.6)	(3) %	37.1	35.1	2.0	6 %
Total product sales, net	302.2	237.2	65.0	27 %	445.6	474.3	(28.7)	(6) %
Contract development and manufacturing ("CDMO"):								
Services	26.4	2.7	23.7	NM	39.8	54.5	(14.7)	(27) %
Leases	2.7	(4.5)	7.2	160 %	4.5	4.5	—	— %
Total CDMO revenues	29.1	(1.8)	30.9	NM	44.3	59.0	(14.7)	(25) %
Contracts and grants	6.6	7.3	(0.7)	(10) %	13.1	16.9	(3.8)	(22) %
Total revenues	337.9	242.7	95.2	39 %	503.0	550.2	(47.2)	(9) %
Operating expenses:								
Cost of product sales	134.9	91.0	43.9	48 %	237.8	171.3	66.5	39 %
Cost of CDMO	55.7	78.8	(23.1)	(29 %)	107.9	154.4	(46.5)	(30 %)
Impairment of long-lived assets	306.7	—	306.7	NM	306.7	—	306.7	NM
Research and development	26.0	49.8	(23.8)	(48 %)	66.6	96.2	(29.6)	(31 %)
Selling, general and administrative	91.4	81.1	10.3	13 %	191.9	165.9	26.0	16 %
Amortization of intangible assets	16.1	14.0	2.1	15 %	33.1	28.0	5.1	18 %
Total operating expenses	630.8	314.7	316.1	100 %	944.0	615.8	328.2	53 %
Loss from operations	(292.9)	(72.0)	(220.9)	NM	(441.0)	(65.6)	(375.4)	NM
Other income (expense):								
Interest expense	(28.6)	(7.8)	(20.8)	NM	(46.5)	(16.0)	(30.5)	191 %
Gain on sale of business	74.9	—	74.9	NM	74.9	—	74.9	NM
Other, net	(3.6)	(3.0)	(0.6)	(20 %)	1.3	(5.0)	6.3	(126 %)
Total other income (expense), net	42.7	(10.8)	53.5	NM	29.7	(21.0)	50.7	NM
Loss before income taxes	(250.2)	(82.8)	(167.4)	NM	(411.3)	(86.6)	(324.7)	NM
Income tax provision (benefit)	11.1	(26.4)	37.5	(142 %)	33.0	(26.5)	59.5	NM
Net loss	$ (261.3)	$ (56.4)	$ (204.9)	NM	$ (444.3)	$ (60.1)	$ (384.2)	NM

NM - Not meaningful

Three Months Ended June 30, 2023 Compared with Three Months Ended June 30, 2022

Revenues and gross margin

Total revenues increased $95.2 million, or 39%, to $337.9 million for the three months ended June 30, 2023. The increase was due to increases in Products revenue of $65.0 million and Services revenue of $30.9 million, partially offset by a decrease in Contracts and grants revenue of $0.7 million.

Consolidated gross margin increased $75.1 million, or 114%, to $140.7 million for the three months ended June 30, 2023. Consolidated gross margin percentage increased 15 percentage points to 42.5% for the three months ended June 30, 2023. These increases were due to increases in Products gross margin of $21.1 million and Services gross margin of $54.0 million. Consolidated gross margin percentage excludes contracts and grants revenues because the related costs are R&D expenses.

See "Segment Results" for an expanded discussion of revenues and gross profit margin.

Impairment of long-lived assets

The Company recorded a non-cash impairment charge of $306.7 million during the three months ended June 30, 2023 related to certain asset groups within our CDMO 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.

Prior to recording the impairment charge, the Company performed recoverability tests on the impacted asset groups within the CDMO reporting unit and concluded that the asset groups were not recoverable as the undiscounted expected cash flows did not exceed their carrying values. The indicators for the impairment were related to the deterioration in performance and resulting downward revisions to our internal CDMO forecasts, including future expected cash flows, that took place during the preparation of our financial statements for the three months ended June 30, 2023.

Unallocated corporate operating expenses

R&D expenses

R&D expenses decreased $23.8 million, or 48%, to $26.0 million for the three months ended June 30, 2023. The decrease was primarily due to the sale of our development program for CHIKV VLP to Bavarian Nordic, which was a significant contributor to prior period R&D expense.

Selling, general and administrative expenses

Selling, general and administrative expenses increased $10.3 million, or 13%, to $91.4 million for the three months ended June 30, 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. Selling, general and administrative costs as a percentage of total revenue decreased 6.4% to 27.0% for the three months ended June 30, 2023.

Amortization of intangible assets

Amortization of intangible assets increased $2.1 million, or 15%, to $16.1 million for the three months ended June 30, 2023. The increase was primarily due to amortization expense for intangible assets related to TEMBEXA, which was newly acquired in the third quarter of 2022 and did not factor into the prior period. The increase was partially offset by a decrease in amortization expense resulting from the intangibles sold with our travel health business to Bavarian Nordic.

Interest expense

Interest expense increased $20.8 million to $28.6 million for the three months ended June 30, 2023. The increase was primarily due to higher interest costs related to our syndicated borrowings and one-time debt service costs attributable to the negotiation of the Credit Agreement Amendment, partially offset by a decrease related to the termination of our interest rate swap hedging agreements.

Gain on sale of business

Gain on sale of business was $74.9 million for the three months ended June 30, 2023, which was attributable to the sale of our travel health business to Bavarian Nordic on May 15, 2023.

Other, net

Other, net increased $0.6 million to $3.6 million in expense for the three months ended June 30, 2023. The increase was primarily due to a decrease in interest income due to lower cash balances, partially offset by an increase from favorable foreign exchange revaluations.

Income tax provision (benefit)

Income tax provision increased $37.5 million to $11.1 million for the three months ended June 30, 2023. The increase was primarily due to a valuation allowance charge.

Six Months Ended June 30, 2023 Compared with Six Months Ended June 30, 2022

Revenues and gross margin

Total revenues decreased $47.2 million, or 9%, to $503.0 million for the six months ended June 30, 2023. The decrease was due to declines in Total product sales of $28.7 million, Services revenue of $14.7 million and contracts and grants revenue of $3.8 million.

Consolidated gross margin decreased $63.4 million, or 31%, to $144.2 million for the six months ended June 30, 2023. Consolidated gross margin percentage decreased 9 percentage points to 29.4% for the six months ended June 30, 2023. The decrease was due to a decrease in Products gross margin of $95.2 million, partially offset by an increase in Services gross margin of $31.8 million. Consolidated gross margin percentage excludes contracts and grants revenues because the related costs are R&D expenses.

See "Segment Results" for an expanded discussion of revenues and gross profit margin.

Impairment of long-lived assets

During the six months ended June 30, 2023, we recognized a non-cash impairment charge of $306.7 million. See the three months ended June 30, 2023 explanation above for more details related to the reason for the impairment charge.

Unallocated corporate operating expenses

R&D expenses

R&D expenses decreased $29.6 million, or 31%, to $66.6 million for the six months ended June 30, 2023. The decrease was primarily due to the sale of our development program for CHIKV VLP to Bavarian Nordic, which was a significant contributor to prior period R&D expense.

Selling, general and administrative expenses

Selling, general and administrative expenses increased $26.0 million, or 16%, to $191.9 million for the six months ended June 30, 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. Selling, general and administrative costs as a percentage of total revenue increased 8.0% to 38.2% for the six months ended June 30, 2023.

Amortization of intangible assets

Amortization of intangible assets increased $5.1 million, or 18%, to $33.1 million for the six months ended June 30, 2023. The increase was primarily due to amortization expense for intangible assets related to TEMBEXA, which was acquired in the third quarter of 2022 and did not factor into the prior period. The increase was partially offset by a decrease in amortization expense resulting from the intangibles sold with our travel health business to Bavarian Nordic.

Interest expense

Interest expense increased $30.5 million, or 191%, to $46.5 million for the six months ended June 30, 2023. The increase was primarily due to higher interest costs related to our syndicated borrowings and one-time debt service costs attributable to the negotiation of the Credit Agreement Amendment, partially offset by a decrease related to the termination of our interest rate swap hedging agreements.

Other, net

Other, net decreased $6.3 million to $1.3 million in income for the six months ended June 30, 2023. The decrease was primarily due to higher interest rates, partially offset by lower average cash balances during the period.

Gain on sale of business

Gain on sale of business was $74.9 million for the six months ended June 30, 2023, which was attributable to the sale of our travel health business to Bavarian Nordic on May 15, 2023.

Income tax provision (benefit)

Income tax provision increased $59.5 million to $33.0 million for the six months ended June 30, 2023. The increase was largely due to the decline in income before income taxes and a valuation allowance charge in the second quarter of 2023. The effective tax rate was (8)% for the six months ended June 30, 2023 as compared with 31% in 2022. The effective annual tax rate decreased largely due to a valuation charge.

SEGMENT RESULTS

PRODUCTS SEGMENT

	Products Segment					
	Three Months Ended June 30,			Six Months Ended June 30,		
(dollars in millions)	2023	2022	% Change	2023	2022	% Change
Revenues						
Product sales, net	$ 302.2	$ 237.2	27 %	$ 445.6	$ 474.3	(6 %)
Cost of sales	$ 134.9	$ 91.0	48 %	$ 237.8	$ 171.3	39 %
Less: Changes in fair value of contingent consideration	0.4	1.3	(69 %)	1.9	1.8	6 %
Less: Restructuring costs	—	—	NM	2.0	—	NM
Less: Inventory step-up provision	1.9	—	NM	1.9	—	NM
Adjusted cost of sales [1]	$ 132.6	$ 89.7	48 %	$ 232.0	$ 169.5	37 %
Gross margin [2]	$ 167.3	$ 146.2	14 %	$ 207.8	$ 303.0	(31 %)
Gross margin % [2]	55 %	62 %		47 %	64 %	
Adjusted gross margin [3]	$ 169.6	$ 147.5	15 %	$ 213.6	$ 304.8	(30 %)
Adjusted gross margin % [3]	56 %	62 %		48 %	64 %	

[1] Adjusted cost of sales, which is a non-GAAP financial measure, is calculated as cost of sales less restructuring costs and other special items and non-cash items related to changes in fair value of contingent consideration and inventory step-up provision. The Company's management utilizes Adjusted cost of sales for purposes of evaluating our ongoing operations and for internal planning and forecasting purposes. We believe that this non-GAAP operating measure, when reviewed collectively with our GAAP financial information, provides useful supplementary information to investors in assessing our operating performance.

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

[3] Adjusted gross margin, which is a non-GAAP financial measure, is calculated as revenues less Adjusted cost of sales. Adjusted gross margin %, which is a non-GAAP financial measure, is calculated as Adjusted gross margin divided by revenues. The Company’s management utilizes Adjusted gross margin and Adjusted gross margin % for purposes of evaluating our ongoing operations and for internal planning and forecasting purposes. We believe that these non-GAAP operating measures, when reviewed collectively with our GAAP financial information, provide useful supplemental information to investors in assessing our operating performance.

NM - Not meaningful

Three Months Ended June 30, 2023 Compared with Three Months Ended June 30, 2022

Anthrax MCM

Anthrax MCM sales decreased $74.6 million, or 78%, to $21.2 million for the three months ended June 30, 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 of USG purchases, the availability of governmental funding and Company delivery of orders that follow.

NARCAN

NARCAN sales increased $32.3 million, or 32%, to $133.9 million for the three months ended June 30, 2023. The increase was primarily driven by higher branded NARCAN sales to U.S. public interest channels and Canadian retail sales, 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.

Smallpox MCM

Smallpox MCM sales increased $107.9 million to $123.9 million for the three months ended June 30, 2023. The increase was primarily due to the exercise and full delivery in the quarter of a $120 million option by the USG to purchase ACAM2000, under which we delivered the full amount, partially offset by lower VIG sales due to timing. 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 Company delivery of orders that follow.

Other Products

Other Products sales decreased $0.6 million, or 3%, to $23.2 million for the three months ended June 30, 2023. The decrease was primarily due to lower BAT product sales, partially offset by higher RSDL sales, due to timing.

Cost of Sales and Gross Margin

Cost of product sales increased $43.9 million, or 48%, to $134.9 million for the three months ended June 30, 2023. The increase was primarily due to higher sales of ACAM2000 and NARCAN, partially offset by lower sales of CYFENDUS, coupled with higher allocations to product COGS at our Bayview facility and an increase in Trobigard inventory related costs.

Product gross margin increased $21.1 million, or 14%, to $167.3 million for the three months ended June 30, 2023. Product gross margin percentage decreased 7 percentage points to 55% for the three months ended June 30, 2023. The decrease in gross margin percentage was largely due to increases in shutdown related costs and inventory write-offs. Product adjusted gross margin excludes the impacts of non-cash items related to the inventory step-up provision of $1.9 million and the changes in the fair value of contingent consideration of $0.4 million.

Six Months Ended June 30, 2023 Compared with Six Months Ended June 30, 2022

Anthrax MCM

Anthrax MCM sales decreased $162.1 million, or 78%, to $43.1 million for the six months ended June 30, 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 of USG purchases, the availability of governmental funding and Company delivery of orders that follow.

NARCAN

NARCAN sales increased $39.7 million, or 20%, to $234.3 million for the six months ended June 30, 2023. The increase was primarily driven by higher branded NARCAN sales to U.S. public interest channels and Canadian retail sales, 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.

Smallpox MCM

Smallpox MCM sales increased $91.7 million to $131.1 million for the six months ended June 30, 2023. The increase was primarily due to the exercise and full delivery in the quarter of a $120 million option by the USG to purchase ACAM2000, under which we delivered the full amount, partially offset by lower VIG sales due to timing. 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 Company delivery of orders that follow.

Other Products

Other Products sales increased $2.0 million, or 6%, to $37.1 million for the six months ended June 30, 2023. The increase was primarily due to higher Vivotif and Vaxchora product sales, partially offset by lower RSDL and BAT product sales, due to timing.

Cost of Sales and Gross Margin

Cost of product sales increased $66.5 million, or 39%, to $237.8 million for the six months ended June 30, 2023. The increase was primarily due to higher sales of ACAM2000 and NARCAN, partially offset by lower sales of CYFENDUS, coupled with higher allocations to product COGS at our Bayview facility, shutdown costs and inventory write-offs.

Product gross margin decreased $95.2 million, or 31%, to $207.8 million for the six months ended June 30, 2023. Product gross margin percentage decreased 17 percentage points to 47% for the six months ended June 30, 2023. The decrease was largely due to lower sales volumes and higher shutdown related costs and inventory write-offs. Product adjusted gross margin excludes the impacts of restructuring costs of $2.0 million, non-cash items related to the inventory step-up provision of $1.9 million and the changes in the fair value of contingent consideration of $1.9 million.

SERVICES SEGMENT

	Services Segment					
	Three Months Ended June 30,			Six Months Ended June 30,		
(dollars in millions)	2023	2022	% Change	2023	2022	% Change
Revenues						
CDMO revenues	$ 29.1	$ (1.8)	NM	$ 44.3	$ 59.0	(25 %)
Cost of services	$ 55.7	$ 78.8	(29 %)	$ 107.9	$ 154.4	(30 %)
Gross margin [1]	$ (26.6)	$ (80.6)	67 %	$ (63.6)	$ (95.4)	33 %
Gross margin % [1]	(91)%	NM		(144)%	(162)%	

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

NM - Not meaningful

Three Months Ended June 30, 2023 Compared with Three Months Ended June 30, 2022

CDMO revenues

CDMO services revenues increased $23.7 million to $26.4 million for the three months ended June 30, 2023. The increase was driven by a recognition of revenue related to the resolution of a customer's outstanding obligation and work at our Canton facility for a CDMO customer. In the prior year quarter, there was a reversal of revenue related to the halt in manufacturing under the Janssen Agreement.

CDMO lease revenues increased $7.2 million, or 160%, to $2.7 million for the three months ended June 30, 2023. The lease revenue in the current year quarter is related to a CDMO customer in our Canton facility. In the prior year quarter, we had a reversal of revenue recognized related to the Janssen Agreement termination.

Cost of Services and Gross Margin

Cost of services decreased $23.1 million, or 29%, to $55.7 million for the three months ended June 30, 2023. The decrease was primarily due to reduced production activities at our Bayview facility related to the halt in manufacturing under the Janssen Agreement, partially offset by higher costs at our Camden facility related to additional investments in quality enhancements and improvement initiatives as well as increased in production at our Canton facility related work for a CDMO customer.

Services gross margin increased $54.0 million to $(26.6) million for the three months ended June 30, 2023. Services gross margin percentage improved to (91)% for the three months ended June 30, 2023. The improvement was primarily due to one-time costs and reserves related to the Janssen Agreement in the prior year quarter, partially offset by additional investments in quality enhancement and improvement initiatives at the Company's Camden facility in the current year.

Six Months Ended June 30, 2023 Compared with Six Months Ended June 30, 2022

CDMO revenues

CDMO services revenues decreased $14.7 million, or 27%, to $39.8 million for the six months ended June 30, 2023. The decrease was driven by $10.9 million less revenue related to reduced production activities at the Company's Bayview facility as a result of a halt in manufacturing under the Janssen Agreement in 2022. Additionally, the decrease also reflects reduced production at the Camden facility. The decreases were slightly offset by an increase in production at our Canton facility for a CDMO customer.

CDMO lease revenues were consistent with prior year at $4.5 million for the six months ended June 30, 2023.

Cost of Services and Gross Margin

Cost of services decreased $46.5 million, or 30%, to $107.9 million for the six months ended June 30, 2023. The decrease was primarily due to reduced production activities across our CDMO network, 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 CDMO customer.

Services gross margin increased $31.8 million to $(63.6) million for the six months ended June 30, 2023. Services gross margin percentage improved 18 percentage points to (144)% for the six months ended June 30, 2023. The improvement was primarily due one-time costs and reserves related to the Janssen agreement in the prior year quarter, partially offset by the full six month impact of additional investments in quality enhancement and improvement initiatives at the Company's Camden facility in the current year.

OTHER REVENUE

Three Months Ended June 30, 2023 Compared with Three Months Ended June 30, 2022

Contracts and Grants

Contract and grants revenue decreased $0.7 million, or 10%, to $6.6 million for the three months ended June 30, 2023. The decrease was due to changes in the mix and timing of developmental initiatives.

Six Months Ended June 30, 2023 Compared with Six Months Ended June 30, 2022

Contracts and Grants

Contract and grants revenue decreased $3.8 million, or 22%, to $13.1 million for the six months ended June 30, 2023. The decrease was due to changes in the mix and timing of developmental initiatives.

FINANCIAL CONDITION, LIQUIDITY AND CAPITAL RESOURCES

Our financial condition is summarized as follows:

(dollars in millions)	June 30, 2023	December 31, 2022	Change %
Financial assets:			
Cash and cash equivalents	$ 88.6	$ 642.6	(86)%
Borrowings:			
Debt, current portion	$ 455.2	$ 957.3	(52)%
Debt, net of current portion	448.0	448.5	— %
Total borrowings	$ 903.2	$ 1,405.8	(36)%
Working capital:			
Current assets	$ 777.7	$ 1,210.7	(36)%
Current liabilities	693.2	1,229.9	(44)%
Total working capital	$ 84.5	$ (19.2)	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 our Revolving Credit Facility, our Term Loan Facility, and other lines of credit we have established from time to time. We also obtain financing from the sale of our common stock upon exercise of stock options and participation in an at-the market equity offering program (the "ATM Program"). As of June 30, 2023, we had unrestricted cash and cash equivalents of $88.6 million and remaining capacity under our Revolving Credit Facility of $49.3 million.

Going Concern

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

As of June 30, 2023, there is $250.2 million outstanding on our Revolving Credit Facility and $206.1 million on our Term Loan Facility that mature in May 2025. The Company determined that there is substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation considered the potential mitigating effect of management’s plans that have not been fully implemented. Management may evaluate the mitigating effect of its plans to determine if it is probable that (1) the plans will be effectively implemented within one year after the date the financial statements are issued, and (2) when implemented, the plans will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern. The Company's plans include (A) amending the agreement for the Senior Secured Credit Facilities, which occurred on May 15, 2023 with the Fourth Amendment to Amended and Restated Credit Agreement, Waiver and First Amendment to Amended and Restated Collateral Agreement (the “Credit Agreement Amendment”), and (B) the execution of the capital raise requirement prescribed in the Credit Agreement Amendment, as further described below.

While the Company executed the Credit Agreement Amendment and extended the maturity date on the Senior Secured Credit Facilities to May 15, 2025, the Credit Agreement Amendment also requires the Company to raise at least $75.0 million through the issuance of equity and/or unsecured indebtedness by April 30, 2024 and that we make quarterly principal payments on the Term Loan Facility of approximately $3.9 million commencing with the quarter ended June 30, 2023. As a result of this provision, the Company has determined it is appropriate to continue to classify the debt as a current liability on the condensed consolidated balance sheets. While the Company expects to complete these actions, management cannot make the assumption that it is probable that the Company will be successful. As a result, the Company continues to evaluate a number of uncertain factors related to its assessment of its ability to satisfy the capital raise requirement, including its ability to comply with the term and

operating and financial covenants required by the Senior Secured Credit Facilities, other market conditions, economic conditions, particularly in the pharmaceutical and biotechnology industry, disruptions or volatility caused by factors such as lingering impacts of the COVID-19 pandemic, regional conflicts, inflation, and supply chain disruptions.

The Company had $88.6 million of cash on hand at June 30, 2023. On January 9, 2023, the Company announced the 2023 Plan intended to reduce operating costs, improve operating margins, and continue advancing the Company's ongoing commitment to profitable growth. The Plan includes a reduction of the Company's current workforce by approximately five percent. These actions, in combination with other cost reduction initiatives, are expected to result in annualized savings of over $60.0 million when fully implemented.

At-the-Market Equity Offering Facility

We may, from time to time, sell up to $150.0 million aggregate gross sales price of shares of our common stock through Evercore Group L.L.C. and RBC Capital Markets, LLC, as sales agents, under an "at-the-market" equity offering program (the "ATM Program") that we entered into on May 18, 2023. During the three months ended June 30, 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 June 30, 2023, $140.9 million aggregate gross sales price of shares of our common stock remains available for issuance under the ATM Program. We intend to use proceeds obtained from the sale of shares under the ATM Program for general corporate purposes.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2023 and 2022:

(in millions)	Six Months Ended June 30, 2023	2022
Net cash provided by (used in):		
Operating activities	$ (298.4)	$ (52.9)
Investing activities	242.6	(64.3)
Financing activities	(497.4)	(101.2)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(0.8)	0.4
Net change in cash, cash equivalents and restricted cash	$ (554.0)	$ (218.0)

Operating Activities:

Net cash used in operating activities was $298.4 million for the six months ended June 30, 2023 compared with $52.9 million for the six months ended June 30, 2022. The increase of $245.5 million in net cash used in operating activities was primarily due to net loss excluding non-cash items of $116.4 million, including impairment of long-lived asset charges of $306.7 million, coupled with negative working capital changes of $182.0 million, primarily due to increases in receivables, an accumulation of inventory and prepaid expenses, and an increase in payments for taxes, partially offset by an increase in our accounts payable.

Investing Activities:

Net cash provided by investing activities was $242.6 million for the six months ended June 30, 2023 compared with net cash used in investing activities of $64.3 million for the six months ended June 30, 2022. The increase of $306.9 million in net cash provided by investing activities was primarily due to proceeds from the sale of the travel health business during the second quarter of 2023, partially offset by purchases of property, plant and equipment.

Financing Activities:

Net cash used in financing activities was $497.4 million for the six months ended June 30, 2023 compared with $101.2 million for the six months ended June 30, 2022. The increase of $396.2 million in net cash used in financing activities was primarily due to principal payments on the Senior Secured Credit Facilities, partially offset by proceeds from the sale of stock through our ATM Program.

Debt

As of June 30, 2023, the Company has $909.3 million of fixed and variable rate debt with varying maturities. See Note 10, "Debt" in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q) for further discussion.

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 CDMO services;
- development contracts and grant funding;
- proceeds from the sale of our common stock through the ATM Program; and
- our Senior Secured Credit Facilities and any replacement or other lines of credit we may establish from time to time.

There are numerous risks and uncertainties associated with product sales and with the development and commercialization of our product candidates. We may seek additional external financing to provide additional financial flexibility. Our future capital requirements will depend on many factors, including (but not limited to):

- the level, timing and cost of product sales and CDMO services;
- the extent to which we acquire or invest in and integrate companies, businesses, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs; and
- the costs of commercialization activities, including product marketing, sales and distribution.

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

If we raise funds by issuing equity securities, including through the ATM Program, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our 3.875% Senior Unsecured Notes due 2028 (the "Senior Unsecured Notes") and the Senior Secured Credit Facilities, which could limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities, buying back shares or declaring dividends. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

Economic conditions, including market volatility and adverse impacts on financial markets as a result of the lingering impacts of the COVID-19 pandemic, may make it more difficult to obtain financing on attractive terms, or at all. Any new debt funding, if available, may be on terms less favorable to us than our Senior Secured Credit Facilities or the Senior Unsecured Notes. If financing is unavailable or lost, our business, operating results, financial condition and cash flows would be adversely affected, and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

Unused Credit Capacity

Available room under the Revolving Credit Facility as of June 30, 2023 and December 31, 2022 was:

(in millions)	June 30, 2023	December 31, 2022
Total Capacity	$ 300.0	$ 600.0
Less:		
Outstanding Letters of Credit	0.5	1.3
Outstanding Indebtedness	250.2	598.0
Unused Capacity	$ 49.3	$ 0.7

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For a discussion of additional risks arising from our operations, see “Item 1A-Risk Factors” of this Quarterly Report on Form 10-Q.

Market risk

We have interest rate and foreign currency market risk. Because of the short-term maturities of our cash and cash equivalents, we believe that an increase in market rates would likely not have a significant impact on the realized value of our investments.

Interest rate risk

We have debt with a mix of fixed and variable rates of interest. We terminated our interest rate swaps in June 2023, and we are satisfied with the current fix-float mix of the Company's debt portfolio. Floating rate debt carries interest based generally on the eurocurrency rate, as defined in our Amended Credit Agreement, plus an applicable margin. Increases in interest rates could result in an increase in interest payments for our floating rate debt.

We have assessed our exposure to changes in interest rates by analyzing the sensitivity to our operating results assuming various changes in market interest rates. A hypothetical increase of one percentage point in the eurocurrency rate as of June 30, 2023 would increase our interest expense by approximately $4.6 million annually.

Foreign currency exchange rate risk

We have exposure to foreign currency exchange rate fluctuations worldwide and primarily with respect to the Euro, Canadian dollar, Swiss franc and British pound. We manage our foreign currency exchange rate risk primarily by 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 practical. 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 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

Our management, with the participation of our interim chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (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 June 30, 2023, our interim chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting

There have been no changes in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act that occurred during the three months ended June 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 16, "Litigation" in Part I, item 1, of this Quarterly Report on Form 10-Q.

ITEM 1A. RISK FACTORS

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

RISK FACTOR SUMMARY

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

- Reduced demand for and/or funding for procurement of CYFENDUS and/or BioThrax vaccines or ACAM2000 and discontinuation of funding of our other USG procurement and development contracts.
- Inability to secure follow-on product procurement contracts with the USG upon the expiration of any of our existing procurement contracts.

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

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

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

- Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain.
- We may fail to capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.

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

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

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

- Development and commercialization of pharmaceutical products are subject to evolving private and public sector competition.
- NARCAN Nasal Spray is currently subject to branded and generic competition in the U.S. and may be subject to branded and generic competition in Canada. In addition, the success of NARCAN Nasal Spray is subject to our ability to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community.
- Biologic products may be affected by the approval and entry of follow-on biologics, or biosimilars in the United States and other jurisdictions.

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

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

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

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

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

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

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

- Our ability to maintain sufficient cash flow from our operations to pay our substantial debt, both now and in the future.
- Our ability to obtain additional funding and be able to raise capital when needed, including in order to be able to continue as a going concern.
- Our ability to comply with the covenants under our Revolving Credit Facility and Term Loan Facility and other debt agreements.

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

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

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

- Our business or our share price could be negatively affected as a result of the actions of shareholders.
- The price of our common stock has been and remains subject to extreme volatility.

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

GOVERNMENT CONTRACTING RISKS

We currently derive a substantial portion of our revenue from USG procurement of the CYFENDUS vaccine and the TEMBEXA (brincidofovir), oral antiviral and have historically derived a substantial portion of our revenue from USG procurement of the ACAM2000 vaccine and of BioThrax. If the USG's demand for and/or funding for procurement of CYFENDUS, BioThrax and/or ACAM2000 vaccines and/or TEMBEXA (brincidofovir), oral antiviral are substantially reduced, our business, financial condition, operating results and cash flows would be materially harmed.

We derive a substantial portion of our current and expected future revenues from USG procurement of CYFENDUS. As with any approved product, there is a risk that we may encounter challenges causing delays or an inability to deliver CYFENDUS, which may have a material effect on our ability to generate and recognize revenue.

The success of our business and our future operating results are significantly dependent on anticipated funding for the procurement of our anthrax vaccines and the terms of such procurement by the USG, including the price per dose, the number of doses and the timing of deliveries. We have no certainty that funding will be made available for the procurement of our anthrax vaccines. If priorities for the 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, in the past we have derived a substantial portion of our revenues from sales of ACAM2000 vaccine to the USG. If priorities for the SNS change with respect to ACAM2000 vaccine or the USG decides not to exercise additional options under our ACAM2000 contract, our future business, financial condition, operating results and cash flows could be materially harmed.

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. For example, the September 2016 contract award from BARDA for the development and delivery to the SNS of CYFENDUS for post-exposure prophylaxis of anthrax disease consists of a five-year base period of performance and includes options for the delivery of additional doses of CYFENDUS to the SNS and options for an additional clinical study and post-marketing commitments. This contract was extended in September 2021 through 2025 and provides for additional procurement of CYFENDUS for the SNS over 18 months. If levels of government expenditures and authorizations for public health

countermeasure preparedness decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the USG otherwise declines to exercise its options under our existing contracts, our revenues would suffer, as well as our business, financial condition, operating results and cash flows.

There can be no assurance that we will be able to secure follow-on product procurement contracts with the USG upon the expiration of any of our existing procurement contracts.

A significant portion of our revenue is substantially dependent upon product procurement contracts with the USG and foreign governments for our MCMs. Upon the expiration of a procurement contract, we may not be able to negotiate a follow-on procurement contract for the particular product on similar terms. We intend to negotiate follow-on procurement contracts for most of our MCMs upon the expiration of a related procurement contract, but there can be no assurance that we will be successful obtaining any follow-on contracts. Even if we are successful in negotiating a follow-on procurement contract, it may be for a lower product volume, over a shorter period of performance or be on less favorable pricing or other terms. An inability to secure follow-on procurement contracts for our approved products or product candidates could materially and adversely affect our revenues, and our business, financial condition, operating results and cash flows could be harmed.

The government contracting process is typically a competitive bidding process and involves unique risks and requirements.

Our business involves government contracts and grants, which may be awarded through competitive bidding. Competitive bidding for government contracts presents many risks and requirements, including:

- the possibility that we may be ineligible to respond to a request for proposal;
- the commitment of substantial time and attention of management and key employees to the preparation of bids and proposals;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- the submission by third parties of protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- in the event our competitors protest or challenge contract or grant awards made to us through competitive bidding, the potential that we may incur expenses or delays, and that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in the termination, reduction or modification of the awarded contract.

The USG may choose not to award us future contracts for either the development of our new product candidates or for the procurement of our existing MCM products and may instead award such contracts to our competitors. If we are unable to secure particular contracts, we may not be able to operate in the market for products that are provided under those contracts. Additionally, if we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs or resources that we will be required to secure and, if applicable, perform under such contract awards, our growth strategy and our business, financial condition and operating results and cash flows could be materially and adversely affected.

The amounts we are paid under our fixed price government procurement contracts are based on estimates we have made of the time, resources and expenses required for us to perform under those contracts. If our actual costs exceed our estimates, we may not be able to earn an adequate return or may incur a loss under these contracts, which could harm our operating results and materially reduce our net income.

Our current procurement contracts with the U.S. Department of Health ("HHS") and the U.S. Department of Defense ("DoD") are generally fixed price contracts. We expect that any future procurement contracts we successfully secure with the USG would likely also be fixed price contracts. Under a fixed price contract, we are required to deliver our products at a fixed price regardless of the actual costs we incur. Estimating costs that are related to performance in accordance with contract specifications is difficult, particularly where the period of performance is over several years, and when factoring in higher levels of inflation. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of such a contract or cause a loss, which could harm our operating results and materially reduce our net income.

Unfavorable provisions in government contracts, some of which may be customary, may subject our business to material limitations, restrictions and uncertainties and may have a material adverse impact on our business, financial condition, operating results and cash flows.

Government contracts customarily contain provisions that give the USG substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the USG to:

- terminate existing contracts, in whole or in part, for any reason;
- unilaterally reduce or modify contracts or subcontracts;
- decline, in whole or in part, to exercise an option to purchase product under a procurement contract or to fund additional development under a development contract;
- decline to renew a procurement contract;
- claim certain rights to facilities or to products, including intellectual property, developed under the contract;
- require repayment of contract funds spent on construction of facilities in the event of contract default;
- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- suspend or debar the contractor from doing business with the government or a specific government agency;
- pursue civil or criminal remedies under acts such as the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

Generally, government contracts contain provisions permitting unilateral termination or modification, in whole or in part, at the USG's convenience. Under general principles of government contracting law, if the USG terminates a contract for convenience, the government contractor may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the USG terminates a contract for default, the government contractor is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. All of our development and procurement contracts with the USG are terminable at their convenience with these potential consequences.

In addition, our USG contracts grant the USG the right to use technologies developed by us under the government contract or the right to share data related to our technologies, for or on behalf of the USG. Under our USG contracts, we may not be able to limit third parties, including our competitors, from accessing certain of these technology or data rights, including intellectual property, in providing products and services to the USG.

MANUFACTURING RISKS

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

The FDA conducts periodic inspections of our manufacturing facilities for compliance with current good manufacturing practices ("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 CDMO customers, which could adversely affect our business, financial condition, operating results and cash flows. For example, in February 2022, FDA inspected Emergent's Camden facility and issued a Form FDA 483. In August 2022, FDA issued a warning letter to Emergent related to the February 2022 inspection. The warning letter included issues pertaining to equipment cleaning and maintenance; aseptic sterilization technique and procedures; and quality systems. Emergent has responded to the warning letter and sends regular updates to the FDA on remediation activities and improvements. Emergent continues to make significant progress with, and is approaching completion of, the corrective and preventive action commitments in the Company's warning letter responses.

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

Any interruptions in our manufacturing operations could result in our inability to produce products and product candidates for delivery to satisfy the demands of our customers in a timely manner, which would reduce our revenues and materially harm our business, financial condition, operating results and cash flows. A number of factors could cause interruptions, including:

- equipment malfunctions or failures;
- technology malfunctions;

- cyber-attacks;
- work stoppages or slowdowns, particularly due to the impact of COVID-19;
- civil unrest and protests, including by animal rights activists;
- injunctions;
- damage to or destruction of our manufacturing equipment, or of one or more of our facilities;
- findings and recommendations of health authorities or qualified persons in connection with facility inspections;
- ongoing supply chain interruptions from the COVID-19 pandemic, including lower available plasma levels caused by the pandemic (which has the potential to impact our plasma based products); and
- product contamination or tampering.

The factors listed above could cause disruptions at any of our manufacturing facilities. We do not have any redundant manufacturing facilities for any of our products. Accordingly, any damage to, or disruption or destruction of one or more of our facilities could impede our ability to manufacture our products, and our product candidates and our ability to provide manufacturing and development services for external customers, result in losses and delays, including delays in the performance of our contractual obligations or delays in our clinical trials, any of which could be costly to us and materially harm our business, financial condition, operating results and cash flows.

Providers of MCMs could be subject to an increased risk of terrorist activities. The USG has designated both our Lansing, Michigan and our Bayview bulk manufacturing facility in Baltimore, Maryland as facilities requiring additional security. Although we continually evaluate and update security measures, there can be no assurance that any additional security measures would protect these facilities from terrorist efforts determined to disrupt our manufacturing activities.

Problems may arise during the production of our products and product candidates, as well as those we produce for our CDMO customers, due to the complexity of the processes involved in their development, manufacturing and shipment or other factors. Significant delays in product manufacturing or development and our ability to ramp up production to meet the needs of our customers could cause delays in recognizing revenues, which would harm our business, financial condition, operating results and cash flows.

The majority of our products and product candidates are biologics. Manufacturing biologics, especially in large quantities, is complex. The products must be made consistently and in compliance with a clearly-defined manufacturing process. Problems during manufacturing may arise for a variety of reasons, including problems with raw materials, equipment malfunction and failure to follow specific protocols and procedures. Slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation, contamination including from particulates among other things, filtration, filling, labeling, packaging, storage and shipping, potency and stability issues and other quality control testing, may result in lot failures or manufacturing shut-downs, delays in the release of lots, product recalls, spoilage or regulatory action. Such deviations may require us to revise manufacturing processes or change manufacturers. Additionally, as our equipment ages, it will need to be replaced, which has the potential to result in similar consequences. Success rates can also vary dramatically at different stages of the manufacturing process, which can reduce yields and increase costs. From time to time, we may experience deviations in the manufacturing process that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation, or other restrictions on the marketing or manufacturing of a product, any of which could be costly to us, damage our reputation and negatively impact our business. Regulatory action, including the issuance of Forms FDA 483 and warning letters can also have an impact.

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

We are contractually required to ship our biologic products at a prescribed temperature range and variations from that temperature range could result in loss of product and could significantly and adversely impact our revenues, which would harm our business, financial condition, operating results and cash flows.

In addition, we may not be able to ramp up our manufacturing processes to meet the rapidly changing demand or specifications of our customers on the desired timeframe, if at all. Our inability to ramp up manufacturing to meet the demand or

specifications of our customers or the inability to timely obtain regulatory authorization to produce the products or product candidates of our customers could also harm our business, financial condition, operating results and cash flows.

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

We are unable to sell any products and product candidates that fail to satisfy certain testing specifications. For example, we must provide the FDA with the results of certain tests, including potency tests, before certain lots are released for sale. Potency testing of each applicable lot is performed against qualified control lots that we maintain. We continually monitor the status of such reference lots for FDA compliance and periodically produce and qualify a new reference lot to replace the existing reference lot. If we are unable to satisfy USG requirements for the release of our products or product candidates, our ability to supply such products and product candidates to authorized buyers would be impaired until such time as we become able to meet such requirements, which could materially harm our future business, financial condition, operating results and cash flows.

Our operations, including our use of hazardous materials, chemicals, bacteria and viruses, require us to comply with regulatory requirements and expose us to significant potential liabilities.

Our operations involve the use of hazardous materials, including chemicals, bacteria and viruses, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf, are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. Under the Federal Select Agent Program, pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act, we are required to register with and be inspected by the CDC and the Animal and Plant Health Inspection Service if we have in our possession, or if we use or transfer, select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires stringent safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel and establishes a comprehensive national database of registered entities. We are also subject to a variety of environmental and occupational health and safety laws. Compliance with current or future laws and regulations in this area can require significant costs and we could be subject to substantial fines and penalties in the event of noncompliance. In addition, the risk of contamination or injury from these materials cannot be completely eliminated. In such event, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials. From time to time, we have been involved in remediation activities and may be so involved in the future. Any related cost or liability might not be fully covered by insurance, could exceed our resources and could have a material adverse effect on our business, financial condition, operating results and cash flows. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS, U.S. Department of Agriculture and the DoD, as well as regulatory authorities in Canada and Switzerland.

PRODUCT DEVELOPMENT AND COMMERCIALIZATION RISKS

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

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

Our growth depends on our success in developing and commercializing our product candidates. If we are unable to commercialize these product candidates or experience significant delays or unanticipated costs in doing so, our business would be materially and adversely affected.

We have invested significant efforts and financial resources in the development of our vaccines, therapeutics and medical device product candidates and the acquisition of additional product candidates. In addition to our product sales, our ability to generate revenue is dependent on a number of factors, including the success of our development programs, the USG's interest in providing development funding for or procuring certain of our product candidates, and the commercial viability of our acquired or developed product candidates. The commercial success of our product candidates can depend on many factors, including accomplishing the following in an economical manner:

- successful development, formulation and cGMP or QSR scale-up of manufacturing that meets FDA and/or foreign regulatory requirements;
- successful program partnering;
- successful completion of clinical or non-clinical development;
- receipt of marketing approvals, clearances, or other authorizations from the FDA and equivalent foreign regulatory authorities;
- establishment of commercial manufacturing processes and product supply arrangements;
- training of a commercial sales force for the product;
- successful registration and maintenance of relevant patent and/or other proprietary protection;
- competitive pricing and market access; and
- acceptance of the product by potential government and other customers.

In particular, the success of NARCAN Nasal Spray, including in over-the-counter form, is subject to 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 the trials;
- government or regulatory restrictions or delays; and
- greater than anticipated costs of trials.

Pre-clinical and clinical testing for certain of our MCM product candidates may face additional difficulties and uncertainties because they cannot ethically or feasibly be tested in human subjects. In the U.S. we expect to rely on the Animal Rule to obtain regulatory approval for some of our MCM product candidates. The Animal Rule permits, for certain limited diseases and circumstances, the use of animal efficacy studies, together with human clinical safety and immunogenicity trials, to support an application for marketing approval. For a product approved under the Animal Rule, certain additional post-marketing requirements apply. For example, to the extent feasible and ethical, applicants must conduct post-marketing clinical studies, such as field studies in the event of an outbreak or act of bioterrorism, to assess the drug's safety and effectiveness. It is possible that

results from the animal efficacy studies used to support approval under the Animal Rule may not be predictive of the actual efficacy of our product candidates in humans.

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

We may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.

We continue to evaluate our product development strategy and, as a result, may modify our strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different product candidates or may delay or halt the development of various product candidates. We may change or refocus our existing product development, commercialization and manufacturing activities based on government funding decisions and other factors. This could require changes in our facilities and our personnel. Any product development changes that we implement may not be successful. In particular, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates or choose candidates for which government development funds are not available. Our decisions to allocate our R&D, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better business opportunities. Similarly, our decisions to delay or terminate product development programs could also cause us to miss valuable opportunities.

REGULATORY AND COMPLIANCE RISKS

There are a number of complex laws and regulations that pertain to government contracts and compliance with those laws and regulations require significant time and cost, which could have a material adverse effect on our business, financial condition, operating results and cash flows.

As a manufacturer and supplier of MCMs to the USG addressing PHTs, we must comply with numerous laws and regulations relating to the procurement, formation, administration and performance of government contracts. These laws and regulations govern how we transact business with our government clients and, in some instances, impose additional costs and related obligations on our operations. For a detailed description of the most significant regulations that affect our government contracting business, see the prior discussion under “Regulation - Government Contracting.”

We may be subject to government investigations of compliance with government acquisition regulations. USG agencies routinely audit and investigate government contractors for compliance with applicable laws and standards. Even though we take significant precautions to identify, prevent and deter fraud, misconduct and non-compliance, we face the risk that our personnel or outside partners may engage in misconduct, fraud or improper activities. If we are audited or investigated and such audit or investigation were to uncover improper or illegal activities, we could be subject to civil and criminal fines and penalties, administrative sanctions, including suspension or debarment from government contracting, and suffer significant reputational harm. The loss of our status as an eligible government contractor or significant fines or penalties associated with contract non-compliance or resulting from investigations could have a material adverse effect on our business.

Our long-term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize product candidates we develop or acquire and, if we are not successful, our business, financial condition, operating results and cash flows may suffer.

Our product candidates and the activities associated with them are subject to extensive FDA regulation and oversight. This includes, but is not limited to, laws and regulations governing product development, product labeling, product testing, manufacturing, storage, product distribution, record keeping, and advertising and promotion. In limited circumstances, governments may have the authority to procure products that have not obtained regulatory approval to stockpile for emergency preparedness and to respond to public health emergencies. In other circumstances, failure to obtain regulatory approval for a product candidate will prevent us from selling and commercializing the product candidate.

In the United States, to obtain authorization from FDA to market and sell any of our future drug, biologic, or vaccine products, we will be required to submit an NDA or BLA to the FDA. Under the FDCA, the PHSA, and FDA’s implementation of those statutes, a company must support an NDA or BLA with substantial evidence that the product candidate is effective and evidence that the product is safe. Ordinarily, FDA requires data from adequate and well-controlled clinical trials, including Phase 3 trials conducted in patients with the disease or condition being targeted, to demonstrate that a drug meets the statutory standards for approval. Once an NDA or BLA is submitted, the FDA has substantial discretion and may refuse to accept our application or

may decide that our data are insufficient to support approval and require additional pre-clinical, clinical or other studies. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed, or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Likewise, the data in our device submissions may be insufficient to support approval, de novo classification or clearance where required, and we may not be able to demonstrate to the satisfaction of the FDA that our devices are safe or effective for their intended uses or, for a 510(k) device, that they are substantially equivalent to the predicate. Even if we are granted 510(k) clearances, de novo authorizations, or PMA approvals, they may include significant limitations on the indications for use for the device.

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

However, our MCM product candidates may be eligible for approval under the FDA's "Animal Rule," under which findings from adequate and well controlled animal efficacy studies may serve as the basis of an approval when it is not feasible or ethical to conduct efficacy trials in humans. We cannot guarantee that the FDA will permit us to proceed with approval or licensure of any of our MCM product candidates under the Animal Rule. Even if we are able to proceed under the Animal Rule, product development can take a considerable amount of time, and the FDA may decide that our data are insufficient to support approval and require additional pre-clinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. Furthermore, products approved under the Animal Rule are subject to certain additional post-marketing requirements. We cannot guarantee that we will be able to meet this regulatory requirement even if one or more of our product candidates are approved under the Animal Rule.

The process of obtaining these regulatory approvals is expensive, often takes many years if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidate involved. Changes in the regulatory approval process may cause delays in the approval or other marketing authorization, or rejection of an application. There is a high rate of failure inherent in the medical product development process, and potential products that appear promising at early stages of development may fail for a number of reasons, and positive results from pre-clinical studies may not be predictive of similar results in human clinical trials. Similarly, promising results from earlier clinical trials of a product candidate may not be replicated in later clinical trials.

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

Unapproved and investigational stage products are also subject to the FDA's laws and regulations governing advertising and promotion, which prohibit the promotion of both unapproved products and unapproved uses of approved products. There is some risk that the FDA could conclude that our communications relating to unapproved products or unapproved uses of approved products constitute the promotion of an unapproved product or product use in violation of FDA laws and regulations. There is also a risk that a regulatory authority in another country could take a similar position under that country's laws and regulations and conclude that we have violated the laws and regulations related to product development, approval, or promotion in that country. If the FDA or any foreign regulatory authority determines that any of our communications constitute pre-approval promotion or promotion of an off-label use, FDA could request that we modify our promotional materials, issue an untitled letter or warning letter, or subject us to regulatory or enforcement actions, including injunction, seizure, civil fine or criminal penalties.

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

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

The FDA and other agencies, including the U.S. Department of Justice ("DOJ") and the HHS Office of Inspector General ("OIG"), closely regulate and monitor the marketing and promotion of medical products to ensure that they are marketed in a manner consistent with the FDA-approved label. For drugs products, we must promote the product in a manner consistent with

the full prescribing information or, for 510(k) cleared devices, consistent with the cleared indication. The FDA, DOJ, and OIG impose stringent restrictions on manufacturers' communications regarding unapproved/uncleared products and unapproved/uncleared uses of approved/cleared products. If we market unapproved/uncleared products or market our approved/cleared products for unapproved/uncleared indications, we may be subject to enforcement action. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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

In addition, discovery of previously unknown adverse events or other problems with our products, manufacturing partners or manufacturing processes, or failure to comply with regulatory requirements, may result in various penalties and sanctions. For all FDA-regulated products, if the FDA finds that a manufacturer has failed to comply with applicable laws and regulations, or that a product is ineffective or poses an unreasonable health risk, it can institute or seek a wide variety of enforcement actions and other remedies, including but not limited to:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- refusal to approve pending applications or supplements to approved applications that are submitted;
- delay in or refusal to approve/clear/authorize pending PMA applications, 510(k) premarket submissions, or de novo authorization requests;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

in more rigorous coverage criteria and additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "ACA"), passed in 2010 and substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. However, some provisions of the ACA have yet to be fully implemented and certain provisions have been subject to legal and political challenges, as well as efforts by the last Presidential administration to repeal or replace certain aspects of the ACA. On January 28, 2021, however, the President issued an executive order to strengthen implementation of the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing penalties as of January 1, 2019 for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, the current Presidential administration issued an executive order initiating a special enrollment period during 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. It is unclear how healthcare reform measures enacted by Congress or implemented by the current Presidential administration or other challenges to the ACA, if any, will impact the ACA or our business.

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

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

Additionally, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program ("SIP"), to import certain prescription drugs from Canada into the United States. The final rule is currently the subject of ongoing litigation. At least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada, and at least three states (Colorado, Florida, and New Mexico) have submitted SIPs to FDA for review and approval.

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

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

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

- the federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, overtly or covertly, to induce, or in return for, either the referral of an individual, or the purchase, lease, prescribing or recommendation of an item, good, facility or service reimbursable by a federally funded health care program, such as the Medicare or Medicaid program. The term "remuneration" has been interpreted broadly and may constrain our marketing practices, educational programs, pricing policies and relationships with health care providers or other entities, among other activities;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal health care program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability, including mandatory treble damages and significant per-claim penalties.
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement, in connection with the delivery of, or payment for, health care benefits, items or services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their respective implementing regulations mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy, security and transmission of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," or independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;
- the Physician Payments Sunshine Act and its implementing regulations require certain manufacturers of drugs, biologics, medical devices and medical supplies for which payment is available under Medicare, Medicaid or the Centers for Medicare & Medicaid Services (CMS) to report certain payments and transfers of value made to U.S. physicians, other healthcare providers and teaching hospitals, and ownership or investment interests held by physicians, other healthcare providers and their immediate family members; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; state, local and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, obtain pharmaceutical agent licensure, and/or otherwise restrict payments that may be made to health care providers and entities; and state, local and foreign

laws that require drug manufacturers to report information related to payments and other transfers of value to health care providers or entities, or marketing expenditures.

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

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

Efforts to ensure that our business arrangements with third parties will comply with health care laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws, we may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, integrity obligations, exclusion from government funded health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If a third party fails to comply with applicable laws and regulations while acting on our behalf, we may also be subject to criminal, civil, and administrative penalties, including those listed above.

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

- Diversion of management time and attention;
- Significant legal fees and payment of damages or penalties;
- Limitations on our ability to continue certain operations;
- Decreased product demand; and
- Injury to our reputation.

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

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

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

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

In addition, if we are found to have made a misrepresentation in the reporting of ASP, we are subject to civil monetary penalties for each such price misrepresentation and for each day in which such price misrepresentation was applied. If we are found to have knowingly submitted false AMP or “best price” information to the government, we may be liable for civil monetary penalties per item of false information. Any refusal of a request for information or knowing provision of false information in connection with an AMP survey verification would also subject us to civil monetary penalties. In addition, our failure to submit monthly/quarterly AMP or “best price” information on a timely basis could result in a civil monetary penalty per day for each day the information is late beyond the due date. Such failure could also be grounds for CMS to terminate our Medicaid drug rebate agreement, under which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot ensure that our submissions will not be found by CMS to be incomplete or incorrect.

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

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

From time to time, we sell unapproved MCMs to government entities under certain circumstances. While this is permissible in some cases, the extent to which we may be able to lawfully offer to sell and sell unapproved products in many jurisdictions may be unclear or ambiguous. Such sales could subject us to regulatory enforcement action, product liability and reputational risk.

Under certain and narrow circumstances, MCMs may be procured by government entities prior to approval by the FDA or other regulatory authorities, a practice which we follow in connection with certain MCMs, including TROBIGARD (and CYFENDUS, prior to its approval by the FDA) in the United States. In the United States, the Secretary of HHS has the authority to contract to purchase MCMs for the SNS prior to FDA approval of the relevant MCM in specified circumstances. FDA also has the authority to permit the emergency use of medical products that have not yet been approved by the FDA under an EUA. An EUA terminates when the EUA is revoked or the emergency declaration underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, clearance, or other marketing authorization for a product. An EUA has not been granted for TROBIGARD. Absent an applicable exception, our MCM product candidates generally will have to be approved, licensed, or cleared by the FDA or other regulatory authorities in the relevant country through traditional pathways before we can sell those products to governments. Additionally, the laws in certain jurisdictions regarding the ability of government entities to purchase unapproved product candidates can be ambiguous, and the permissibility of exporting unapproved products from the United States and importing them to foreign countries may be unclear in some instances. Nevertheless, government bodies, such as U.S. federal entities other than HHS, state and local governments within the United States, and foreign governments have sought and may further seek to procure our MCM product candidates that are not yet approved. In this situation, we would expect to assess the permissibility and liability implications of supplying our product candidates to such entities on a case-by-case basis, which presents certain challenges, both in the case of U.S. and foreign governments, and particularly under emergency conditions. In addition, agencies or branches of one country's government may take different positions regarding the permissibility of such sales than another country's government or even other agencies or branches of the same government. If local enforcement authorities disagree with our conclusion that such activities are permissible, they may take enforcement action against us.

In addition, the sale of unapproved products also could give rise to product liability claims for which we may not be able to obtain adequate indemnification or insurance coverage. For example, despite liability protections applicable to claims arising under U.S. law and resulting from the use of certain unlicensed or unauthorized MCMs, such as a declaration issued under the PREP Act, plaintiffs still may bring lawsuits, among other things, that their claims are not barred under the PREP Act.

In the event that a user of one or more of our products experiences an adverse event, we may be subject to additional reputational risk if the product has not been approved by the FDA or the corresponding regulatory authority of another country, particularly because we will not have approved labeling regarding the safety or efficacy of those products. In addition, legislatures and other governmental bodies that have oversight responsibility for procuring agencies may raise concerns after the fact, even if procurement was permissible at the time, which could result in negative publicity, reputational risk and harm to our business prospects.

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

Even after regulatory approval is received, if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, they could be subject to restrictions, penalties or withdrawal from the market.

Any vaccine, therapeutic product or medical device for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to the continual requirements of and review by the FDA and other regulatory bodies. Our approved products are subject to these requirements and ongoing review. For drugs and vaccines, these requirements include submissions of safety and other post-marketing information and reports, plasma donor testing, registration requirements, cGMP, requirements relating to potency and stability, quality control, quality assurance, restrictions on advertising and promotion, import and export restrictions and recordkeeping requirements. Requirements for medical devices are similar and include QSR compliance, establishment registration and device listing; record keeping; restrictions on advertising and promotion; post-market surveillance, and restrictions on import and export. In addition, various state laws require that companies that manufacture and/or distribute drug products within the state obtain and maintain a manufacturer or distributor license, as appropriate. Some states have similar requirements for devices. Because of the breadth of these laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Government regulators enforce cGMP, QSR, and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect domestic and foreign manufacturing facilities without prior notice at reasonable times and in a reasonable manner. Health Canada may conduct similar inspections of our domestic and foreign facilities where products offered and sold in Canada are produced, or related formulation and filling operations are conducted.

The FDA, Health Canada, and other foreign regulatory agencies conduct periodic inspections of our facilities. Following several of these inspections, regulatory authorities have issued inspectional observations, some of which were significant, but all of which are being, or have been, addressed through corrective actions. If, in connection with any future inspection, regulatory authorities find that we are not in substantial compliance with all applicable requirements, or if they are not satisfied with the corrective actions we take, our regulators may undertake enforcement action against us, which may include:

- warning letters, untitled letters, and other communications;
- product seizure or withdrawal of the product from the market;
- restrictions on the marketing or manufacturing of a product;
- suspension or withdrawal of regulatory approvals or refusal to approve pending applications or other marketing submissions, or supplements to approved applications;
- fines or disgorgement of profits or revenue; and
- injunctions or the imposition of civil or criminal penalties.

Similar action may be taken against us should we fail to comply with regulatory requirements, or later discover previously unknown problems with our products or manufacturing processes. For instance, our products are tested regularly to determine if they satisfy potency and stability requirements for their required shelf lives. Failure to meet potency, stability or other specification requirements could result in delays in distributions, recalls or other consequences. In November 2022, a specific batch of our RSDL kits was recalled due to leakage, which could cause the product not to perform as effectively as intended. We identified and remediated the cause leading to the November 2022 recall, as well as completed all required actions, notices and report submissions related to the recalled batch. We are currently awaiting formal closure of the recall.

Even if regulatory approval, clearance, or other marketing authorization of a product is granted, the approval, clearance, or marketing authorization may be subject to limitations on the indicated uses for which the product may be marketed or sold or to the conditions of approval. Regulatory approval or other authorization may also contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. If we experience any of these post-approval events, our business, financial condition, operating results and cash flows could be materially and adversely affected.

Additionally, companies may not promote unapproved products or unapproved uses of approved products (i.e. “off-label” uses or uses that are not described in the product’s approved labeling and/or that differ from the uses approved or cleared by the applicable regulatory agencies). A company that is found to have improperly promoted an unapproved/uncleared product or an unapproved/uncleared use of an approved/cleared product may be subject to significant liability, including civil and administrative remedies (such as entering into corporate integrity agreements with the USG), as well as criminal sanctions. If our employees or agents engage in marketing of an unapproved/uncleared product or the unapproved/uncleared use of an approved/cleared product, we could be subject to civil or criminal investigations and monetary and injunctive penalties, which could adversely impact our ability to conduct business in certain markets, negatively affect our business, financial condition, operating results and cash flows, and damage our reputation.

Failure to obtain or maintain regulatory approval in international jurisdictions could prevent us from marketing our products abroad and could limit the growth of our business.

We currently sell certain of our products outside the United States and intend to expand the countries in which we sell our products and have received market authorization under the mutual recognition procedure to sell BioThrax in France, Italy, the Netherlands, Poland, and the United Kingdom. To market or sell our products in foreign jurisdictions under normal circumstances, we generally need to obtain separate regulatory approvals and comply with numerous and varying requirements or use alternative “emergency use” or other exemptions from general approval and import requirements. Approval by the FDA in the United States or the mutual recognition procedure in the European member states does not ensure approval by all foreign regulatory authorities. The approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review beyond that required by the FDA or under the mutual recognition procedure. There is also a risk that a regulatory authority in another country could conclude that we have violated the rules and regulations related to product development, approval or promotion in that country. Therefore, there is a risk that we could be subject to a foreign enforcement action if found to be in violation of such laws and regulations. We and our collaborators may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and we may be unable to successfully commercialize our products in desired jurisdictions internationally if no alternate procurement pathway is identified for authorized government customers in a particular jurisdiction. We have limited experience in preparing, filing and prosecuting the applications necessary to gain foreign regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process. Our reliance on third parties can introduce additional uncertainty into the process.

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

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

As we continue to expand our commercialization activities outside of the United States, we are subject to an increased risk of violating, and must dedicate additional resources towards avoiding inadvertently conducting activities in a manner that violates, the FCPA, the U.K. Bribery Act, Canada's Corruption of Foreign Public Officials Act, and other similar foreign anti-bribery laws that prohibit corporations and individuals from corruptly paying, offering to pay, or authorizing the payment of anything of value, directly or indirectly, to any foreign government official, government staff member, political party or party official, or political candidate in an attempt to influence a person working in an official capacity or otherwise obtain an improper advantage. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the Company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Some anti-bribery laws also apply to private sector bribery. Compliance with the FCPA and other anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals and other parts of the health system are operated by the government, and doctors, hospital employees, and other health care providers are considered foreign officials. Certain payments to hospital employees and other health care professionals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

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

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

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

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

COMPETITIVE AND POLITICAL RISKS

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

The development and commercialization of new biopharmaceutical and medical technology products is highly competitive and subject to rapid technological advances. We will continue to face future competition from other companies and governments, universities and other non-profit research organizations in respect to our products, any products that we acquire, our current product candidates and any products we may seek to develop or commercialize in the future. The market for products can be

subject to development of safer, more effective, more convenient or less costly products. The market for current products can also depend on what resources can be devoted to marketing or selling products, or how companies are positioned to adapt more quickly to new technologies, respond to scientific advances or patient preferences and needs, initiate or withstand substantial price competition and/or procure third-party licensing and collaborative arrangements.

There are a number of companies with products or product candidates addressing PHT preparedness that are competing with us for both USG procurement and development resources. Factors to consider include competitors' financial, technical, marketing and selling resources as well as potential leverage that their intellectual property estates may offer.

Any reduction in demand for our products or reduction or loss of development funding for our products or product candidates in favor of a competing product could lead to a loss of market share for our products and cause reduced revenues, margins and levels of profitability for us, which could adversely affect our business, financial condition, operating results and cash flows.

Our biologic products may face risks of competition from biosimilar manufacturers.

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

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

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

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

Sales of generic versions of NARCAN at prices lower than our branded product or provided at no cost by Teva have the potential to erode our sales and could impact our product revenue related to NARCAN. For example, certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician, mandate the dispensing of generic products rather than branded products where a generic version is available. In addition, in January 2019, the FDA released new proposed template Drug Facts Labels to assist sponsors of investigational naloxone nasal sprays and auto-injectors seeking approval from the FDA for over-the-counter naloxone products. In November 2022, the FDA announced its preliminary assessment that naloxone nasal spray products up to 4mg and naloxone auto-injector products for intramuscular or subcutaneous use up to 2mg have the potential to be approvable as safe and effective for nonprescription use.

NARCAN Nasal Spray also faces branded competition Kloxxado™, (naloxone HCl) nasal spray 8mg, a branded product developed by Hikma Pharmaceuticals, Inc., Amphastar Pharmaceuticals, Inc.'s naloxone injection product, Teleflex Medical Inc.'s Intranasal Mucosal Atomization Device and Zimhi™ (naloxone), a branded injectable product developed by Adamis.

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

Political or social factors may delay or impair our ability to market and sell our products and may require us to spend significant management time and financial resources to address these issues.

Products developed to counter the potential impact of PHTs are subject to changing political and social environments. The political responses and social awareness of the risks of these threats on military personnel or civilians and the level of emphasis placed on such risks by the USG may vary over time. If the threat of terrorism were to decline, then the public perception of the risk on public health and safety may be reduced. This perception, as well as political or social pressures (including as a result of negative publicity we have received based on our longstanding ties to the USG), could delay or cause resistance to bringing our products in development to market or limit pricing or purchases of our products, any of which could negatively affect our revenues and our business, financial condition, operating results and cash flows.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Lawsuits brought against us by third parties or activists, even if not successful, could require us to spend significant management time and financial resources defending the related litigation and could potentially damage the public's perception of us and our products. Any publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of our MCMs and thereby limit the demand for our products, which would adversely affect our business, financial condition, operating results and cash flows.

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

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

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

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

INTELLECTUAL PROPERTY RISKS

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

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

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

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

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

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

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

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

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

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

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

We also rely upon unpatented proprietary technology, processes, and know-how, particularly as to our proprietary manufacturing processes. These types of confidential information and trade secrets can be difficult to protect. We seek to protect this confidential information, in part, through agreements with our employees, consultants, and third parties, as well as confidentiality policies and audits, although these may not always be successful in protecting our trade secrets and confidential information.

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

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

Although we intend to vigorously enforce our intellectual property rights, there can be no assurance that we will prevail in our enforcement or defense of our patent rights. Our existing patents could be invalidated, found unenforceable, or found not to cover a generic form of our product.

RISKS RELATED TO RELIANCE ON OTHER PARTIES

The loss of any of our non-exclusive, sole-source or single source suppliers, a shortage of related supplies or an increase in the price of inventory supplied to us could have an adverse effect on our business, financial condition and results of operations.

We purchase certain supplies used in our manufacturing processes from non-exclusive, or single sources due to quality considerations, costs or constraints resulting from regulatory requirements. We depend on certain single-source suppliers for key materials and services necessary to manufacture the majority of our products and certain product candidates. For example, we rely on a single-source supplier to provide us with Alhydrogel in sufficient quantities to meet our needs to manufacture 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, such as the naloxone active pharmaceutical ingredient and other excipients, along with the vial, stopper and device.

Where a particular single-source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation

of materials prior to use in our products and product candidates, and the complex nature of manufacturing processes. In addition, we may lose a sole-source supplier due to, among other things, the acquisition of a supplier by a competitor (which may cause the supplier to stop selling its products to us) or the bankruptcy of such a supplier, which may cause the supplier to cease operations. Any reduction or interruption by a sole-source supplier of the supply of materials or key components used in the manufacturing of our products or product candidates, a reduction in quality or an increase in the price of those materials or components could adversely affect us. If we are unable to locate or establish alternative suppliers, our ability to manufacture our products and product candidates could be adversely affected and could harm our revenues, cause us to fail to satisfy contractual commitments, lead to a termination of one or more of our contracts or lead to delays in our clinical trials, any of which could be costly to us and otherwise materially harm our business, financial condition, operating results and cash flows.

We depend on third parties to conduct many of our clinical and non-clinical trials. If these third parties do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates and, as a result, our business, financial condition, operating results and cash flows may suffer.

We depend on third parties, such as independent clinical investigators, contract research organizations and other third-party service providers to conduct the clinical and non-clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical and non-clinical trials, but do not exercise day-to-day control over their activities. Our reliance on these service providers does not relieve us of our regulatory responsibilities, including ensuring that our trials are conducted in accordance with good clinical practice regulations and the plan and protocols contained in the relevant regulatory application. In addition, these organizations may not complete these activities on our anticipated or desired timeframe. We also may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization or other third party may lead us to seek to terminate the relationship and use an alternative service provider, which may prove difficult, costly and result in a delay of our trials. Any delay in or inability to complete our trials could delay or prevent the development, approval and commercialization of our product candidates.

In certain cases, government entities and NGOs conduct studies of our product candidates, and we may seek to rely on these studies in applying for marketing approval for certain of our product candidates. These government entities and NGOs have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. Furthermore, government entities depend on annual Congressional appropriations to fund their development efforts, which may not be approved.

If we are unable to obtain any necessary third-party services on acceptable terms or if these service providers do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for our product candidates may be delayed or prevented.

LEGAL AND REPUTATIONAL RISKS

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

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

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

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

We rely significantly on information technology systems and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively or result in data leakage of proprietary and confidential business and employee information.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. We previously contracted with the USG and pharmaceutical companies for the development and manufacture of a significant quantity of COVID-19 vaccines, which raised our security profile and heightened potential risks that malicious actors may seek to disrupt our systems or misappropriate our information. The size and complexity of our computer systems and those of many of our business partners, collaborators and other third parties make them potentially vulnerable to interruption, invasion, computer viruses, destruction, malicious intrusion and additional related disruptions, which may result in the impairment of production and key business processes. Our systems and information are also potentially vulnerable to cyber security incidents through employee error, phishing scams and malfeasance, as well as cyber security incidents involving our business partners, collaborators and other third parties, any of which may expose sensitive data to unauthorized persons. Our systems and those of our business partners and collaborators have in the past been, and in the future likely will be subject to computer viruses, malicious codes, unauthorized access and other cyber security incidents. We are not aware of any significant impact on our operations or financial results from such incidents although, as of the date of this report, we are assessing the potential impact of a cyber security incident involving a business partner of which we were made aware in early May 2023.

No system of protection is adequate to protect against all such threats, even if they are deemed to be industry standard, and there can be no assurance that we will be able to repel any such attacks. Cyber security incidents could lead to the loss of trade secrets or other intellectual property or the public exposure of personal information, including sensitive personal information, of our employees, clinical trial patients, customers and others. Responding to any such threats may also be expensive and time-consuming. Any such unauthorized access to our information, whether through an incident involving our information technology systems or those of our business partners, collaborators or other third parties, could disrupt our business operations, result in the loss of assets, and have a material adverse effect on our reputation, business, financial condition, or results of operations.

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

We face product liability exposure, which could cause us to incur substantial liabilities and negatively affect our business, financial condition and results of operations.

We face an inherent risk of product liability exposure related to the sale of our products, any other products that we successfully acquire or develop and the testing of our product candidates in clinical trials.

One measure of protection against such lawsuits is coverage under the PREP Act, which was signed into law in December 2005. The PREP Act creates liability protection for manufacturers of biodefense countermeasures when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is meant to provide liability protection from all claims under federal or state law for loss arising out of the administration or use of a covered countermeasure under a government contract. The Secretary of HHS has issued PREP Act declarations covering countermeasures for smallpox, mpox, and other orthopox; anthrax; and botulinum toxin. These declarations apply to certain of our products, namely BioThrax, ACAM2000, raxibacumab, Anthrasil, BAT and VIGIV products, as covered countermeasures. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct or for cases brought in non-U.S. tribunals or under non-U.S. law. We cannot predict whether the Secretary of HHS will renew the declarations when they expire, whether Congress will fund the relevant PREP Act compensation programs, or whether the necessary prerequisites for immunity would be triggered with respect to our products or product candidates.

Additionally, certain of our products, namely BioThrax and RSDL, are under the SAFETY Act, which provides certain product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. Although BioThrax and RSDL are designated and certified under the SAFETY Act, the law may not provide adequate protection from claims made against us.

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

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

The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. Further product liability insurance may be difficult and expensive to obtain. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy all potential liabilities. For example, we may not have sufficient insurance against potential liabilities associated with a possible large-scale deployment of BioThrax vaccine as a countermeasure to a bioterrorism threat. We rely on PREP Act protection for BioThrax, raxibacumab, ACAM2000, Anthrasil, BAT and VIGIV products, and SAFETY Act protection for BioThrax and RSDL products in addition to our insurance coverage to help mitigate our product liability exposure for these products. Additionally, potential product liability claims related to our commercial products, including NARCAN, may be made by patients, health care providers or others who sell or consume these products. Such claims may be made even with respect to those products that possess regulatory approval for commercial sale. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition, operating results and cash flows.

FINANCIAL RISKS

We have incurred significant indebtedness in connection with our acquisitions and servicing our debt requires a significant amount of cash. We may not have sufficient cash flow from our operations to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to further refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We may also seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing can have significant adverse consequences for our business, including:

- requiring us to dedicate a substantial portion of cash flows from operations to payment on our debt, which would reduce available funds for other corporate initiatives;
- increasing the amount of interest that we have to pay on debt with variable interest rates, if market rates of interest increase, to the extent we are unable to offset such risk through our hedging instruments;
- subjecting us, as under our Senior Secured Credit Facilities and the indenture governing the Senior Unsecured Notes, to restrictive covenants that reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing;
- requiring us to pledge our assets as collateral, which could limit our ability to obtain additional debt financing;
- limiting our flexibility in planning for, or reacting to, general adverse economic and industry conditions; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

We may not have sufficient funds or be able to obtain additional financing to pay the amounts due under our indebtedness. In addition, failure to comply with the covenants under our Senior Secured Credit Facilities and other debt agreements, including

the maintenance of a specified consolidated net leverage ratio, debt service coverage ratio, Consolidated EBITDA level and minimum liquidity level under our Senior Secured Credit Facilities, could result in an event of default under those agreements. An event of default could result in the acceleration of amounts due under a particular debt agreement and a cross default and acceleration under other debt agreements, and we may not have sufficient funds to pay or be able to obtain additional financing to make any accelerated payments.

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 $206.1 million as of June 30, 2023 and the ability to borrow up to $300.0 million under our Revolving Credit Facility under which we had $250.2 million of outstanding borrowings as of June 30, 2023. On August 7, 2020, we completed an offering of $450.0 million aggregate principal amount of Senior Unsecured Notes, of which $353.0 million of the net proceeds were used to pay down our Revolving Credit Facility. We may also seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing can have significant adverse consequences for our business, including:

- the level, timing and cost of product sales and CDMO services;
- the extent to which we acquire or invest in and integrate companies, businesses, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
- the extent to which we repurchase common stock under any future share repurchase program; and
- the costs of commercialization activities, including product marketing, sales and distribution.

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

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

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

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

As of June 30, 2023, we had unrestricted cash and cash equivalents of $88.6 million and remaining capacity under our Revolving Credit Facility of $49.3 million. Also as of June 30, 2023, there was $250.2 million outstanding on our Revolving Credit Facility and $206.1 million on our Term Loan Facility that mature in May 2025. Certain provisions within the Credit Agreement Amendment require further action from the Company, most notably the requirement to raise not less than $75.0 million through the issuance of equity and/or unsecured indebtedness by April 30, 2024 and that the Company make quarterly principal payments of approximately $3.9 million on the Term Loan Facility. As a result, the Company determined that there is substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial

statements are issued. We will need to obtain substantial additional funding in connection with our continuing operations, which cannot be assured.

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements. In August 2021, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a “well-known seasoned issuer” under SEC rules, this shelf registration statement, effective until August 9, 2024, allows us to issue an unrestricted amount of equity, debt and certain other types of securities through one or more future primary or secondary offerings. If we do not file a new shelf registration statement prior to the expiration of our automatic shell registration statement (whether by lapse of time due to us no longer qualifying as a "well-known seasoned issuer"), the existing shelf registration statement will expire, and we will not be able to publicly raise capital or issue debt until a new registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatically effective shelf registration statement at a future date when we may need to raise funds publicly.

If we raise funds by issuing equity securities, including through our ATM Program, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants, like those contained in our Senior Secured Credit Facilities and the indenture governing the Senior Unsecured Notes, limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities or declaring dividends. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us. Our Senior Secured Credit Facilities as well as the indenture governing the Senior Unsecured Notes restrict our ability to incur additional indebtedness.

Economic conditions may make it difficult to obtain financing on attractive terms, or at all. If financing is unavailable or lost, our business, operating results, financial condition and cash flows would be adversely affected, and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

We may not maintain profitability in future periods or on a consistent basis.

Although we have been profitable on an annual basis since becoming a public company, we have not been profitable for every quarter during that time. Our profitability has been substantially dependent on product sales, which historically have fluctuated significantly from quarter to quarter, and we expect that they will continue to fluctuate significantly based primarily on the timing of our fulfillment of orders from the USG. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

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

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

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

We have a significant amount of intangible assets and property, plant and equipment on our balance sheet. We have recorded a significant amount of goodwill on our consolidated balance sheet as a result of acquisitions. As of June 30, 2023, the only reporting unit that has goodwill associated with it is our MCM reporting unit.

The impairment tests require us to make an estimate of the fair value of our reporting units. An impairment could be recorded as a result of changes in assumptions, estimates or circumstances, some of which are beyond our control. Since a number of factors may influence determinations of fair value, we are unable to predict whether impairments of intangible assets, goodwill or property, plant and equipment will occur in the future, and there can be 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 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

Our strategy of generating growth through acquisitions may not be successful.

Our business strategy includes growing our business through acquisition and in-licensing transactions. For example, in September 2022, we completed the acquisition from Chimerix, Inc. of its exclusive worldwide rights to brincidofovir, including TEMBEXA and related assets. We may not be successful in identifying, effectively evaluating, structuring, acquiring or in-licensing, and developing and commercializing additional products on favorable terms, or at all. Competition for attractive product opportunities is intense and may require us to devote substantial resources, both managerial and financial, to an acquisition opportunity. A number of more established companies are also pursuing strategies to acquire or in-license products in the biopharmaceutical field. These companies may have a competitive advantage over us due to their size, cash resources, cost of capital, effective tax rate and greater clinical development and commercialization capabilities.

Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote significant resources to potential acquisitions that are never completed. Even if we are successful in acquiring a company or product, it may not result in a successfully developed or commercialized product or, even if an acquired product is commercialized, competing products or technologies could render a product noncompetitive, uneconomical or obsolete. Moreover, the cost of acquiring other companies or in-licensing products could be substantial, and in order to acquire companies or new products, we may need to incur substantial debt or issue dilutive securities.

If we are unsuccessful in our efforts to acquire other companies, products, or in-license and develop additional products, or if we acquire or in-license unproductive assets, it could have a material adverse effect on the growth of our business, and we could be compelled to record significant impairment charges to write-down the carrying value of our acquired intangible assets, which could materially harm our business, financial condition, operating results and cash flows.

Our failure to successfully integrate acquired businesses and/or assets into our operations could adversely affect our ability to realize the benefits of such acquisitions and, therefore, to grow our business.

We may not be able to integrate any acquired business successfully or operate any acquired business profitably. In addition, cost synergies, if achieved at all, may be less than we expect, or may take greater time to achieve than we anticipate.

Issues that could delay or prevent successful integration or cost synergies of an acquired business or products include, among others:

- retaining existing customers and attracting new customers;
- retaining key employees;
- diversion of management attention and resources;
- conforming internal controls, policies and procedures, business cultures and compensation programs;
- consolidating corporate and administrative infrastructures;
- successfully executing technology transfers and obtaining required regulatory approvals;
- consolidating sales and marketing operations;
- identifying and eliminating redundant and underperforming operations and assets;
- assumption of known and unknown liabilities;

- coordinating geographically dispersed organizations;
- managing tax costs or inefficiencies associated with integrating operations; and
- risks associated with intellectual property rights related to an acquisition or collaboration.

If we are unable to successfully integrate pending and future acquisitions with our existing businesses, or operate any acquired business profitably, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect the growth of our business, financial condition, operating results and cash flows.

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

On May 15, 2023, pursuant to the Purchase and Sale Agreement, we completed the previously announced sale to Bavarian Nordic of our travel health business, including rights to Vaxchora and Vivotif, as well as our development-stage chikungunya vaccine candidate CHIKV VLP, our manufacturing site in Bern, Switzerland and certain of our development facilities in San Diego, California for a cash purchase price of $270.0 million, subject to certain customary adjustments. In addition, we may receive milestone payments of up to $80.0 million related to the development of CHIKV VLP and receipt of marketing approval and authorization in the U.S. and Europe, and sales-based milestone payments of up to $30.0 million based on aggregate net sales of Vaxchora and Vivotif in calendar year 2026.

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

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

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

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

Provisions in our certificate of incorporation and by-laws and under Delaware law may discourage acquisition proposals, delay a change in control or prevent transactions that stockholders may consider favorable.

Provisions in our certificate of incorporation and by-laws may discourage, delay or prevent a merger, acquisition or other changes in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management.

These provisions include:

- the classification of our directors;
- limitations on changing the size of our Board of Directors;
- limitations on the removal of directors;
- limitations on filling vacancies on the Board of Directors;
- advance notice requirements for stockholder nominations of candidates for election to the Board of Directors and other proposals;
- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and

- the ability of our Board of Directors to designate the terms of and issue a new series of preferred stock without stockholder approval.

The affirmative vote of a majority of our Board of Directors or the holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation or by-laws. The affirmative vote of either a majority of the directors present at a meeting of our Board of Directors or holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws.

In addition, we are subject to Section 203 of the Delaware General Corporation Law ("Section 203"). In general and subject to certain exceptions, Section 203 prohibits a publicly-held corporation from engaging in a business combination with an interested stockholder, generally a person which, together with its affiliates, owns or within the last three years has owned 15% or more of the corporation's voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us.

Our Board of Directors may implement a new stockholder rights plan without stockholder approval, which could prevent a change in control of us in instances in which some stockholders may believe a change in control is in their best interests.

Our Board of Directors may implement a stockholder rights plan without stockholder approval, which may have anti-takeover effects, potentially preventing a change in control of us in instances in which some stockholders may believe a change in control is in their best interests. This could cause substantial dilution to a person or group that attempts to acquire us on terms that our Board of Directors does not believe are in our best interests or those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

Our stock price is volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has been, and is likely to continue to be, volatile. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this “Risk Factors” section, or for reasons unrelated to our operations, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as industry conditions and general financial, economic and political instability. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through August 1, 2023, our common stock has traded as high as $137.61 per share and as low as $4.17 per share. The market price of our common stock may be influenced by many factors, including, among others:

- contracts, decisions and procurement policies by the USG affecting our anthrax vaccines and our other products and product candidates;
- CDMO contracts related to COVID-19 with collaboration partners;
- the success of competitive products or technologies;
- results of clinical and non-clinical trials of our product candidates;
- announcements of acquisitions, financings or other transactions by us;
- litigation or legal proceedings;
- public concern as to the safety of our products;
- termination or delay of a development program;
- the recruitment or departure of key personnel;
- variations in our product revenue and profitability; and
- the other factors described in this “Risk Factors” section.

Because we currently do not pay dividends, investors will benefit from an investment in our common stock only if it appreciates in value.

We currently do not pay dividends on our common stock. Our Senior Secured Credit Facilities and the indenture governing our Senior Unsecured Notes limit and any future debt agreements that we enter into may limit our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders based on current expectations.

Future sales of our common stock or other securities convertible into common stock, or the perception that such sales or issuances could occur, could result in dilution of our stockholders and could cause our share price to decline.

Our board of directors is authorized, without stockholder approval, to cause us to issue additional shares of our common stock or to raise capital through the issuance of preferred shares or the sale of debt securities that are convertible into common stock, options, warrants and other rights, on terms and for consideration as our board of directors in its sole discretion may determine. In addition, under the Credit Agreement Amendment, we are required to increase our liquidity by April 30, 2024 by raising at least $75 million of equity or unsecured indebtedness. We also require substantial additional funding to be able to continue as a going concern and we may seek to achieve such funding through future sales of our common stock or other securities convertible into our common stock. Sales of substantial amounts of our common stock or the issuance of preferred shares, convertible debt, options, restricted stock units, performance stock units, warrants and other rights, or the perception that such sales or issuances could occur could cause the market price of our common stock to decrease significantly. As of June 30, 2023, we had 51,792,971 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

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.

Our success is dependent on our continued ability to attract, motivate and retain key personnel, and any failure to attract or retain key personnel may negatively affect our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel (including quality and manufacturing personnel). If we are unable to retain the services of one or more of the principal members of senior management or other key employees, our ability to implement our business strategy could be materially harmed. We face intense competition for qualified employees from biopharmaceutical companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. We believe part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including equity incentive awards. If we cannot offer a competitive compensation package to attract and retain the qualified personnel necessary for the continued development of our business, we may not be able to maintain our operations or grow our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent sales of unregistered securities

Not applicable.

Use of proceeds

Not applicable.

Purchases of equity securities

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

During the three months ended June 30, 2023, none of the Company's directors or Section 16 reporting officers adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

ITEM 6. EXHIBITS

The exhibits required to be filed by Item 601 of Regulation S-K are listed in the Exhibit Index immediately preceding the exhibits hereto.

Exhibit Index

Exhibit Number	Description
10.1	First Amendment to the Consent, Limited Waiver, and Third Amendment to the Amended and Restated Credit Agreement dated February 14, 2023 among the Company, as borrower, certain subsidiaries of the Company, as guarantors, Wells Fargo Bank, National Association, as administrative agent, and certain lenders party thereto (incorporated by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K filed on March 1, 2023)
10.2 †	Fourth Amendment to Amended and Restated Credit Agreement, Waiver and First Amendment to Amended and Restated Collateral Agreement, dated May 15, 2023, among Emergent BioSolutions Inc., the guarantors party thereto, the lenders party thereto, and Wells Fargo Bank, National Association, as administrative agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 18, 2023).
10.3	Equity Distribution Agreement, dated May 17, 2023, between Emergent BioSolutions Inc., Evercore Group L.L.C. and RBC Capital Markets, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on May 18, 2023).
10.4 #	Modification No. 13, effective March 30, 2023, to the BARDA AV7909 Contract.
10.5 #	Modification No. 14, effective March 30, 2023, to the BARDA AV7909 Contract.
10.6 #*	Modification No. 9, effective May 24, 2023, to the ACAM2000 Contract.
10.7 #	Modification No. 10, effective May 26, 2023, to the ACAM2000 Contract.
10.8*	Emergent BioSolutions Inc. Amended and Restated Stock Incentive Plan (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-8, filed on June 5, 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 #*	Consulting Agreement, dated as of July 7, 2023 and effective as of Jul 7, 2023, by and between Emergent BioSolutions Inc. and Haywood Miller.
31.1 #	Certification of the Chief Executive Officer, pursuant to Exchange Act Rule 13a-14(a).
31.2 #	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).
32.1 #	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2 #	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101 #	The following financial information related to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, formatted in iXBRL (Inline Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows, (v) the Condensed Consolidated Statement of Changes in Stockholders' Equity; and (vi) the related Notes to the Condensed Consolidated Financial Statements.
104 #	Cover Page Interactive Data File, formatted in iXBRL and contained in Exhibit 101.

Filed herewith.

† Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because of the identified confidential portions (i) are not material and (ii) are items the Company customarily and actually treats such information as private or confidential.

* Management or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements 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/HAYWOOD MILLER
Haywood Miller
Interim Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2023

By: /s/RICHARD S. LINDAHL
Richard S. Lindahl
Executive Vice President, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Date: August 8, 2023

Certain identified information has been marked in the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 5

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00013	See Block 16C	OS309412	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR-BARDA	ASPR-BARDA	ASPR-BARDA	ASPR-BARDA
200 Independence Ave., S.W.		200 Independence Ave., S.W.	
Room 640-G		Room 638-G	
Washington DC 20201		Washington DC 20201	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC.
EMERGENT PRODUCT DEVELOPMENT GAITHE
300 PROFESSIONAL DR # 100
GAITHERSBURG MD 208793419

CODE 1365869 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

X 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201600030C

10B. DATED *(SEE ITEM 13)* 09/30/2016

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)* Net Increase: [**]
See Schedule

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

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

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

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

Tax ID Number: [**]
DUNS Number: [**]
UEI: [**]
The purpose of this modification is to modify ARTICLES B.2 BASE PERIOD, B.3 OPTION PRICES, F.3 DELIVERIES, G.1 CONTRACTING OFFICER, G.4. INVOICE SUBMISSION, AND I.3. ADDITIONAL CONTRACT CLAUSES.

Funds Obligated Prior to this Modification: [**]
Funds Obligated with Mod #13: [**]
Total Funds Obligated to Date: [**]

Continued ...

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
Kelly Warfield SVP, S&D	YIFAN YANG

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Electronically signed by: Kelly Warfield Reason: I approve this document Date: Mar 30, 2023 11:08 EDT *(Signature of person authorized to sign)*	Mar 30, 2023	Yifan Yang -S *(Signature of Contracting Officer)* Digitally signed by Yifan Yang -S Date: 2023.03.30 12:12:41 -04'00'	

Previous edition unusable

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

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

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Expiration Date: Aug 31, 2025 OTA: N Period of Performance: 09/30/2016 to 08/31/2025 Change Item 1 to read as follows(amount shown is the obligated amount):				
1	CLIN 0001 and CLIN 0002 for Licensure, Approval, and Clearance or Product through the FDA/Initial Purchase, Storage, and Delivery of Product Accounting Info: 2016.1990007.26201 Appr. Yr.: 2016 CAN: 1990007 Object Class: 26201 Funded: [**] Accounting Info: 2023.1995361.26025 Appr. Yr.: 2023 CAN: 1995361 Object Class: 26025 Funded: [**] FOB: Destination				[**]
	Change Item 10 to read as follows(amount shown is the obligated amount):				
10	CLIN 0010 Additional Surge Capacity (EUA) Accounting Info: 2021.1991073.26088 Appr. Yr.: 2021 CAN: 1991073 Object Class:26088 Funded: [**] Accounting Info: 2021.1990178.26088 Appr. Yr.: 2021 CAN: 1990178 Object Class:26088 Funded: [**]				[**]

The purpose of this modification is to modify ARTICLES B.2 BASE PERIOD, B.3 OPTION PRICES, F.3 DELIVERIES, G.1 CONTRACTING OFFICER, G.4. INVOICE SUBMISSION, AND I.3. ADDITIONAL CONTRACT CLAUSES.

ARTICLE B.2. BASE PERIOD is hereby modified as follows:

CLIN	Period of Performance	Supplies/Services	Total Est. Cost	Fixed Fee [**]	Total Cost Plus Fixed Fee
COST REIMBURSEMENT					
0001 (Funded)	09/30/2016 - **08/31/2025**	Licensure, approval, and clearance of product through the FDA	**[**]**	[**]	**[**] (Funded)**

ARTICLE B.3. OPTION PRICES – CLIN 0010 is modified as follows:

CLIN	Period of Performance	Supplies/Services	Doses	Price per Dose	Total Cost	Additional Doses****
CLIN 0010 (Option Quantity)***	09/30/2021 - **04/30/2023**	Additional Surge Capacity (EUA)	[**]	[**]	[**]	Dose number TBD
			[**]	[**]		
		TOTAL	[**]	[**]	[**] (Funded)	

*The first [**] doses procured under the options will be [**] per dose (regardless of the year these doses may be procured). As of the signing of this Modification to the Contract, [**] doses have been delivered. With the exercising of CLIN 0010, [**] doses of the [**] doses will be priced at a [**] discount and will fulfill Contractor's per dose cumulative reduction obligation regarding the first [**] doses procured under the options. All doses will be billed at the price of [**].

Under **CLIN 0010, a total of [**] doses are expected to be procured at the unit prices stated above and may include the delivery of Short Dated Doses and Additional Doses as set forth herein. CLIN 0010 pricing includes the [**] within its agreed upon pricing for [**] doses delivered.

***CLIN **0010** is funded

**** Additional Doses may be delivered to BARDA as consideration under the provision Article B.5.I. In the event Contractor delivers doses[**] from the date of manufacture (See Article B.5.I), Contractor will provide a [**] equivalent of additional doses to the Government. As set forth in Article B.5.I, BARDA may accept [**] (doses >[**] from the date of manufacture) if such doses are delivered along with the appropriate number of [**]). [**]shall be calculated as [**].

ARTICLE F.3. DELIVERIES is hereby modified as follows:

Email Addresses: CO – [**]
COR – [**]

ARTICLE G.1. CONTRACTING OFFICER is hereby modified as follows:

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Yifan Yang

HHS/OS/ASPR/BARDA
400 7th Street, SW
Washington DC 20024
[**]

ARTICLE G.4. INVOICE SUBMISSION is hereby modified as follows:

Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP)
• All Invoice submissions for goods and or services delivered to facilitate payments must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP).
• Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in the applicable Prompt Payment clause included in the contract, or the clause 52.212-4 Contract Terms and Conditions – Commercial Items included in commercial items contracts. The IPP website address is: https://www.ipp.gov.
• The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive

- Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts. o Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
- The Contractor POC will receive two emails from **IPP Customer Support**, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

• If your company is already registered to use IPP, you will not be required to re-register.
• If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

Additional Office of the Assistant Secretary for Preparedness and Response (ASPR) requirements:

(i) The contractor shall submit monthly invoices under this contract unless otherwise agreed upon by all parties. For indefinite delivery and blanket purchase agreement vehicles, separate invoices must be submitted for each order.
(ii) Invoices must break-out price/cost by contract line item number (CLIN) as specified in the pricing section of the contract.
(iii) Invoices must include the Dun & Bradstreet Number (DUNS) of the Contractor.
(iv) Invoices that include time and materials or labor hours CLINS must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).
(v) Invoices that include cost-reimbursement CLINs must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts.
At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.
• Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
• Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
• Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
• Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;

• Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
• Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
• Fee – amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

I.3. ADDITIONAL CONTRACT CLAUSES is modified to include the following clause:

HHSAR 352.232-71 Electronic Submission of Payment Requests (FEB 2022)
(a) *Definitions.* As used in this clause—
Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.
(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.
(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.
(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(End of clause)

End of Modification #13

Certain identified information has been marked in the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 4

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00014	See Block 16C	OS313747	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	ASPR-BARDA	ASPR-BARDA 200 Independence Ave., S.W. Room 638-G Washington DC 20201	ASPR-BARDA

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR # 100 GAITHERSBURG MD 208793419	(x)	9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201600030C
		10B. DATED *(SEE ITEM 13)* 09/30/2016

CODE	1365869	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
2023.1995361.26088 Net Increase: [**]

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

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

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

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

Tax ID Number: [**]
DUNS Number: [**]
UEI: [**]
The purpose of this modification is to exercise CLIN 0011 and update ARTICLES B.3 OPTION PRICES, B.5. ADVANCE UNDERSTANDINGS, C.1. STATEMENT OF WORK, AND SECTION J - LIST OF ATTACHMENTS.

Funds Obligated Prior to this Modification: $[**]
Funds Obligated with Mod #14: $[**]
Total Funds Obligated to Date: $[**]

Continued ...

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
Paul Williams SVP, Products Business		Jonathan Gonzalez	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Paul Williams *Electronically signed by: Paul Williams Reason: I approve this document Date: Jun 16, 2023 11:03 EDT* *(Signature of person authorized to sign)*	Jun 16, 2023	Jonathan F. Gonzalez -S Digitally signed by Jonathan F. Gonzalez -S Date: 2023.06.16 15:47:29 -04'00' *(Signature of Contracting Officer)*	

Previous edition unusable

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

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

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Expiration Date: Aug 31, 2025 OTA: N Appr. Yr.: 2023 CAN: 1995361 Object Class: 26088 Period of Performance: 09/30/2016 to 08/31/2025 Add Item 11 as follows:				
11	CLIN 0011 Additional Surge Capacity (EUA and Licensure) Obligated Amount: [**]				[**]

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

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

CLIN	Period of Performance	Supplies/ Services	Doses*	Price per Dose	Total Not to Exceed Cost
0011 (Option Quantity)	June 13, 2023 through October 31, 2023	Additional Surge Capacity (EUA and Licensure)	TBD	[**] ([**] from date of manufacture) [**] ([**] from date of manufacture)	[**] (Funded)

*Under **CLIN 0011** no less than [**] and up to [**] doses are expected to be procured at the unit prices stated above.

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

n. CLIN 0011

- For CLIN 0011, BARDA agrees to receiving doses that are [**] from their manufacturing date ([**]).
- These anthrax vaccine doses will have two different unit prices depending on the age of the vaccine post-manufacture. Vaccine doses delivered [**] from their manufacture date will be charged a dose price of [**]per dose. Vaccines delivered with a [**]life greater than [**] post-manufacture will be charged a unit dose price of [**]per dose. BARDA will not accept any vaccine older than [**] post-manufacture.

The following table is provided as an estimate of doses to be delivered under CLIN 011 but subject to change:

Product	Dating	Price per Dose (USD)	Estimated Quantity for Delivery (Including Camden Lots)
Base Doses	[**] from date of manufacture	[**]	[**]doses
[**]	[**] from date of manufacture	[**]	[**] doses

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

ARTICLE C.1. STATEMENT OF WORK

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

SECTION J – LIST OF ATTACHMENTS is modified as follows:

1. Statement of Work, dated June 12, 2023, 10 pages

All other terms and conditions of this contract remain unchanged.

End of Modification #14

ATTACHMENT 1: STATEMENT OF WORK

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

1.0 Contractual Statement of Work

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

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

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

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

1.3 CLIN 0001 - Approval of Emergency Use Authorization (EUA), licensure, approval, and clearance of product through the FDA (Base)
This section identifies representative tasks and sub-tasks for CLIN 0001 with associated WBS code for each task or subtask.

[**] Program Management
Emergent shall provide program management activities. The activities shall include but are not limited to:

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

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

[**] Non-Clinical Toxicology

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

- [**]

[**] Non-Clinical Efficacy

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

- [**]

[**] Clinical Evaluation

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

- [**]

[**] Regulatory Activities

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

[**]

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

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

- [**]

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

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

[**] Program Management

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

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

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

[**] Clinical Evaluation

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

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

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

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

[**]

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

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

- [**]

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

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

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

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

-

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

[**]. .

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

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

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

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

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

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

These anthrax vaccine doses will have [**]. Vaccine doses delivered [**].

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

1.9 Reporting Requirements and Deliverables Reports

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

Monthly Technical Progress Reports

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

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

Annual Progress Reports

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

Draft Final Report and Final Report

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

FDA Regulatory Agency Correspondence, Meeting Summaries, and Submissions

With regard to interactions with the FDA, Emergent shall:

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

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

Key Deliverables

A summary of Key Deliverables for this contract follow

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

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

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

Certain identified information has been marked in the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00009	See Block 16C		

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR/SNS	ASPR/SNS	US DEPT OF HEALTH & HUMAN SERVICES	ASPR/SNS
ASPR/SNS		ASPR/SNS	
2945 FLOWERS ROAD		2945 FLOWERS ROAD	
ATLANTA, GA 30341		ATLANTA, GA 30341	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. Attn: STEVE RAMBO EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR GAITHERSBURG MD 208793419	(x)	9B. DATED *(SEE ITEM 11)*
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50119C00071
		10B. DATED *(SEE ITEM 13)* 08/30/2019

CODE 1365869	FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

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

Net Decrease: [**]

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

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

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

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

Tax ID Number: [**]
DUNS Number: [**]
UEI: CNPVCR8DK7M8

Points of Contact:
COR:[**]
CO: [**]
ASPR Contracts Consultant: [**]
EMERGENT: [**]

Continued ...

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
Clark Baker VP, Business Operations		KIMBERLY L. GOLDEN	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Electronically signed by: Clark Baker Reason: I approve this document Date: May 24, 2023 15:08 EDT *(Signature of person authorized to sign)*	May 24, 2023	*(Signature of Contracting Officer)*	

Previous edition unusable

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

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

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	OTA: N Period of Performance: 08/30/2019 to 08/29/2029 Change Item 3 to read as follows(amount shown is the obligated amount):				
3	Option 1001 - Task 4 Relabeling of ACAM2000 1 JOB @ [**] Obligated Amount: [**] Accounting Info: 2020.199SN20.25235 Appr. Yr.: 2020 CAN: 199SN20 Object Class: 25235 Funded: [**] Delivery Location: 10635 Marina Drive Attn: Mike King Olive Branch, MS 38654 Change Item 4 to read as follows(amount shown is the obligated amount):				[**]
4	ACAM2000 Relabeling Obligated Amount: [**] Accounting Info: 2021.199SN21.25102 Appr. Yr.: 2021 CAN: 199SN21 Object Class: 25102 Funded: [**]				[**]

The purpose of this modification to the contract, P00009, is to deobligate the unliquidated funding for Task 4, Relabeling of ACAM2000 from fiscal years 2020 and 2021 appropriations.

As a result of this deobligation action, the following changes are made:

a. The total value of Line Item 3, Task 4: Relabeling of ACAM2000, added per P00001, is hereby [**] from a total funded value [**] to a balance of [**].

b. The total value of Line Item 4, Task 4: ACAM Relabeling, exercised per P00003, is hereby [**] from a total funded value of [**] to a balance of [**].

c. The Total Obligated Value under the contract is hereby [**], from [**] to a Funded Balance of [**]

All other terms and conditions of the contract remain unchanged as a result of this modification, P00009.

Certain identified information has been marked in the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00010	See Block 16C	OS313044	

6. ISSUED BY CODE ASPR/SNS

ASPR/SNS
ASPR/SNS
2945 FLOWERS ROAD
ATLANTA, GA 30341

7. ADMINISTERED BY *(If other than Item 6)* CODE ASPR/SNS

US DEPT OF HEALTH & HUMAN SERVICES
ASPR/SNS
2945 FLOWERS ROAD
ATLANTA, GA 30341

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC.
Attn: STEVE RAMBO
EMERGENT PRODUCT DEVELOPMENT GAITHE
300 PROFESSIONAL DR
GAITHERSBURG MD 208793419

CODE 1365869 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

X 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50119C00071

10B. DATED *(SEE ITEM 13)* 08/30/2019

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
2023.199SN23.26088 Net Increase: [**]

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

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

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

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

Tax ID Number: [**]
DUNS Number: [**]
UEI: CNPVCR8DK7M8

Points of Contact:
COR:[**]
CO: [**]
ASPR Contracts Consultant: [**]
EMERGENT: [**]

Continued ...

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
Paul Williams SVP, Products Business Head	KIMBERLY L. GOLDEN

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
PAUL WILLIAMS Electronically signed by: PAUL WILLIAMS Reason: I approve this document Date: May 26, 2023 12:56 EDT	5-26-2023	Kimberly Golden	5-26-2023
(Signature of person authorized to sign)		*(Signature of Contracting Officer)*	

Previous edition unusable

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

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

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	OTA: N Appr. Yr.: 2023 CAN: 199SN23 Object Class: 26088 Period of Performance: 08/30/2019 to 08/29/2029 Add Item 9 as follows:				
9	ACAM2000 Vaccine Qty [**] Obligated Amount: [**]				[**]

The purpose of this modification is to exercise option 3001 for [**] doses of ACAM2000 to sustain operational capability of ACAM2000 for Fiscal Year (FY) 2023.

1. The period of performance for ACAM2000 product to be delivered for Task 1, under Option 3001 is updated from 10/01/21-10/30/22 to 10/31/22-6/30/23.
2. The minimum annual procurement order for this modification is [**] doses of ACAM2000 kits with a minimum shelf life of [**] with supply ranging from [**].

Quantities	Shelf Life *
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**] as of June 7, 2023

3. EPDG will provide the potency testing under CLIN 30001 for existing ACAM2000 doses in the SNS by [**]. Any further testing for ACAM2000 or Wetvax will be subject to future discussions.

4. Funding is hereby obligated in the amount of [**] for [**] by doses at [**] per dose.

5. The revised funding obligation amount will be increased from [**] by [**] to [**].

6. All other terms and conditions remain the same.

Certain identified information has been marked in the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

PRIVILEGED AND CONFIDENTIAL

July 7, 2023

Via Email
Dr. Zsolt Harsanyi
[**]

Re: Emergent BioSolutions – Interim CEO

Dear Dr. Harsanyi:

This letter confirms that the Board of Directors ("Board") of Emergent BioSolutions Inc. (collectively with its designated affiliates, the "Company") has engaged Haywood Miller of Berkeley Research Group, LLC ("BRG") as Interim Chief Executive Officer ("ICEO") for the Company. This letter and any attachments set forth the agreement ("Agreement") between the parties.

SCOPE OF SERVICES

The Board has requested that the ICEO provide professional services as directed by or overseen by the Board ("Services"):

- Provide overall executive leadership and foster a culture of collaboration and responsibility for the executive team and other employees;
- Ensure clear and effective communication;
- Assume leadership role for strategic initiatives including the development of a long-term business strategy, implementation plan, and related financial projections;
- Work closely with other members of the senior management team, Board and outside advisors on issues and actions important to the Company;
- Engage with lenders as needed and appropriate to refinance or restructure the existing indebtedness of the Company;
- Work together with other members of the senior management team to drive implementation of expense reduction initiatives including any refinement or change management activities as appropriate;
- Represent the organization to appropriate stakeholders including shareholders, customers, lenders, suppliers and other parties as necessary;
- Report regularly to the Board of Directors on the above items; and
- Other items as mutually agreed.

For avoidance of doubt, this letter reflects [**] and is not intended to replace existing agreements.

Any services provided by BRG other than the Services provided by the ICEO are subject to the [**]. The ICEO will perform his duties and responsibilities diligently and to the best of his abilities, in compliance with all applicable laws, regulations, and the Company's internal policies and procedures. The Company agrees that the ICEO will continue as an employee of BRG and may continue to provide his services to other companies during the term of this Agreement, provided, however, that such services do not interfere or conflict with the business of the company or the terms of this Agreement. The Company acknowledges that all payments for the time charges of the ICEO incurred in the performance of Services hereunder to Company will be made to BRG.

The ICEO who provides Services to the Company under this Agreement is an independent contractor and is not, and will not be deemed to be an employee of the Company.

FEES AND EXPENSES

The Company will compensate BRG in the amount of $125,000 per month (or prorated portion thereof) for the ICEO's Services on this engagement.

The Board acknowledges that completion and success fees are customary components of engagements as outlined and agree to work with BRG to amend this agreement to include reasonable and customary completion and success fees, as appropriate and in the sole discretion of the Board.

In addition to Professional Fees, BRG will be reimbursed for reasonable and documented direct out-of pocket expenses related to the ICEO's provision of Services consistent with the Company's travel and reimbursement policies, a copy of which has been or will be furnished to ICEO and BRG.

BRG will submit reasonably detailed invoices to the Company, for all Services rendered and expenses incurred. BRG will bill for Services monthly and will provide customary descriptions regarding the Services rendered. BRG will provide additional details regarding Services rendered upon request by Company. BRG's invoice statements shall be paid within thirty (30) days of the invoice date. Company agrees it will review BRG's invoices upon receipt and will advise BRG of any objection to or dispute with the invoice and the work reflected in the invoice within fourteen (14) days of receipt of the invoice.

Without liability, BRG reserves the right to withhold delivery of Services, testimony, reports or data (written or oral), or suspend work, if the account on this engagement is not current.

Please remit payments by wire to:
[**]

COMPANY RESPONSIBILITIES

The Company will undertake responsibilities to (a) provide reliable and accurate detailed information, materials, and documentation and (b) make decisions and take future actions, as the Company determines in its sole discretion, on any recommendations made by the ICEO in connection with this Agreement. BRG's delivery of services and the fees charged are dependent on the Company's timely and effective completion of its responsibilities and timely decisions and approvals made by the Company's management.

In connection with any Chapter 11 filing, if the Company wishes to continue to retain the ICEO for Services, the Company will apply promptly to the Bankruptcy Court for approval of the Company's retention of the ICEO and BRG under the terms of this Agreement. The form of retention application and proposed order shall be reasonably acceptable to BRG. BRG shall have no obligation to provide any further Services if the Company becomes a debtor under the Bankruptcy Code unless BRG's retention under the terms of this Agreement is approved by a final order of the Bankruptcy Court reasonably acceptable to BRG. The Company shall assist, or cause its counsel to assist, with filing, serving and noticing of papers related to BRG's fee and expense applications. The CEO and BRG reserve the right to request approval of additional compensation in circumstances where extraordinary results may warrant such additional compensation.

CONFIDENTIALITY and Related Matters

ICEO agrees to enter into the usual and customary agreements the Company has with its other executive officers regarding confidentiality, intellectual property rights, indemnification, non-solicitation of Company personnel and non-competition with the Company's business.

ARBITRATION

This Agreement shall be interpreted and controlled by the laws of the state of Delaware. Any controversy, dispute, or claim between Company on the one hand and BRG on the other hand of whatever nature arising out of, in connection with, or in relation to the interpretation, performance or breach of this Agreement, including any claim based on contract, tort, or statute, ("Claims") shall be resolved at the request of any party to this agreement, by final and binding arbitration, administered either by (a) Judicial Arbitration & Mediation Services, Inc. (JAMS), pursuant to Streamlined Arbitration Rules & Procedures or (b) the American Arbitration Association ("AAA") (with a sole arbitrator) in accordance with its Commercial Arbitration Rules, and judgment upon any award rendered by the arbitrator may be entered by any State or Federal Court having jurisdiction thereof. Any such arbitration shall take place in a venue agreed to by the parties to this Agreement, and in the event the parties are unable to reach an agreement on venue within a reasonable period of time, such arbitration shall take place in Massachusetts. If a party to any arbitration proceeding filed in connection with this Agreement fails to pay any costs of the arbitration required to be paid by such party in the time required for payment, the

arbitrator is authorized to provide an appropriate remedy, including an entry of a default and an arbitration award on the merits against such party.

LIMITATION OF LIABILITY

The ICEO will receive the benefit of the indemnification and advancement provisions provided by the Company to its directors, officers and any equivalently placed employees, whether under the Company's charter or by-laws, by contract or otherwise.

The Company shall specifically include and cover the ICEO with direct coverage under the Company's policy for liability insurance covering its directors, officers and any equivalently placed employees ("D&O insurance"). The Company shall, at the request of BRG, provide BRG a copy of Company's current D&O policy, a certificate(s) of insurance evidencing the policy is in full force and effect, and a copy of the signed board resolutions and any other documents as BRG may reasonably request evidencing the appointment of the ICEO. Company will maintain such D&O insurance coverage for the period through which claims can be made against such persons.

Notwithstanding any other provision in this Agreement to the contrary, the Company's indemnification and advancement obligations shall be primary to (and without allocation against) any similar indemnification and advancement obligations of BRG, its affiliates and insurers to the indemnitees (which shall be secondary), and the Company's D&O insurance coverage for the indemnitees shall be specifically primary to (and without allocation against) any other valid and collectible insurance coverage that may apply to the indemnitees (whether provided by BRG or otherwise).

IN NO EVENT SHALL THE COMPANY THE ICEO, OR BRGBE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES OF ANY KIND IN CONNECTION WITH THIS AGREEMENT, EVEN IF THEY HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE ICEO AND BRG SHALL NOT BE LIABLE TO THE COMPANY, OR ANY PARTY ASSERTING CLAIMS ON BEHALF OF THE COMPANY, EXCEPT FOR DIRECT DAMAGES FOUND IN A FINAL DETERMINATION TO BE THE DIRECT RESULT OF THE BAD FAITH, SELF-DEALING, OR INTENTIONAL MISCONDUCT OF BRG. BRG'S AGGREGATE LIABILITY, WHETHER IN TORT, CONTRACT, OR OTHERWISE, IS LIMITED TO THE AMOUNT OF FEES PAID TO BRG FOR SERVICES UNDER THIS AGREEMENT (THE "LIABILITY CAP"). THE LIABILITY CAP IS THE TOTAL LIMIT OF BRG'S AGGREGATE LIABILITY FOR ANY AND ALL CLAIMS OR DEMANDS BY ANYONE PURSUANT TO THIS AGREEMENT, INCLUDING LIABILITY TO THE COMPANYAND TO ANY OTHERS MAKING CLAIMS RELATING TO THE WORK PERFORMED BY BRG PURSUANT TO THIS AGREEMENT.

OTHER TERMS

The interpretation and application of the terms of this Agreement shall be governed and construed in accordance with the laws of the state of Delaware.

The waiver by any party and the breach of any of the provisions of this Agreement shall not operate or be construed as a waiver of any subsequent breach hereof. This Agreement shall be binding upon and inure to the benefit of the parties and their respective successors, assigns, legal representatives, executors, administrators and heirs. The parties may not assign this Agreement or any rights or obligations hereunder to any party without the prior written consent of the other parties. Each of the provisions of this Agreement is a separate and distinct agreement and independent of all others, so that if any provision hereof shall be held to be invalid or unenforceable for any reason, such invalidity or enforceability shall not affect the validity or enforceability of any other provisions hereof. No amendment or modification of this Agreement shall be effective unless in writing and signed by both parties hereto.

* * * *

We look forward to working with you on this matter. Please sign and return a copy of this agreement signifying your agreement with the terms and provisions herein.

Sincerely,

Eric B. Miller
General Counsel

AGREED AND ACCEPTED:

Board of Directors of Emergent BioSolutions Inc.

DocuSigned by:
By Dr. Zsolt Harsanyi
7B4E2FC7EBBF425...
Dr. Zsolt Harsanyi
Emergent BioSolutions Inc.

EXHIBIT 31.1

CERTIFICATION

I, Haywood Miller, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Emergent BioSolutions Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information, and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2023

/s/HAYWOOD MILLER
Haywood Miller
Interim Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Richard S. Lindahl, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Emergent BioSolutions Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information, and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2023

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

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Haywood Miller, Interim Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2023

/s/HAYWOOD MILLER
Haywood Miller
Interim Chief Executive Officer

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Richard S. Lindahl, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2023

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