

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 September 30, 2022**

OR

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

**For the transition period from to**

Commission file number: 001-33137

**EMERGENT**  
**EMERGENT BIOSOLUTIONS INC.**

*(Exact Name of Registrant as Specified in Its Charter)*

**Delaware**

*(State or Other Jurisdiction of  
Incorporation or Organization)*

**14-1902018**

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

**400 Professional Drive Suite 400**

**Gaithersburg, Maryland 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**

<i>Title of each class</i>	<i>Trading Symbol</i>	<i>Name of each exchange on which registered</i>
<b>Common Stock, Par Value \$0.001 per share</b>	<b>EBS</b>	<b>New York Stock Exchange</b>

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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 November 1, 2022 the registrant had 49,888,218 shares of common stock outstanding.

Emergent BioSolutions Inc.  
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## PART I. FINANCIAL INFORMATION

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q and the documents we incorporate by reference include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding the future performance of Emergent BioSolutions Inc. or our business strategy, future operations, future financial position, future revenues and earnings, projected costs, prospects, plans and objectives of management and the ongoing impact of the COVID-19 pandemic, are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "estimate," "expect," "forecast," "intend," "may," "plan," "should," "will," and similar expressions or variations thereof, or 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. We cannot guarantee that any forward-looking statement will be accurate. You should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. You are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by law and the rules of the Securities and Exchange Commission (the "SEC"), we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

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

- the availability of U.S. Government ("USG") funding for contracts related to procurement of our medical countermeasures, including AV7909 (Anthrax vaccine adsorbed (AVA), adjuvanted), BioThrax® (Anthrax Vaccine Adsorbed) and ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live), among others, as well as contracts related to development of medical countermeasures;
- our ability to meet our commitments to quality and compliance in all of our manufacturing operations;
- the impact of the 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;
- our ability to obtain and maintain regulatory approvals for our product candidates and the timing of any such approvals;
- the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices and other regulatory obligations;
- our ability to negotiate additional USG procurement or follow-on contracts for our Public Health Threat ("PHT") products that have expired or will be expiring;
- 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 services fees from Janssen Pharmaceuticals, Inc. or other CDMO customers;
- the outcomes associated with pending shareholder litigation and government investigations;
- our ability to comply with the operating and financial covenants required by our senior secured credit facilities (Senior Secured Credit Facilities) and our 3.875% Senior Unsecured Notes due 2028;
- the procurement of products by USG entities under regulatory exemptions prior to approval by the U.S. Food and Drug Administration ("FDA") and corresponding procurement by government entities outside of the United States under regulatory exemptions prior to approval by the corresponding regulatory authorities in the applicable country;
- the extent of any ongoing impact of the COVID-19 pandemic on our supply chains and potential future impact thereof on our markets, operations and employees as well as those of our customers and suppliers;

- the impact on our revenues from and duration of declines in sales of our vaccine products that target travelers due to the reduction of international travel caused by the COVID-19 pandemic;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria, contribute to our overall business strategy, and align with our underlying assumptions that formed the basis of acquisition;
- our ability to commercialize, market and manufacture new product candidates successfully; 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 Factor Summary", "Risk Factors", "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Quantitative and Qualitative Disclosures about Market Risk", as well as the risks identified in our other reports filed with the SEC. New factors emerge from time to time, and it is not possible for management to predict all such factors, nor can it assess the impact of any such factor on the business or the extent to which any factor, or combination of factors, may cause results to differ materially from those contained in any forward-looking statement.

#### NOTE REGARDING COMPANY REFERENCES

References in this report to "Emergent," the "Company," "we," "us," and "our" refer to Emergent BioSolutions Inc. and its consolidated subsidiaries.

#### NOTE REGARDING TRADE NAMES

Emergent®, BioThrax®, BaciThrax®, RSDL®, BAT®, Trobigard®, Anthrasil®, CNJ-016®, ACAM2000®, Vivotif®, Vaxchora®, NARCAN®, Ebanga™, 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.  
Condensed Consolidated Balance Sheets  
(in millions, except per share amounts)

	September 30, 2022 (unaudited)	December 31, 2021
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 240.9	\$ 576.1
Restricted cash	0.1	0.2
Accounts receivable, net	191.3	274.7
Inventories, net	546.3	350.8
Prepaid expenses and other current assets	139.9	70.3
Total current assets	1,118.5	1,272.1
Property, plant and equipment, net	806.7	800.1
Intangible assets, net	722.7	604.6
Goodwill	224.9	224.9
Other assets	35.7	57.3
Total assets	\$ 2,908.5	\$ 2,959.0
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 103.8	\$ 128.9
Accrued expenses	35.9	51.7
Accrued compensation	82.5	88.7
Debt, current portion	21.2	31.6
Other current liabilities	25.0	72.9
Total current liabilities	268.4	373.8
Debt, net of current portion	1,032.1	809.4
Deferred tax liability	113.8	94.9
Other liabilities	44.9	61.9
Total liabilities	1,459.2	1,340.0
Stockholders' equity:		
Preferred stock, \$0.001 par value; 15.0 shares authorized, no shares issued or outstanding	—	—
Common stock, \$0.001 par value; 200.0 shares authorized, 55.5 and 55.1 shares issued; 49.9 and 51.3 shares outstanding, respectively	0.1	0.1
Treasury stock, at cost, 5.6 and 3.8 common shares, respectively	(227.7)	(152.2)
Additional paid-in capital	860.1	829.4
Accumulated other comprehensive loss, net	(5.2)	(16.1)
Retained earnings	822.0	957.8
Total stockholders' equity	1,449.3	1,619.0
Total liabilities and stockholders' equity	\$ 2,908.5	\$ 2,959.0

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
<b>Revenues:</b>				
Product sales, net	\$ 186.2	\$ 270.5	\$ 660.5	\$ 589.6
<b>CDMO:</b>				
Services	36.2	112.6	90.7	283.7
Leases	0.2	(71.0)	4.7	132.6
Total CDMO	36.4	41.6	95.4	416.3
Contracts and grants	17.4	16.9	34.3	63.6
<b>Total revenues</b>	<b>240.0</b>	<b>329.0</b>	<b>790.2</b>	<b>1,069.5</b>
<b>Operating expenses:</b>				
Cost of product sales	85.5	103.2	256.8	237.0
Cost of CDMO	63.1	114.3	217.5	307.6
Research and development	39.2	49.6	135.4	151.0
Selling, general and administrative	80.2	82.1	246.1	254.2
Amortization of intangible assets	14.0	14.5	42.0	44.5
<b>Total operating expenses</b>	<b>282.0</b>	<b>363.7</b>	<b>897.8</b>	<b>994.3</b>
<b>Income (loss) from operations</b>	<b>(42.0)</b>	<b>(34.7)</b>	<b>(107.6)</b>	<b>75.2</b>
<b>Other income (expense):</b>				
Interest expense	(8.5)	(8.4)	(24.5)	(25.5)
Other, net	(13.4)	(2.4)	(18.4)	(2.8)
<b>Total other income (expense), net</b>	<b>(21.9)</b>	<b>(10.8)</b>	<b>(42.9)</b>	<b>(28.3)</b>
<b>Income (loss) before income taxes</b>	<b>(63.9)</b>	<b>(45.5)</b>	<b>(150.5)</b>	<b>46.9</b>
Income tax benefit (provision)	(11.8)	12.8	14.7	(5.3)
<b>Net income (loss)</b>	<b>\$ (75.7)</b>	<b>\$ (32.7)</b>	<b>\$ (135.8)</b>	<b>\$ 41.6</b>
<b>Net income (loss) per common share</b>				
Basic	\$ (1.52)	\$ (0.61)	\$ (2.71)	\$ 0.78
Diluted	\$ (1.52)	\$ (0.61)	\$ (2.71)	\$ 0.77
<b>Shares used in computing net loss per common share</b>				
Basic	49.9	53.7	50.2	53.6
Diluted	49.9	53.7	50.2	54.3

*See accompanying notes.*

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net income (loss)	\$ (75.7)	\$ (32.7)	\$ (135.8)	\$ 41.6
Other comprehensive income (loss), net of tax:				
Foreign currency translation adjustment	(1.3)	0.3	(0.4)	(1.4)
Unrealized gains (losses) on hedging activities	2.2	(1.0)	11.3	3.6
Total other comprehensive income (loss), net of tax	0.9	(0.7)	10.9	2.2
Comprehensive income (loss), net of tax	<u>\$ (74.8)</u>	<u>\$ (33.4)</u>	<u>\$ (124.9)</u>	<u>\$ 43.8</u>

*See accompanying notes.*

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows used in operating activities:		
Net income (loss)	\$ (135.8)	\$ 41.6
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Share-based compensation expense	33.4	32.3
Depreciation and amortization	107.7	94.6
Adjustment for prior period lease receivables (Note 10)	—	86.1
Change in fair value of contingent consideration, net	2.4	2.6
Amortization of deferred financing costs	3.1	3.1
Deferred income taxes	23.0	0.6
Other	13.0	5.1
Changes in operating assets and liabilities:		
Accounts receivable	76.2	(114.7)
Inventories	(112.2)	(58.0)
Prepaid expenses and other assets	(29.2)	(54.8)
Accounts payable	(9.0)	3.5
Accrued expenses and other liabilities	(98.0)	(19.3)
Accrued compensation	(5.7)	(11.1)
Contract liabilities	4.2	(19.5)
Net cash used in operating activities:	(126.9)	(7.9)
Cash flows used in investing activities:		
Purchases of property, plant and equipment	(92.2)	(178.3)
Asset acquisitions	(243.7)	—
Net cash used in investing activities:	(335.9)	(178.3)
Cash flows provided by (used in) financing activities:		
Proceeds from revolving credit facility	238.0	—
Purchases of treasury stock	(81.9)	—
Principal payments on term loan facility	(25.3)	(16.9)
Principal payments on convertible senior notes	—	(10.6)
Proceeds from share-based compensation activity	3.0	12.5
Taxes paid for share-based compensation activity	(5.7)	(13.5)
Contingent consideration payments	—	(2.5)
Net cash provided by (used in) financing activities:	128.1	(31.0)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(0.6)	(0.3)
Net change in cash, cash equivalents and restricted cash	(335.3)	(217.5)
Cash, cash equivalents and restricted cash at beginning of period	576.3	621.5
Cash, cash equivalents and restricted cash at end of period	\$ 241.0	\$ 404.0
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	\$ 26.7	\$ 27.3
Cash paid during the period for income taxes	\$ 23.9	\$ 57.6
Supplemental information on non-cash investing and financing activities:		
Purchases of property, plant and equipment unpaid at period end	\$ 10.0	\$ 20.6
Reconciliation of cash and cash equivalents and restricted cash at September 30, 2022 and December 31, 2021:		
Cash and cash equivalents	\$ 240.9	\$ 576.1
Restricted cash	0.1	0.2
Total	\$ 241.0	\$ 576.3

See accompanying notes.



Emergent BioSolutions Inc.  
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 Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
<b>Balance at December 31, 2021</b>	55.1	\$ 0.1	(3.8)	\$ (152.2)	\$ 829.4	\$ (16.1)	\$ 957.8	\$ 1,619.0
Share-based compensation activity	0.4	—	—	—	30.7	—	—	30.7
Net loss	—	—	—	—	—	—	(135.8)	(135.8)
Repurchases of stock	—	—	(1.8)	(75.5)	—	—	—	(75.5)
Other comprehensive income, net of tax	—	—	—	—	—	10.9	—	10.9
<b>Balance at September 30, 2022</b>	55.5	\$ 0.1	(5.6)	\$ (227.7)	\$ 860.1	\$ (5.2)	\$ 822.0	\$ 1,449.3
<b>Balance at June 30, 2022</b>	55.5	\$ 0.1	(5.6)	\$ (227.7)	\$ 849.2	\$ (6.1)	\$ 897.7	\$ 1,513.2
Share-based compensation activity	—	—	—	—	10.9	—	—	10.9
Net loss	—	—	—	—	—	—	(75.7)	(75.7)
Repurchases of stock	—	—	—	—	—	—	—	—
Other comprehensive income, net of tax	—	—	—	—	—	0.9	—	0.9
<b>Balance at September 30, 2022</b>	55.5	\$ 0.1	(5.6)	\$ (227.7)	\$ 860.1	\$ (5.2)	\$ 822.0	\$ 1,449.3
<b>Balance at December 31, 2020</b>	54.3	\$ 0.1	(1.2)	\$ (39.6)	\$ 784.9	\$ (25.3)	\$ 726.9	\$ 1,447.0
Share-based compensation activity	0.6	—	—	—	31.9	—	—	31.9
Net income	—	—	—	—	—	—	41.6	41.6
Other comprehensive income, net of tax	—	—	—	—	—	2.2	—	2.2
<b>Balance at September 30, 2021</b>	54.9	\$ 0.1	(1.2)	\$ (39.6)	\$ 816.8	\$ (23.1)	\$ 768.5	\$ 1,522.7
<b>Balance at June 30, 2021</b>	54.9	\$ 0.1	(1.2)	\$ (39.6)	\$ 804.4	\$ (22.4)	\$ 801.2	\$ 1,543.7
Share-based compensation activity	—	—	—	—	12.4	—	—	12.4
Net loss	—	—	—	—	—	—	(32.7)	(32.7)
Other comprehensive loss, net of tax	—	—	—	—	—	(0.7)	—	(0.7)
<b>Balance at September 30, 2021</b>	54.9	\$ 0.1	(1.2)	\$ (39.6)	\$ 816.8	\$ (23.1)	\$ 768.5	\$ 1,522.7

See accompanying notes.

## 1. 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.

The Company is focused on the following five distinct PHT categories: chemical, biological, radiological, nuclear and explosives (CBRNE); emerging infectious diseases (EID); travel health; emerging health crises; and acute/emergency care. The Company has a product portfolio of thirteen products (vaccines, therapeutics and drug-device combination products). The revenue generated by the products comprises a substantial portion of the Company's revenue. The Company also has one product candidate that is procured under special circumstances by the U.S. government (USG), although it is not approved by the U.S. Food and Drug Administration (FDA). The Company structures the business with a focus on markets and customers. As such, the key components of the business structure include the following three business lines: Government - Medical Countermeasures (MCM) Products, Commercial Products, and CDMO Services. The Company operates as two operating segments: 1) a products segment (Products) consisting of the Government - MCM and Commercial business lines and 2) a services segment (Services) focused on CDMO (Note 14, "Segment information").

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

#### Government - MCM Products

- AV7909<sup>®</sup>, is a procured product candidate being developed as a next generation anthrax vaccine for post-exposure prophylaxis of disease resulting from suspected or confirmed *Bacillus anthracis* exposure. The USG has largely switched from procuring BioThrax to AV7909 for the Strategic National Stockpile (SNS) prior to its approval by the FDA;
- BioThrax<sup>®</sup>, the only vaccine licensed by the FDA, for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- ACAM2000<sup>®</sup>, 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;
- BAT<sup>®</sup>, the only heptavalent antitoxin licensed by the FDA and Health Canada for the treatment of botulism;
- CNJ-016<sup>®</sup>, also referred to as VIGIV, the only polyclonal antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination;
- Raxibacumab injection, a fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax;
- Anthrasil<sup>®</sup>, the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of inhalational anthrax;
- RSDL<sup>®</sup>, the only medical device cleared by the FDA to remove or neutralize the following chemical warfare agents from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin; and
- Trobigard<sup>®</sup> atropine sulfate, obidoxime chloride AUTO-INJECTOR, is a combination drug-device auto-injector procured product candidate that contains atropine sulfate and obidoxime chloride. It has not been approved by the FDA, but it is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure.
- TEMBEXA<sup>®</sup>, an oral antiviral formulated as 100 mg tablets and 10 mg/mL oral suspension dosed once weekly for two weeks. It has been approved by the FDA for the treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates.

- Ebanga™ (ansuvimab-zykl, formerly referred to as mAb114) is a monoclonal antibody with antiviral activity provided through a single IV infusion for the treatment of Ebola. Under the terms of a collaboration with Ridgeback Biotherapeutics, Emergent will be responsible for the manufacturing, sale, and distribution of Ebanga™ in the United States and Canada, and Ridgeback Biotherapeutics will serve as the global access partner for Ebanga™.

#### Commercial Products

- NARCAN® (naloxone HCl) Nasal Spray, the first needle-free formulation of naloxone approved by the FDA and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression;
- Vaxchora® (Cholera Vaccine, Live, Oral), the only single-dose oral vaccine licensed by the FDA and the European Medicines Agency (EMA) for the prevention of cholera; and
- Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever.

#### Services - Contract Development and Manufacturing

The Company's services line focused on CDMO offerings covers 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 spanning the pharmaceutical and biotechnology industries as well as the USG and non-governmental organizations. The Company's technology platforms include mammalian, microbial, viral, plasma and advanced therapies utilizing the Company's core capabilities for manufacturing to third parties on a clinical and commercial (small and large) scale. Additional services include fill/finish formulation and analytical development services for injectable and other sterile products, inclusive of process design, technical transfer, manufacturing validations, aseptic filling, lyophilization, final packaging and stability studies, as well as manufacturing of vial and pre-filled syringe formats on multiple platforms.

#### **Asset Acquisition**

During the three months ended September 30, 2022, the Company acquired from Chimerix ("the Seller") the exclusive worldwide rights to brincidofovir, including TEMBEXA® and related assets (the "Transaction"). TEMBEXA is a medical countermeasure for smallpox approved by the FDA in June 2021. Under the terms of the Asset Purchase Agreement (the "Purchase Agreement"), the Company paid \$238.0 million upon closing of the Transaction, and is subject to potential milestone payments of up to \$124.0 million contingent on the potential exercise by the U.S. government of procurement options. The closing payment and the milestone payments were based on the actual procurement value of the procurement contract (the "BARDA Contract") with the Biomedical Advanced Research and Development Authority ("BARDA"). Each milestone payment is associated with the exercise of future BARDA procurement options of TEMBEXA following the BARDA Contract base period. The Seller is also eligible to receive up to \$12.5 million in regulatory milestones associated with the Symbio Pharmaceuticals Ltd. brincidofovir licensing arrangements assumed by the Company in the Transaction. The milestone payments will be recorded when the associated procurement options have been exercised and/or the regulatory milestones have been met and the consideration is paid or becomes payable.

The Seller may also earn a 20% royalty on future gross profit of TEMBEXA in the United States associated with volumes above 1.7 million treatment courses of therapy during the exclusivity period of TEMBEXA. Outside of the United States, the Purchase Agreement also allows the Seller to earn a 15% royalty on all gross profit associated with TEMBEXA sales during the exclusivity period of TEMBEXA on a market-to-market basis. Refer to Note 6, "Intangible assets" for additional information around the impacts of this asset acquisition on the current period results.

## 2. Basis of presentation and principles of consolidation

### Basis of presentation

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 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, 2021, 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 September 30, 2022. 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 September 30, 2022, there is \$238.0 million outstanding on the revolver loan and \$371.3 million on the term loan that matures in October 2023, which is within one year of the date that the consolidated financial statements are issued for the quarter ended September 30, 2022. 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 plan to alleviate the substantial doubt includes amending its existing revolver loan and term loan that are due October 2023.

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

As the replacement of the Company's current debt facility is conditional upon the execution of agreements with new or existing third parties, which are considered outside of the Company's control, until such time as they are completed, the refinancing cannot be considered to be probable to occur as of the date of this report. 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.

### Significant accounting policies

During the nine months ended September 30, 2022, there have been no significant changes to the Company's summary of significant accounting policies contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC that have materially impacted the presentation of the Company's financial statements. During the nine months ended September 30, 2022, the Company revised the reporting that the chief operating decision maker ("the CODM") reviews in order to assess Company performance. The CODM manages the business with a focus on two reportable segments: 1) Products segment consisting of the Government - MCM and

Commercial business lines and 2) Services segment focused on CDMO. This change is further outlined in Note 14, "Segment information".

#### **Fair value measurements**

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a non-recurring basis. The Company has cash held in money market accounts (level 1) and time deposits (level 2), contingent purchase consideration (level 3) and interest rate swaps arrangements (level 2) that are measured at fair value on a recurring basis (Note 7, "Fair value measurements" and Note 8, "Derivative instruments and hedging activities").

On a non-recurring basis, the Company measures its long-lived assets as part of impairment evaluations using fair value measurements. Goodwill is allocated to the Company's reporting units, which are one level below its operating segments. The Company evaluates goodwill and other indefinite-lived intangible assets for impairment annually as of October 1 and earlier if an event or other circumstance indicates that the carrying value of the asset may not be recoverable. If the Company believes that as a result of its qualitative assessment it is more likely than not that the fair value of a reporting unit or other indefinite-lived intangible asset is greater than its carrying amount, the quantitative impairment test is not required. If however it is determined that it is not more likely than not that the fair value of a reporting unit or other indefinite-lived intangible asset is greater than its carrying amount, a quantitative test is required. Long-lived assets such as intangible assets and property, plant and equipment are not required to be tested for impairment annually. Instead, long-lived assets are tested for impairment whenever circumstances indicate that the carrying amount of the asset may not be recoverable, such as when there is an adverse change in the market relating to those related assets. The impairment test first requires a comparison of undiscounted future cash flows to the carrying value of the asset. Determining the need for a detailed impairment analysis requires the exercise of judgment about several business factors, including the timing of expected future cash flows and assumptions about the economic environment.

As of September 30, 2022 and December 31, 2021, the Company had no other significant assets or liabilities that were measured at fair value.

#### **Recently issued accounting standards**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) that the Company adopts as of the pronouncement's specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have or may have a material impact on the consolidated financial statements or disclosures.

##### Recently Adopted

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

In March 2020, the FASB issued Topic 848, which was further amended in January 2021. Topic 848 provides relief for impacted areas as it relates to impending reference rate reform. It contains optional expedients and exceptions to debt arrangements, contracts, hedging relationships, and other areas or transactions that are impacted by reference rate reform. This guidance is effective upon issuance for all entities and elections of certain optional expedients are required to apply the provisions of the guidance. As of September 30, 2022, the Company adopted this ASU with no material impact to our consolidated financial statements.

### 3. Inventories, net

Inventories, net consisted of the following:

	September 30, 2022	December 31, 2021
Raw materials and supplies	\$ 277.4	\$ 217.5
Work-in-process	138.3	95.8
Finished goods	130.6	37.5
Total inventories, net <sup>(1)</sup>	<u>\$ 546.3</u>	<u>\$ 350.8</u>

<sup>(1)</sup> During the three months ended September 30, 2022, the Company acquired certain assets through an asset acquisition, the Transaction, and the related inventories of \$84.8 million were included in our inventories balances as of September 30, 2022.

Inventories, net is stated at the lower of cost or net realizable value. For additional information related to the termination of the manufacturing services agreement (the "Agreement") with Janssen Pharmaceuticals, Inc. ("Janssen") and associated evaluation of inventory as of September 30, 2022, refer to Note 10, "Revenue recognition."

### 4. Property, plant and equipment, net

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

	September 30, 2022	December 31, 2021
Land and improvements	\$ 53.5	\$ 52.1
Buildings, building improvements and leasehold improvements	321.9	269.7
Furniture and equipment	551.2	513.5
Software	65.3	60.7
Construction-in-progress	181.0	223.2
Property, plant and equipment, gross	<u>\$ 1,172.9</u>	<u>\$ 1,119.2</u>
Less: Accumulated depreciation & amortization	<u>(366.2)</u>	<u>(319.1)</u>
Total property, plant and equipment, net	<u>\$ 806.7</u>	<u>\$ 800.1</u>

As of September 30, 2022 and December 31, 2021, construction-in-progress primarily included costs incurred related to construction to advance the Company's CDMO capabilities.

Property, plant and equipment, net is stated at cost, less accumulated depreciation and amortization. During the nine months ended September 30, 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. For additional information related to the termination of the Agreement, refer to Note 10, "Revenue recognition".

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**5. Leases**

The Company is the lessee for operating leases for offices, research and development facilities and manufacturing facilities. The Company determines if an arrangement is a lease at inception. Operating leases are included in right-of-use (ROU) assets and liabilities. For a discussion of lessor activities, see Note 10, "Revenue recognition".

The components of lease expense were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating lease cost:				
Amortization of right-of-use assets	\$ 1.4	\$ 1.4	\$ 4.2	\$ 4.2
Interest on lease liabilities	0.3	0.3	0.8	1.0
Total operating lease cost	<u>\$ 1.7</u>	<u>\$ 1.7</u>	<u>\$ 5.0</u>	<u>\$ 5.2</u>

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

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

<i>(In millions, except lease term and discount rate)</i>	Balance Sheet Location	September 30, 2022	December 31, 2021
Operating lease right-of-use assets	Other assets	\$ 20.5	\$ 28.3
Operating lease liabilities, current portion	Other current liabilities	5.7	5.8
Operating lease liabilities	Other liabilities	15.8	24.2
Total operating lease liabilities		<u>\$ 21.5</u>	<u>\$ 30.0</u>
Operating leases:			
Weighted average remaining lease term (years)		5.9	7.0
Weighted average discount rate		4.0 %	4.1 %

During the three months ended September 30, 2022, the Company exercised the option to purchase our Rockville manufacturing facility. As a result, the Company removed the related operating lease right-of-use asset and operating lease liability of \$3.5 million and \$3.4 million, respectively. The purchased assets have been properly included in "Property, plant and equipment, net" on our condensed consolidated balance sheet as of September 30, 2022.

## 6. Intangible assets

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:

Asset Type	Estimated Life	September 30, 2022			December 31, 2021		
		Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Products <sup>(1)</sup>	8-22 years	\$ 958.1	\$ 235.4	\$ 722.7	\$ 798.0	\$ 193.5	\$ 604.5
CDMO	8 years	5.5	5.5	—	5.5	5.4	0.1
Total intangible assets		\$ 963.6	\$ 240.9	\$ 722.7	\$ 803.5	\$ 198.9	\$ 604.6

<sup>(1)</sup> During the three months ended September 30, 2022, we acquired certain assets through asset acquisitions, and the related intangible assets were assigned to the "Products" asset type, of which \$154.7 million was related to the Transaction.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Amortization Expense	\$ 14.0	\$ 14.5	\$ 42.0	\$ 44.5

As of September 30, 2022, the weighted average amortization period remaining for intangible assets was 11.4 years.

The table below summarizes the changes in the carrying amount of the Company's goodwill balance:

Goodwill, December 31, 2021	\$ 224.9
Foreign currency translation adjustments	—
Goodwill, September 30, 2022	<u>\$ 224.9</u>

The carrying amount of goodwill included accumulated impairments of \$41.7 million as of September 30, 2022 and December 31, 2021, respectively.

The Company has \$224.9 million of total goodwill which is composed of our Products and Services segments. There is the risk of future impairments in our reporting units as any further deterioration in their performance compared to forecast, changes in order volumes or delivery schedules for major customers, as well as any changes in economic forecasts and expected recovery in the biopharmaceutical industry, may require the Company to complete additional impairment tests in future quarters and could result in the reporting unit's fair value falling below carrying value in subsequent quarters. In the event the Company experiences factors that it believes indicate a decline in fair value, including negative changes to long-term growth rates or if discount rates increase, we may be required to record impairments of goodwill and other identified intangible assets. Further, if the composition of the Company's reporting unit's assets and liabilities were to change and result in an increase in the reporting unit's carrying value, it could lead to additional impairment testing and further impairment losses.



## 7. 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:

	September 30, 2022				December 31, 2021			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
<b>Assets:</b>								
Money market accounts	\$ 25.3	\$ 25.3	\$ —	\$ —	\$ 152.4	\$ 152.4	\$ —	\$ —
Time deposits	50.4	—	50.4	—	200.0	—	200.0	—
Derivative instruments	—	—	—	—	—	—	—	—
Total	\$ 75.7	\$ 25.3	\$ 50.4	\$ —	\$ 352.4	\$ 152.4	\$ 200.0	\$ —
<b>Liabilities:</b>								
Contingent consideration	\$ 7.8	\$ —	\$ —	\$ 7.8	\$ 37.2	\$ —	\$ —	\$ 37.2
Derivative instruments	—	—	—	—	6.1	—	6.1	—
Total	\$ 7.8	\$ —	\$ —	\$ 7.8	\$ 43.3	\$ —	\$ 6.1	\$ 37.2

### Contingent consideration

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

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

	Liability for Contingent Consideration
Balance at December 31, 2021	\$ 37.2
Change in fair value	2.4
Settlements	(31.8)
Balance at September 30, 2022	\$ 7.8

As of September 30, 2022 and December 31, 2021, the current portion of the contingent consideration liability was \$3.5 million and \$32.7 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.

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

Contingent Consideration Liability	Fair Value as of September 30, 2022	Valuation Technique	Unobservable Input	Range	Weighted Average
Revenue milestone and royalty based	7.8	Discounted cash flow	Discount rate	10.1%	10.1%
			Probability of payment	25% - 50%	40.0%
			Projected year of payment	2022 - 2028	2024

#### Derivative instruments

Refer to Note 8, "Derivative instruments and hedging activities" for more information about the Company's derivative instruments.

#### Non-variable rate debt

As of September 30, 2022 and December 31, 2021, the fair value of the Company's 3.875% Senior Unsecured Notes was \$299.9 million and \$433.3 million, respectively. The fair value was determined through market sources, which are level 2 inputs and directly observable. The carrying amounts of the Company's other long-term variable interest rate debt arrangements approximate their fair values (see Note 9, "Debt").

### 8. Derivative instruments and hedging activities

#### Risk management objective of using derivatives

The Company is exposed to certain risks arising from both its business operations and economic conditions. The Company principally manages its exposures to a wide variety of business and operational risks through management of its core business activities. The Company manages economic risks, including interest rate, liquidity and credit risk primarily by managing the amount, sources and duration of its assets and liabilities and the use of derivative financial instruments. Specifically, the Company has entered into interest rate swaps to manage exposures that arise from payments of variable interest rate debt associated with the Company's senior secured credit agreements.

If current fair values of designated interest rate swaps remained static over the next twelve months, the Company would reclassify \$9.0 million of net deferred gains from accumulated other comprehensive loss into the condensed consolidated statement of operations over the next twelve-month period. All outstanding cash flow hedges mature in October 2023.

As of September 30, 2022, the Company had the following outstanding interest rate derivatives that were designated as cash flow hedges of interest rate risk:

<i>(in millions, except number of instruments)</i>	Number of Instruments	Notional
Interest rate swaps	7	\$350.0

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

	Asset Derivatives				Liability Derivatives			
	September 30, 2022		December 31, 2021		September 30, 2022		December 31, 2021	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Interest Rate Swaps	Other Current Assets	\$ 8.9	Other Current Assets	\$ —	Other Current Liabilities	\$ —	Other Current Liabilities	\$ 4.5
	Other Assets	\$ 0.4	Other Assets	\$ —	Other Liabilities	\$ —	Other Liabilities	\$ 1.6

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

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

	Cumulative Amount of Gain/(Loss) Recognized in OCI on Derivatives		Location of Loss Reclassified from Accumulated OCL into Income (Loss)	Amount of Loss Reclassified from Accumulated OCL into Income (Loss)	
	September 30, 2022	December 31, 2021		Nine Months Ended September 30, 2022	September 30, 2021
	Interest Rate Swaps	\$ 9.3		\$ (6.1)	Interest expense

## 9. Debt

The components of debt were as follows:

	September 30, 2022	December 31, 2021
Senior secured credit agreement - Term loan due 2023	\$ 371.3	\$ 396.6
Senior secured credit agreement - Revolver loan due 2023	238.0	—
3.875% Senior Unsecured Notes due 2028	450.0	450.0
Other	3.0	3.0
Total debt	\$ 1,062.3	\$ 849.6
Current portion of long-term debt, net of debt issuance costs	(21.2)	(31.6)
Unamortized debt issuance costs	(9.0)	(8.5)
Non-current portion of debt	\$ 1,032.1	\$ 809.4

As of September 30, 2022 and December 31, 2021 there was \$238.0 million and no outstanding revolver balance, respectively. The Company classifies debt issuance costs associated with the revolver loan as other current assets and other assets on the Company's consolidated balance sheets. As of September 30, 2022, the Company

had \$4.1 million and \$4.9 million of debt issuance costs associated with the revolver loan classified as other current assets and other assets, respectively. As of December 31, 2021, the Company had approximately \$2.0 million and \$1.6 million of debt issuance costs associated with the revolver loan that were classified as other current assets and other assets, respectively.

### 3.875% Senior Unsecured Notes due 2028

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

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

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

### Senior secured credit agreement

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

The Amended Credit Agreement includes (i) a Revolving Credit Facility of \$600.0 million and (ii) a Term Loan Facility with a principal amount of \$450.0 million. The Company may request incremental term loan facilities or increases in the Revolving Credit Facility (each an "Incremental Loan") as long as certain requirements involving the Company's net leverage ratio will be maintained on a pro forma basis. Borrowings under the Revolving Credit Facility and the Term Loan Facility bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.25% to 2.25% per annum, depending on the Company's consolidated net leverage ratio or (b) a base rate (which is the highest of the prime rate, the federal funds rate plus 0.50%, and a eurocurrency rate for an interest period of one month plus 1% plus a margin ranging from 0.25% to 1.25%, depending on the Company's consolidated net leverage ratio). The Company is required to make quarterly payments on the last business day of each calendar quarter under the Amended Credit Agreement for accrued and unpaid interest on the outstanding principal balance, based on the above interest rates. In addition, the Company is required to pay commitment fees ranging from 0.15% to 0.35% per annum, depending on the Company's consolidated net leverage ratio, for the average daily unused commitments under the Revolving Credit Facility. The Company is to repay the outstanding principal amount of the Term Loan Facility in quarterly installments on the last business day of each calendar quarter based on an annual percentage equal to 2.5% of the original principal amount of the Term Loan Facility during each of the first two years of the Term Loan Facility, 5% of the original principal amount of the Term Loan Facility during the third year of the Term Loan Facility and 7.5% of the original principal amount of the Term Loan Facility during each year of the remainder of the term of the Term Loan Facility until the maturity date of the Term Loan Facility, at which time the entire unpaid principal balance of the Term Loan Facility will be due and payable. The Company has the right to prepay the Term Loan

Facility without premium or penalty. The Revolving Credit Facility and the Term Loan Facility mature on October 13, 2023.

The Amended Credit Agreement also requires mandatory prepayments of the Term Loan Facility in the event the Company or its Subsidiaries (a) incur indebtedness not otherwise permitted under the Amended Credit Agreement or (b) receive cash proceeds in excess of \$100.0 million during the term of the Credit Agreement from certain dispositions of property or from casualty events involving their property, subject to certain reinvestment rights. The financial covenants under the Amended Credit Agreement currently require the quarterly presentation of a minimum consolidated 12-month rolling debt service coverage ratio of 2.50 to 1.00, and a maximum consolidated net leverage ratio of 4.50 to 1.00 (subject to an increase to 5.00 to 1.00 for an applicable four quarter period, at the election of the Company, in connection with a permitted acquisition having an aggregate consideration in excess of \$75.0 million). Negative covenants in the Amended Credit Agreement, among other things, limit the ability of the Company to incur indebtedness and liens, dispose of assets, make investments, enter into certain merger or consolidation transactions and make restricted payments. As of the date of these financial statements, the Company is in compliance with all affirmative and negative covenants.

## 10. Revenue Recognition

The Company operates as two operating segments (Note 14, "Segment information"). The Company's revenues disaggregated by the major sources were as follows:

	Three Months Ended September 30, 2022			Three Months Ended September 30, 2021		
	U.S. Government	Non-U.S. Government	Total	U.S. Government	Non-U.S. Government	Total
Product sales, net	\$ 33.4	\$ 152.8	\$ 186.2	\$ 129.9	\$ 140.6	\$ 270.5
CDMO:						
Services	—	36.2	36.2	—	112.6	112.6
Leases	—	0.2	0.2	(86.0)	15.0	(71.0)
Total CDMO	\$ —	\$ 36.4	\$ 36.4	\$ (86.0)	\$ 127.6	\$ 41.6
Contracts and grants	16.4	1.0	17.4	16.3	0.6	16.9
Total revenues	\$ 49.8	\$ 190.2	\$ 240.0	\$ 60.2	\$ 268.8	\$ 329.0

	Nine Months Ended September 30, 2022			Nine Months Ended September 30, 2021		
	U.S. Government	Non-U.S. Government	Total	U.S. Government	Non-U.S. Government	Total
Product sales, net	\$ 255.0	\$ 405.5	\$ 660.5	\$ 252.6	\$ 337.0	\$ 589.6
CDMO:						
Services	—	90.7	90.7	—	283.7	283.7
Leases	—	4.7	4.7	81.9	50.7	132.6
Total CDMO	\$ —	\$ 95.4	\$ 95.4	\$ 81.9	\$ 334.4	\$ 416.3
Contracts and grants	31.7	2.6	34.3	60.7	2.9	63.6
Total revenues	\$ 286.7	\$ 503.5	\$ 790.2	\$ 395.2	\$ 674.3	\$ 1,069.5

### 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 a manufacturing services 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.COVID-2-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 including through mediation and/or arbitration.

During the three months ended September 30, 2022, there were no impacts on previously recognized revenue or depreciation related to the conclusion of the Agreement. As of September 30, 2022, the Company has no billed or unbilled net accounts receivable related to the Agreement.

The Company has \$131.0 million of raw materials inventory recorded in its condensed consolidated balance sheet as of September 30, 2022, representing materials purchased for the Agreement which Janssen has not reimbursed. The Company evaluated the net realizable value of this inventory as of September 30, 2022, concluding that because the Agreement specifies the Company is entitled to, among other things, reimbursement of raw materials and non-cancelable orders in the event of a contract termination for any reason, the Company is entitled to payment from Janssen for these raw materials. Therefore, this inventory remains an asset on the condensed consolidated balance sheet as of September 30, 2022. Additionally, the Company has an immaterial amount of non-cancelable orders as of September 30, 2022 which have not been received and Janssen has not reimbursed. The Company also recorded approximately \$13.6 million to other assets, which relates to termination penalties and certain inventory related items.

#### BARDA COVID-19 Development Public-Private Partnership

In 2020, the Company announced the issuance of a task order under its existing 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"). The BARDA COVID-19 Development Public Private Partnership is considered a lease and is accounted for under ASC 842. The initial task order had a contract value of up to \$628.2 million and included the reservation of manufacturing capacity and accelerated expansion of fill/finish capacity valued at \$542.7 million and \$85.5 million, respectively. Subsequently, the task order was expanded to include incremental capital activities which increased the value to \$650.8 million. On November 1, 2021, the Company and BARDA mutually agreed to the completion of the Company's CIADM contract and associated task orders, including the BARDA COVID-19 Development Public Private Partnership. The Company did not recognize lease revenues under this arrangement during the three and nine months ended September 30, 2022. During the three and nine months ended September 30, 2021, the Company reversed lease revenues of \$86.0 million and recognized lease revenues of \$81.9 million, respectively, related to this arrangement.

#### 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 remaining term on the Company's operating lease components approximates 2.5 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 Janssen Agreement as discussed above, the Company estimates future operating lease revenues to be \$0.2 million in the remainder of 2022, \$5.1 million in 2023, \$0.9 million in 2024, \$0.9 million in 2025 and \$2.7 million in years beyond 2025.

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Transaction price allocated to remaining performance obligations

As of September 30, 2022, the Company has future contract value on unsatisfied performance obligations of approximately \$453.9 million associated with all arrangements entered into by the Company. The Company expects to recognize a majority of the \$453.9 million of unsatisfied performance obligations within the next 24 months. The amount and timing of revenue recognition for unsatisfied performance obligations can change. The future revenues associated with unsatisfied performance obligations exclude the value of unexercised option periods in the Company's revenue arrangements. Often the timing of manufacturing activities changes based on customer needs and resource availability. Government funding appropriations can impact the timing of product deliveries. The success of the Company's development activities that receive development funding support from the USG under development contracts can also impact the timing of revenue recognition.

Contract assets

The Company considers accounts receivable and deferred costs associated with revenue generating contracts, which are not included in inventory or property, plant and equipment and the Company does not currently have a contractual right to bill, to be contract assets. As of September 30, 2022 and December 31, 2021, the Company had \$33.9 million and \$21.5 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:

December 31, 2021	\$	16.4
Deferral of revenue		30.4
Revenue recognized		(16.5)
September 30, 2022	\$	30.3

As of September 30, 2022 and December 31, 2021, the current portion of contract liabilities was \$24.8 million and \$11.7 million, respectively, and was included in other current liabilities on the balance sheet.

Accounts receivable

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

	September 30, 2022	December 31, 2021
Billed, net	\$ 119.0	\$ 224.9
Unbilled	72.3	49.8
Total accounts receivable, net	\$ 191.3	\$ 274.7

As of September 30, 2022 and December 31, 2021, the allowances for doubtful accounts was \$0.7 million and \$3.2 million, respectively.



## 11. Income taxes

The estimated effective annual tax rate as of September 30, 2022 and 2021 for the years ended December 31, 2022 and 2021, excluding the impact of discrete adjustments, was 3% and 24%, respectively. The decrease in the estimated effective annual tax rate is primarily due to decreased profitability, the impact of certain permanent adjustments, and a valuation allowance charge. The Company recorded discrete tax benefits of \$10.9 million and \$10.3 million for the three and nine months ended September 30, 2022, respectively, and \$1.7 million and \$7.2 million, for the three and nine months ended September 30, 2021, respectively. The discrete tax benefit in 2022 was primarily due to return to provision adjustments and the benefit of the release of an indemnified uncertain tax position offset by share-based compensation activity. The net discrete benefits in 2021 were primarily due to share-based compensation activity.

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.

As of September 30, 2022, the Company determined that it was more likely than not that deferred tax assets in the U.S. would not be realized due to reductions in estimates of future profitability in the U.S. Accordingly, the Company recorded a provision of \$19.2 million associated with the establishment of a valuation allowance on those deferred tax assets.

## 12. Net income (loss) per share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net income (loss)	\$ (75.7)	\$ (32.7)	\$ (135.8)	\$ 41.6
Denominator:				
Weighted-average number of shares—basic	49.9	53.7	50.2	53.6
Dilutive securities—equity awards	—	—	—	0.7
Weighted-average number of shares—diluted	49.9	53.7	50.2	54.3
Net income (loss) per share - basic	\$ (1.52)	\$ (0.61)	\$ (2.71)	\$ 0.78
Net income (loss) per share - diluted	\$ (1.52)	\$ (0.61)	\$ (2.71)	\$ 0.77

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted net income (loss) per share is computed using the treasury method by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period, adjusted for the potential dilutive effect of other securities if such securities were converted or exercised and are not anti-dilutive. No adjustment for the potential dilutive effect of dilutive securities is reported for the three and nine months ended September 30, 2022 as the effect would have been anti-dilutive due to the Company's net loss.



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In certain instances, awards may be anti-dilutive even if the average market price exceeds the exercise price when the sum of the assumed proceeds exceeds the difference between the market price and the exercise price. The following table presents the share-based awards that are not considered in the diluted income (loss) per share calculation generally because the exercise price of the awards was greater than the average per share closing price during the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Anti-dilutive stock awards	3.3	1.4	2.6	0.6

### 13. Equity

#### Repurchase programs

On November 11, 2021, the Company announced that its Board of Directors authorized management to repurchase up to an aggregate of \$250.0 million of Common Stock under a board-approved Share Repurchase Program, of which \$187.9 million has been utilized to purchase 4.4 million shares as of September 30, 2022. During the three months ended September 30, 2022, there were no shares repurchased. During the nine months ended September 30, 2022, the Company has utilized \$75.5 million to purchase 1.8 million shares. The Share Repurchase Program does not obligate the Company to acquire any specific number of shares. Repurchased shares will be available for use in connection with the Company's stock plans and for other corporate purposes.

#### Share-based compensation

During the nine months ended September 30, 2022, the Company granted stock options to purchase 0.7 million shares of common stock and 1.5 million restricted and performance stock units under the Emergent BioSolutions Inc. Stock Incentive Plan. Typically, the stock option 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. Share-based compensation expense was recorded in the following financial statement line items:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cost of product sales	\$ 1.8	\$ 1.3	\$ 5.4	\$ 4.5
Cost of CDMO	0.4	0.3	1.4	0.8
Research and development	1.3	1.4	3.9	4.5
Selling, general and administrative	7.7	7.4	22.7	22.5
Total share-based compensation expense	<u>\$ 11.2</u>	<u>\$ 10.4</u>	<u>\$ 33.4</u>	<u>\$ 32.3</u>

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Accumulated other comprehensive loss, net of tax

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

	Defined Benefit Pension Plan	Derivative Instruments	Foreign Currency Translation Adjustments	Total
Balance, December 31, 2021	\$ (4.0)	\$ (4.5)	\$ (7.6)	\$ (16.1)
Other comprehensive income (loss) before reclassifications	—	9.4	(0.4)	9.0
Amounts reclassified from accumulated other comprehensive loss	—	1.9	—	1.9
Net current period other comprehensive income (loss)	—	11.3	(0.4)	10.9
Balance, September 30, 2022	<u>\$ (4.0)</u>	<u>\$ 6.8</u>	<u>\$ (8.0)</u>	<u>\$ (5.2)</u>
Balance, June 30, 2022	\$ (4.0)	\$ 4.6	\$ (6.7)	\$ (6.1)
Other comprehensive income (loss) before reclassifications	—	2.6	(1.3)	1.3
Amounts reclassified from accumulated other comprehensive loss	—	(0.4)	—	(0.4)
Net current period other comprehensive income (loss)	—	2.2	(1.3)	0.9
Balance, September 30, 2022	<u>\$ (4.0)</u>	<u>\$ 6.8</u>	<u>\$ (8.0)</u>	<u>\$ (5.2)</u>
Balance, December 31, 2020	\$ (7.7)	\$ (11.0)	\$ (6.6)	\$ (25.3)
Other comprehensive loss before reclassifications	—	(0.7)	(1.4)	(2.1)
Amounts reclassified from accumulated other comprehensive loss	—	4.3	—	4.3
Net current period other comprehensive income (loss)	—	3.6	(1.4)	2.2
Balance, September 30, 2021	<u>\$ (7.7)</u>	<u>\$ (7.4)</u>	<u>\$ (8.0)</u>	<u>\$ (23.1)</u>
Balance, June 30, 2021	\$ (7.7)	\$ (6.4)	\$ (8.3)	\$ (22.4)
Other comprehensive income (loss) before reclassifications	—	(2.3)	0.3	(2.0)
Amounts reclassified from accumulated other comprehensive loss	—	1.3	—	1.3
Net current period other comprehensive income (loss)	—	(1.0)	0.3	(0.7)
Balance, September 30, 2021	<u>\$ (7.7)</u>	<u>\$ (7.4)</u>	<u>\$ (8.0)</u>	<u>\$ (23.1)</u>

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

	Three Months Ended September 30,					
	2022			2021		
	Pretax	Tax Expense	Net of tax	Pretax	Tax Expense	Net of tax
Derivative instruments	\$ 3.0	\$ (0.8)	\$ 2.2	\$ 1.3	\$ (2.3)	\$ (1.0)
Foreign currency translation adjustments	0.1	(1.4)	(1.3)	0.3	—	0.3
Total adjustments	<u>\$ 3.1</u>	<u>\$ (2.2)</u>	<u>\$ 0.9</u>	<u>\$ 1.6</u>	<u>\$ (2.3)</u>	<u>\$ (0.7)</u>

	Nine Months Ended September 30,					
	2022			2021		
	Pretax	Tax Expense	Net of tax	Pretax	Tax Expense	Net of tax
Derivative instruments	\$ 15.4	\$ (4.1)	\$ 11.3	\$ 4.9	\$ (1.3)	\$ 3.6
Foreign currency translation adjustments	2.1	(2.5)	(0.4)	(1.4)	—	(1.4)
Total adjustments	<u>\$ 17.5</u>	<u>\$ (6.6)</u>	<u>\$ 10.9</u>	<u>\$ 3.5</u>	<u>\$ (1.3)</u>	<u>\$ 2.2</u>

#### 14. Segment Information

The Company reports segment information based on the internal reporting used by management for making decisions and assessing performance. During the first quarter of 2022, the Company revised the reporting that the CODM reviews in order to assess Company performance. The CODM manages the business with a focus on two reportable segments: 1) Products segment consisting of the Government - MCM and Commercial business lines and 2) Services segment focused on CDMO. The Company evaluates the performance of these reportable segments based on revenue and adjusted gross margin. Segment revenue includes external customer sales, but it does not include inter-segment services. Adjusted gross margin for each segment is segment revenue less segment cost of sales reduced for significant one-time events. We do not allocate research and development, selling, general and administrative costs, amortization of intangibles assets, interest and other income (expense) or taxes to operating segments in the management reporting reviewed by the CODM. The accounting policies for segment reporting are the same as for the Company as a whole. The Company has recast the related historical information for consistency.

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

	Three Months Ended September 30, 2022				Three Months Ended September 30, 2021			
	Products	Services	Other	Consolidated	Products	Services <sup>(1)</sup>	Other	Consolidated
Revenues	\$ 186.2	\$ 36.4	\$ 17.4	\$ 240.0	\$ 270.5	\$ 41.6	\$ 16.9	\$ 329.0
Less:								
Contracts and grants revenue	—	—	(17.4)	(17.4)	—	—	(16.9)	(16.9)
Cost of product sales	(85.5)	—	—	(85.5)	(103.2)	—	—	(103.2)
Cost of CDMO	—	(63.1)	—	(63.1)	—	(114.3)	—	(114.3)
Gross margin	100.7	(26.7)	—	74.0	167.3	(72.7)	—	94.6
Changes in fair value of contingent consideration	0.6	—	—	0.6	0.9	—	—	0.9
Adjusted gross margin	\$ 101.3	\$ (26.7)	\$ —	\$ 74.6	\$ 168.2	\$ (72.7)	\$ —	\$ 95.5

<sup>(1)</sup> Services revenue and Services adjusted gross margin for the three months ended September 30, 2021 includes the impact of the reversal of \$86.0 million of CDMO leases revenues related to the BARDA COVID-19 Development Public Private Partnership which ended in November 2021.

	Nine Months Ended September 30, 2022				Nine Months Ended September 30, 2021			
	Products	Services	Other	Consolidated	Products	Services <sup>(1)</sup>	Other	Consolidated
Revenues	\$ 660.5	\$ 95.4	\$ 34.3	\$ 790.2	\$ 589.6	\$ 416.3	\$ 63.6	\$ 1,069.5
Less:								
Contracts and grants revenue	—	—	(34.3)	(34.3)	—	—	(63.6)	(63.6)
Cost of product sales	(256.8)	—	—	(256.8)	(237.0)	—	—	(237.0)
Cost of CDMO	—	(217.5)	—	(217.5)	—	(307.6)	—	(307.6)
Gross margin	403.7	(122.1)	—	281.6	352.6	108.7	—	461.3
Changes in fair value of contingent consideration	2.4	—	—	2.4	2.6	—	—	2.6
Adjusted gross margin	\$ 406.1	\$ (122.1)	\$ —	\$ 284.0	\$ 355.2	\$ 108.7	\$ —	\$ 463.9

<sup>(1)</sup> Services revenue and Services adjusted gross margin for the nine months ended September 30, 2021 includes the impact of \$81.9 million of CDMO leases revenues related to the BARDA COVID-19 Development Public Private Partnership which ended in November 2021.

The following table includes depreciation expense for each segment:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Depreciation:				
Products	\$ 11.5	\$ 5.0	\$ 25.6	\$ 20.9
Services	5.6	8.4	34.2	21.3
Other	3.3	1.0	5.7	4.3
Total	\$ 20.4	\$ 14.4	\$ 65.5	\$ 46.5

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.

## 15. Commitments and Contingencies

### Securities and shareholder litigation

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

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

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

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

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

which the parties agreed to stay all proceedings until 30 calendar days after a ruling on the defendants' motion to dismiss the Federal Securities Class Action. The Court approved the Joint Stipulation on March 14, 2022.

In addition to the above actions, the Company has received preliminary inquiries and subpoenas to produce documents related to these matters 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, Senator Murray of the Committee on Health, Education, Labor and Pensions, the Department of Justice, the SEC, the Maryland Attorney General's Office, and the New York Attorney General's Office. The Company is producing and has produced documents as required in response and will continue to cooperate with these government inquiries.

#### Intellectual property

##### ANDA litigation - Teva 2mg

In 2018, Teva Pharmaceuticals Industries Limited and Teva Pharmaceuticals USA (collectively, "Teva") provided a notice to Emergent Devices Inc., a subsidiary of Emergent formerly known as Adapt Pharma Inc. ("EBPA"); Emergent Operations Ireland Limited, a subsidiary of Emergent formerly known as Adapt Pharma Operations Limited ("EIRE"); and Opiant Pharmaceuticals Inc. ("Opiant"). The notice stated that Teva had filed an abbreviated new drug application ("ANDA") with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone HCl) Nasal Spray 2 mg/spray before the expiration of certain Orange Book Listed Patents for the 2 mg/spray dose of NARCAN®. Teva's notice letter alleged that claims of certain Orange Book Listed Patents for the 2 mg/spray dose of NARCAN® were invalid and/or would not be infringed by the activities described in Teva's ANDA. Emergent and Opiant filed complaints against Teva in the U.S. District Court for the District of New Jersey alleging infringement of certain Orange Book Listed Patents for the 2 mg/spray dose of NARCAN. This case was dismissed July 27, 2022.

## 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, 2021. 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" and "Risk Factors" sections of this quarterly report on Form 10-Q 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. (the Company or Emergent) is a global life sciences company focused on providing innovative preparedness and response solutions addressing accidental, deliberate, and naturally occurring Public Health Threats (PHTs). The Company's solutions include a product portfolio, a product development portfolio, and a contract development and manufacturing (CDMO) services portfolio.

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

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

### Government - MCM products

- Anthrax vaccines, including our AV7909 (Anthrax vaccine adsorbed (AVA), adjuvanted) procured product candidate being developed as a next-generation anthrax vaccine for post-exposure prophylaxis and BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the FDA for the general use prophylaxis and post-exposure prophylaxis of anthrax disease. AV7909 has not been approved by the FDA, but is procured by certain authorized government buyers for their use;
- 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;
- 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 botulism;
- CNJ-016® (Vaccinia Immune Globulin Intravenous (Human) (VIGIV)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination;
- Raxibacumab injection, a fully human monoclonal antibody, the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax;
- Anthrasil® (Anthrax Immune Globulin Intravenous (human)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of inhalational anthrax;
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only medical device cleared by the FDA to remove or neutralize the following chemical warfare agents from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin; and
- Trobigard® atropine sulfate, obidoxime chloride AUTO-INJECTOR, a combination drug-device auto-injector procured product candidate that contains atropine sulfate and obidoxime chloride. It has not been approved by the FDA, but is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure.



- TEMBEXA<sup>®</sup>, an oral antiviral formulated as 100 mg tablets and 10 mg/mL oral suspension dosed once weekly for two weeks. It has been approved by the FDA for the treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates; and
- Ebanga<sup>™</sup> (ansuvimab-zykl, formerly referred to as mAb114) is a monoclonal antibody with antiviral activity provided through a single IV infusion for the treatment of Ebola. Under the terms of a collaboration with Ridgeback Biotherapeutics, Emergent will be responsible for the manufacturing, sale, and distribution of Ebanga<sup>™</sup> in the United States and Canada, and Ridgeback Biotherapeutics will serve as the global access partner for Ebanga<sup>™</sup>.

### Commercial products

- NARCAN<sup>®</sup> (naloxone HCl) Nasal Spray, the first needle-free formulation of naloxone approved by the FDA and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression;
- Vaxchora<sup>®</sup> (Cholera Vaccine, Live, Oral), the only single-dose oral vaccine approved by the FDA and EMA for the prevention of cholera; and
- Vivotif<sup>®</sup> (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever.

### 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.

### Asset Acquisition

During the three months ended September 30, 2022, the Company acquired from Chimerix the exclusive worldwide rights to brincidofovir, including TEMBEXA<sup>®</sup> and other related assets. TEMBEXA is a medical countermeasure for smallpox approved by the FDA in June 2021.

### FINANCIAL OPERATIONS OVERVIEW

#### Revenues

We generate product revenues from the sale of our marketed products and procured product candidates which include vaccines, therapeutics and devices which have been described above. The USG is the largest purchaser of our MCM products and primarily purchases our products for the SNS, a national repository of medical countermeasures including critical antibiotics, vaccines, chemical antidotes, antitoxins and other critical medical supplies. The USG primarily purchases our products under long-term, firm fixed-price procurement contracts, generally with annual options. Our opioid overdose reversal product, NARCAN<sup>®</sup> Nasal Spray, and our travel health products, Vivotif and Vaxchora, are sold commercially through wholesalers and distributors, physician-directed or standing order prescriptions at retail pharmacies and to state and local community healthcare agencies, practitioners and hospitals.

We also generate revenue from our CDMO services provided at our established development and manufacturing infrastructure, technology platforms and expertise. Our services include a fully integrated molecule-to-market contract development and manufacturing 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 grants funding from the USG and other non-governmental organizations to perform research and development activities, particularly related to programs addressing certain CBRNE threats and EIDs.

Our revenue, operating results and profitability vary quarterly based on the timing of production and deliveries, the timing of manufacturing services performed and the nature of providing large scale bundles of products and services as needs arise. We



expect continued variability in our quarterly financial statements.

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, utilities and amortization of intangible assets. Variable manufacturing costs primarily consist of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff, contract manufacturing operations, sales-based royalties, shipping and logistics. In addition to the fixed and variable manufacturing costs described above, the cost of product sales depends on utilization of available manufacturing capacity. For our commercial sales, other associated expenses include sales-based royalties (which include fair value adjustments associated with contingent consideration), shipping and logistics.

**CDMO** - The primary expenses that we incur to deliver our CDMO services consist of fixed and variable costs. We operate five facilities that perform manufacturing activities for CDMO services customers. We use the same manufacturing facilities and methods of production for our own products as well as for fulfillment of our CDMO service contracts. Our manufacturing process includes the production of bulk material and performing "fill/finish" work for containment and distribution of biological products. For "fill finish" customers, we receive work in process inventory to be prepared for distribution. When producing bulk material, we generally procure raw materials, manufacture the product and retain the risk of loss through the manufacturing and review process until delivery.

Research and development expenses

We expense research and development costs as incurred. Our research and development expenses consist primarily of:

- personnel-related expenses;
- fees to professional service providers for, among other things, analytical testing, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies;
- costs of CDMO services for clinical trial material; and

- costs of materials and equipment used in clinical trials and research and development.

In many cases, we plan to seek funding for development activities from external sources and third parties, such as governments and non-governmental organizations, or through collaborative partnerships. We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development spending, the number of product candidates under development, the size, structure and duration of any clinical programs that we may initiate, the costs associated with manufacturing and development of our product candidates on a large-scale basis for later stage clinical trials and our ability to use or rely on data generated by government agencies.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of personnel-related costs and professional fees in support of our executives, sales and marketing, business development, government affairs, finance, accounting, information technology, legal, human resource functions and other corporate functions.

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, 2021, as filed with the SEC.

### **New accounting standards**

For a discussion of new accounting standards please see Note 2, "Basis of presentation and principles of consolidation", in Part I item 1, of this Quarterly Report on Form 10-Q.

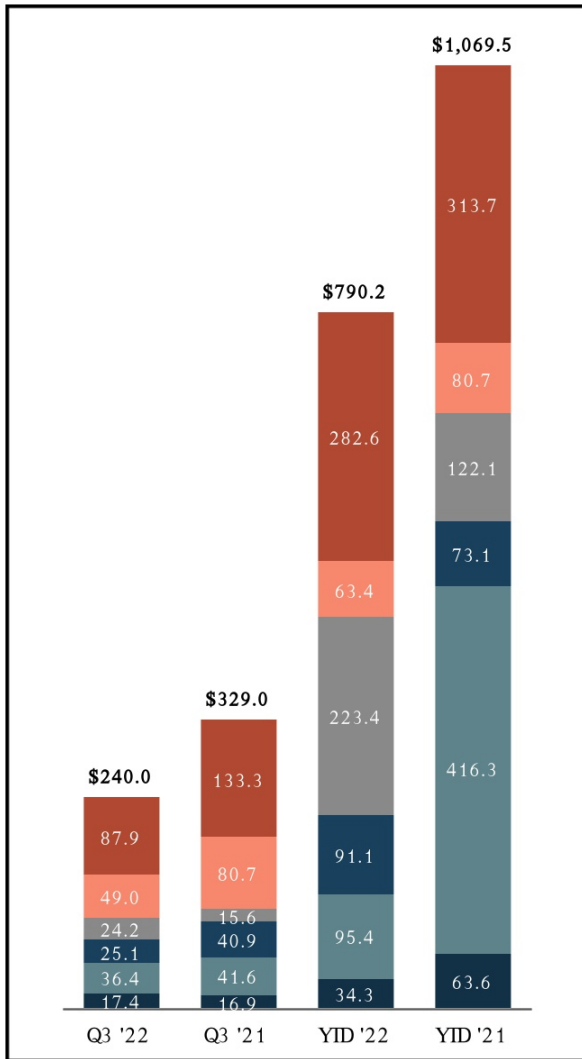
EMERGENT BIOSOLUTIONS INC.  
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS  
(unaudited, amounts in millions, except share and per share amounts)

**RESULTS OF OPERATIONS**

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022	2021	\$ Change	% Change	2022	2021	\$ Change	% Change
Product sales, net:								
Nasal naloxone products	\$ 87.9	\$ 133.3	\$ (45.4)	(34) %	\$ 282.6	\$ 313.7	\$ (31.1)	(10) %
ACAM2000	49.0	80.7	(31.7)	(39) %	63.4	80.7	(17.3)	(21) %
Anthrax vaccines	24.2	15.6	8.6	55 %	223.4	122.1	101.3	83 %
Other product sales	25.1	40.9	(15.8)	(39) %	91.1	73.1	18.0	25 %
Total product sales, net	186.2	270.5	(84.3)	(31) %	660.5	589.6	70.9	12 %
CDMO:								
Services	36.2	112.6	(76.4)	(68) %	90.7	283.7	(193.0)	(68) %
Leases	0.2	(71.0)	71.2	NM	4.7	132.6	(127.9)	(96) %
Total CDMO	36.4	41.6	(5.2)	(13) %	95.4	416.3	(320.9)	(77) %
Contracts and grants	17.4	16.9	0.5	3 %	34.3	63.6	(29.3)	(46) %
Total revenues	240.0	329.0	(89.0)	(27) %	790.2	1,069.5	(279.3)	(26) %
Operating expenses:								
Cost of product sales	85.5	103.2	(17.7)	(17) %	256.8	237.0	19.8	8 %
Cost of CDMO	63.1	114.3	(51.2)	(45) %	217.5	307.6	(90.1)	(29) %
Research and development	39.2	49.6	(10.4)	(21) %	135.4	151.0	(15.6)	(10) %
Selling, general and administrative	80.2	82.1	(1.9)	(2) %	246.1	254.2	(8.1)	(3) %
Amortization of intangible assets	14.0	14.5	(0.5)	(3) %	42.0	44.5	(2.5)	(6) %
Total operating expenses	282.0	363.7	(81.7)	(22) %	897.8	994.3	(96.5)	(10) %
Income (loss) from operations	(42.0)	(34.7)	(7.3)	21 %	(107.6)	75.2	(182.8)	NM
Other income (expense):								
Interest expense	(8.5)	(8.4)	(0.1)	1 %	(24.5)	(25.5)	1.0	(4) %
Other, net	(13.4)	(2.4)	(11.0)	NM	(18.4)	(2.8)	(15.6)	NM
Total other income (expense), net	(21.9)	(10.8)	(11.1)	NM	(42.9)	(28.3)	(14.6)	52 %
Income (loss) before income taxes	(63.9)	(45.5)	(18.4)	40 %	(150.5)	46.9	(197.4)	NM
Income tax benefit (provision)	(11.8)	12.8	(24.6)	NM	14.7	(5.3)	20.0	NM
Net income (loss)	<u>\$ (75.7)</u>	<u>\$ (32.7)</u>	<u>\$ (43.0)</u>	NM	<u>\$ (135.8)</u>	<u>\$ 41.6</u>	<u>\$ (177.4)</u>	NM

NM - Not meaningful

**Total revenues**



Legend	
	Nasal naloxone products
	ACAM2000
	Anthrax vaccines
	Other product sales
	CDMO
	Contracts and grants

**Product sales, net**

Anthrax vaccines

Anthrax vaccine sales increased \$8.6 million to \$24.2 million for the three months ended September 30, 2022. The increase in sales for the three months ended September 30, 2022 was primarily due to an increase in the number of doses sold as a result of the timing of deliveries to the USG.

Anthrax vaccine sales increased \$101.3 million to \$223.4 million for the nine months ended September 30, 2022. The increase in sales for the nine months ended September 30, 2022 was primarily due to an increase in the number of doses sold as a result of the timing of deliveries to the USG.

The price per unit of Anthrax vaccines was largely consistent period over period. Anthrax vaccine product sales are made under annual purchase options exercised by the USG. Fluctuations in revenues result from the timing of the exercise of annual purchase options and the USG purchases and Company delivery of orders that follow.

Nasal naloxone products

Nasal naloxone products sales decreased \$45.4 million to \$87.9 million for the three months ended September 30, 2022. The decrease in sales for the three months ended September 30, 2022 was driven by a reduction in commercial retail sales following the launch of a generic version of NARCAN Nasal Spray 4mg in December 2021, partially offset by strong growth in unit sales of NARCAN Nasal Spray to U.S. public interest customers, as well as from sales of the authorized generic product licensed to Sandoz which launched in December 2021.

Nasal naloxone products sales decreased \$31.1 million to \$282.6 million for the nine months ended September 30, 2022. The decrease in sales for the nine months ended September 30, 2022 was driven by a reduction in commercial retail sales following the launch of a generic version of NARCAN Nasal Spray 4mg in December 2021, partially offset by increase in US public interest, Canadian and authorized generic sales.

ACAM2000

ACAM2000 sales decreased \$31.7 million to \$49.0 million for the three months ended September 30, 2022. The decrease was due to lower number of units sold to the USG, partially offset by an increased number of units sold to non-US customers at a higher price per unit.

ACAM2000 sales decreased \$17.3 million to \$63.4 million for the nine months ended September 30, 2022. The decrease in sales for the nine months ended September 30, 2022 was due to a lower number of units sold to the USG, partially offset by an increased number of units sold to non-US customers at a higher price per unit.

#### Other product sales

Other product sales decreased \$15.8 million to \$25.1 million for the three months ended September 30, 2022. The decrease in sales for the three months ended September 30, 2022 was primarily due to reduced VIG and BAT sales due to timing of deliveries, partially offset by an increase in Anthrasil, RSDL and Vivotif sales.

Other product sales increased \$18.0 million to \$91.1 million for the nine months ended September 30, 2022. The increase in sales for the nine months ended September 30, 2022 was primarily due to increased sales of Vivotif, BAT, and Anthrasil.

### **CDMO**

#### Services

CDMO services revenues decreased \$76.4 million to \$36.2 million for the three months ended September 30, 2022. The decrease in revenues for the three months ended September 30, 2022 is largely due to reduced production activities at the Company's Bayview facility as a result of a halt in manufacturing under the Janssen contract which began in the first quarter 2022 and no activities under the AstraZeneca contract in 2022. The combined services revenues from the Janssen and AstraZeneca contracts decreased \$59.1 million during the three months ended September 30, 2022. Additionally, the Company's Camden facility had reduced production. The declines were partially offset by an increase in services revenues earned at the Company's Winnipeg facility.

CDMO services revenues decreased \$193.0 million to \$90.7 million for the nine months ended September 30, 2022. The decrease in revenues for the nine months ended September 30, 2022 is largely due to reduced production activities at the Company's Bayview facility as a result of a halt in manufacturing under the Janssen contract which began in the first quarter 2022 and no activities under the AstraZeneca contract in 2022. The combined services revenues from the Janssen and AstraZeneca contracts decreased \$169.6 million during the nine months ended September 30, 2022. Additionally, the Company's Camden facility had reduced production. The decreases were partially offset by an increase in manufacturing activities at the Company's Winnipeg facility mentioned above.

#### Leases

CDMO leases revenues increased \$71.2 million to \$0.2 million for the three months ended September

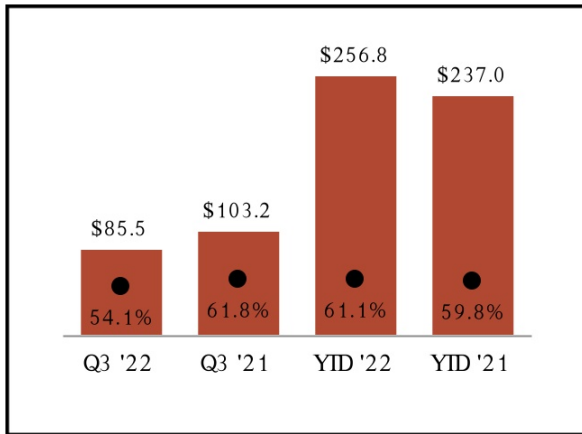
30, 2022. The increase in revenues for the three months ended September 30, 2022 was primarily due to the reversal of \$86.0 million during the three months ended September 30, 2021 associated with the completion of our COVID-19 development public-private partnership with BARDA in November 2021, partially offset by reduced lease revenues under the Janssen contract of \$15.1 million.

CDMO leases revenues decreased \$127.9 million to \$4.7 million for the nine months ended September 30, 2022. The decrease in revenues for the nine months ended September 30, 2022 was primarily due to a reduction of \$81.9 million associated with the completion of our COVID-19 development public-private partnership with BARDA in November 2021 and reduced lease revenues under the Janssen contract of \$46.7 million.

#### Contracts and grants

Contracts and grants revenues were consistent for the three months ended September 30, 2022. Contracts and grants revenues decreased \$29.3 million to \$34.3 million for the nine months ended September 30, 2022. The decrease in revenues for the nine months ended September 30, 2022 was largely due to BARDA's completion of the Center of Innovation and Advanced Development and Manufacturing agreement in November 2021 as well as decreases in development activities associated with various other externally funded research and development projects, most notably the Company's COVID-HIG therapeutic product candidate, as well as decreases in development activities for AV7909. Decreases were partially offset by revenue increases relating to indirect rate adjustments during the quarter.

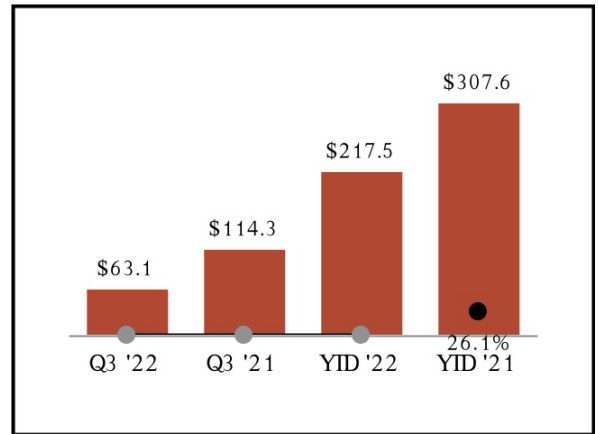
**Cost of product sales**



●	Cost of product sales
●	Gross profit margin for Product segment

Cost of product sales decreased \$17.7 million to \$85.5 million for the three months ended September 30, 2022. The decrease was primarily due to a decrease in product sales. The decrease in gross profit margin for the Product segment for the three months ended September 30, 2022 was due to lower margin for Nasal naloxone products. Cost of product sales increased \$19.8 million to \$256.8 million for the nine months ended September 30, 2022. The increase was primarily due to an increase in products sales. The increase in gross profit margin for the Product segment for the nine months ended September 30, 2022 was largely due to a favorable product revenue mix which was weighted more heavily to higher margin products.

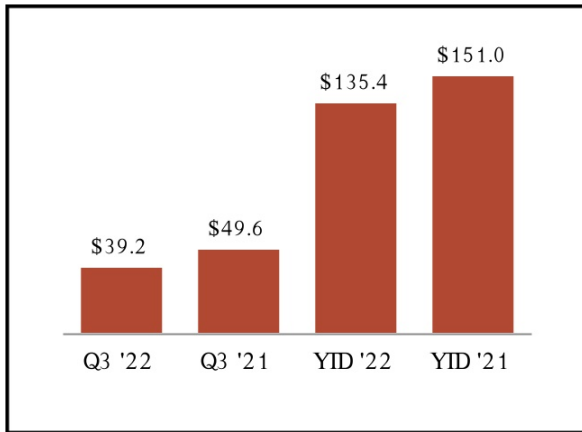
**Cost of CDMO services**



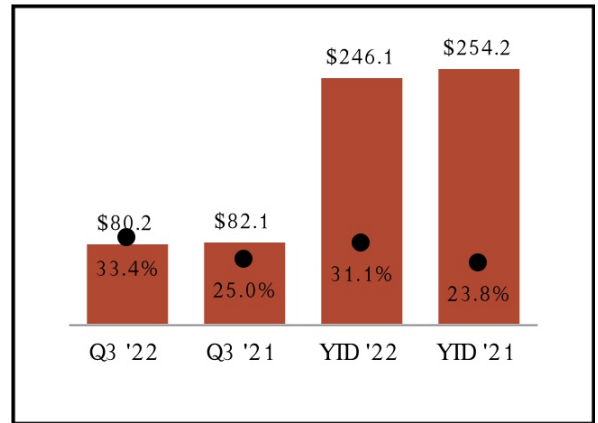
●	Cost of CDMO services
●	Gross profit margin for Services segment
●	Not meaningful

Cost of CDMO services decreased \$51.2 million to \$63.1 million for the three months ended September 30, 2022. The decrease is primarily due to reduced production activities across our CDMO network in Q3 2022 compared with Q3 2021 resulting in decreased raw materials consumption. These decreases were partially offset by the Company's Camden facility due to additional investments in quality enhancement and improvement initiatives. Cost of CDMO services decreased \$90.1 million to \$217.5 million for the nine months ended September 30, 2022. The decrease is primarily due to reduced production activities across our CDMO network, as well as a \$41.5 million inventory write-off in Q2 2021. The decrease in gross profit margin for the Services segment was also impacted by the completion of the BARDA lease in November 2021.

**Research and development expense**



**Selling, general and administrative expenses**



Research and development expense

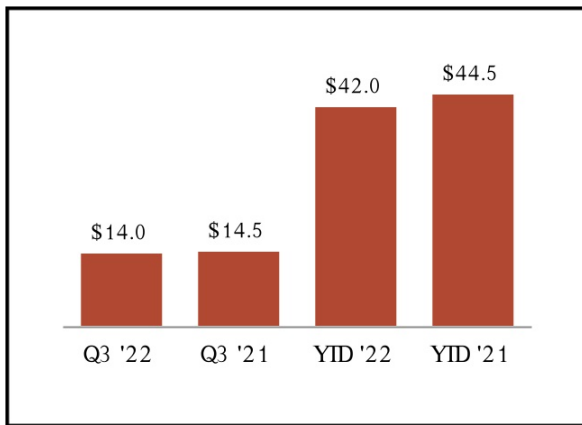
Research and development expense decreased \$10.4 million to \$39.2 million for the three months ended September 30, 2022. The decrease was primarily due to a decrease in spending for the Company's COVID therapeutic product candidates along with a number of other developmental activities, partially offset by an increase in costs associated with the Company's Phase 3 study of our chikungunya virus-like particle vaccine candidate. Research and development expense decreased \$15.6 million to \$135.4 million for the nine months ended September 30, 2022. The decrease was primarily due to a decrease in spending for the Company's COVID therapeutic product candidates along with a number of other developmental activities, partially offset by an increase in costs associated with the Company's Phase 3 study of our chikungunya virus-like particle vaccine candidate.

Selling, general and administrative expenses  
 ● SG&A as a percentage of total revenue

Selling, general and administrative expenses decreased \$1.9 million to \$80.2 million for the three months ended September 30, 2022. The decrease was due to lower professional services and marketing expenses partially offset by increased employee costs, primarily due to increased travel. Selling, general and administrative expenses decreased \$8.1 million to \$246.1 million for the nine months ended September 30, 2022. The decrease was due to lower professional services and marketing expenses partially offset by increased employee costs, primarily due to increased travel costs. Selling, general and administrative costs as a percentage of total revenue increased 8.4% and 7.3% for the three and nine months ended September 30, 2022. The increase was due to a decrease in revenues during the periods, partially offset by a decrease in selling, general and administrative expenses during the periods.



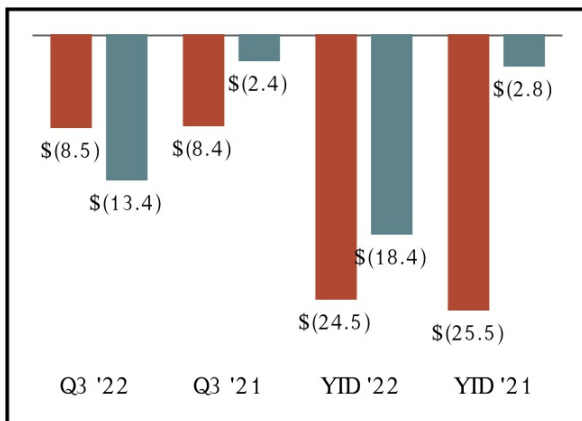
**Amortization of intangible assets**



Amortization expense
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Amortization of intangible assets and the composition of intangible assets amortized during the three and nine months ended September 30, 2022 was consistent with the three and nine months ended September 30, 2021.

**Total other income (expense), net**

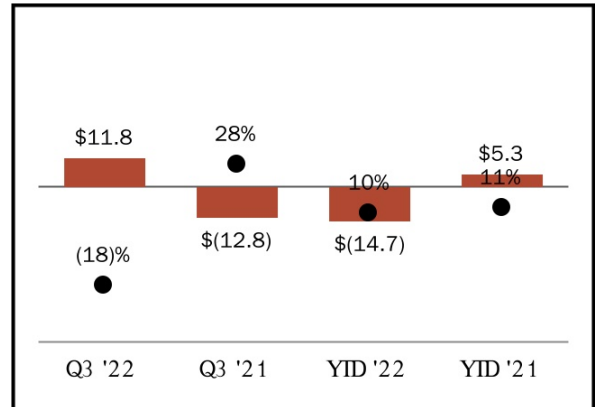


Interest expense
Other income (expense), net

Other income (expense), net decreased \$11.1 million to an expense of \$21.9 million for the three months ended September 30, 2022. The decrease was primarily due to a write-off of a tax indemnity receivable, which is offset in income tax expense (benefit), and unrealized foreign currency losses recorded related to the remeasurement of certain intercompany balances. Interest expense was largely consistent between periods. Other income (expense), net decreased \$14.6 million to an expense of \$42.9

million for the nine months ended September 30, 2022. The decrease was due to a write-off of a tax indemnity receivable, which is offset in income tax expense (benefit), and unrealized foreign currency losses recorded related to the remeasurement of certain intercompany balances. Interest expense was largely consistent between periods.

**Income tax expense (benefit)**



Income tax expense (benefit)
● Effective tax rate

The estimated effective annual tax rate as of September 30, 2022 and 2021 for the years ended December 31, 2022 and 2021, excluding the impact of discrete adjustments, was 3% and 24%, respectively. The decrease in the estimated effective annual tax rate is primarily due to decreased profitability, the impact of certain permanent adjustments, and a valuation allowance charge. The Company recorded discrete tax benefits of \$10.9 million and \$10.3 million for the three and nine months ended September 30, 2022, respectively, and \$1.7 million and \$7.2 million for the three and nine months ended September 30, 2021, respectively. The discrete tax benefit in 2022 was primarily due to return to provision adjustments and the benefit of the release of an indemnified uncertain tax position offset by share-based compensation activity. The net discrete benefits in 2021 were primarily due to share-based compensation activity.

Income tax benefit decreased \$24.6 million to an income tax expense of \$11.8 million for the three months ended September 30, 2022. The decrease in tax benefit was due to a lower estimated effective annual tax rate.

Income tax benefit increased \$20.0 million from an income tax expense of \$5.3 million to an income tax benefit of \$14.7 million for the nine months ended September 30, 2022. The increase in income tax



benefit is largely due to the increase in net loss before income taxes.

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.

As of September 30, 2022, the Company determined that it was more likely than not that deferred tax assets in the U.S. would not be realized due to reductions in estimates of future profitability in the U.S. Accordingly, the Company recorded a provision of \$19.2 million associated with the establishment of a valuation allowance on those deferred tax assets.

## FINANCIAL CONDITION, LIQUIDITY AND CAPITAL RESOURCES

Our financial condition is summarized as follows:

	September 30, 2022	December 31, 2021	Change %
<b>Financial assets:</b>			
Cash and cash equivalents	\$ 240.9	\$ 576.1	(58)%
<b>Borrowings:</b>			
Debt, current portion	\$ 21.2	\$ 31.6	(33)%
Debt, net of current portion	1,032.1	809.4	28 %
Total borrowings	\$ 1,053.3	\$ 841.0	25 %
<b>Working capital:</b>			
Current assets	\$ 1,118.5	\$ 1,272.1	(12)%
Current liabilities	268.4	373.8	(28)%
Total working capital	\$ 850.1	\$ 898.3	(5)%

### Sources of liquidity

We have historically financed our operating and capital expenditures through cash on hand, cash from operations, debt financing and contracts and grants development funding. We also obtain financing from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the last five annual fiscal years through the period ended December 31, 2021. As of September 30, 2022, we had unrestricted cash and cash equivalents of \$240.9 million and capacity under our revolving credit facility of \$360.7 million.

### Going Concern

As of September 30, 2022, there is \$238.0 million outstanding on the revolver loan and \$371.3 million on the term loan that matures in October 2023, which is within one year of the date that the consolidated financial statements are issued for the quarter ended September 30, 2022. 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 plan to alleviate the substantial doubt includes amending its existing revolver loan and term loan that are due October 2023.

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

As the replacement of the Company's current debt facility is conditional upon the execution of agreements with new or existing third parties, which are considered outside of the Company's control, until such time as they are completed, the refinancing cannot be considered to be probable to occur as of the date of this report. 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.

## Cash flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,	
	2022	2021
Net cash provided by (used in):		
Operating activities	\$ (126.9)	\$ (7.9)
Investing activities	(335.9)	(178.3)
Financing activities	128.1	(31.0)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(0.6)	(0.3)
Net change in cash, cash equivalents and restricted cash	<u>\$ (335.3)</u>	<u>\$ (217.5)</u>

## Operating activities

Net cash used in operating activities of \$126.9 million for the nine months ended September 30, 2022 was due to a net income excluding non-cash items of \$46.8 million offset by negative working capital changes of \$173.7 million due to increases in inventory and an increase in payments for our contingent consideration and other accrued expenses, partially offset by collections on receivables.

Net cash used in operating activities of \$7.9 million for the nine months ended September 30, 2021 was due to net income excluding non-cash items of \$266.0 million offset by negative working capital changes of \$273.9 million due to increases in receivables, the accumulation of inventory and prepaid expenses.

The increase of \$119.0 million from cash used in operating activities of \$7.9 million to cash used in operating activities of \$126.9 million is due to a decrease in net income excluding non-cash items of \$219.2 million partially offset by an increase in working capital changes of \$100.2 million.

## Investing activities

Net cash used in investing activities relates to purchases of property, plant and equipment as well as asset acquisitions and was \$335.9 million and \$178.3 million for the nine months ended September 30, 2022 and 2021, respectively. The cash used in investing activities increased during the nine months ended September 30, 2022 largely due the acquisition of TEMBEXA® during the three months ended September 30, 2022.

## Financing activities

Net cash provided by financing activities of \$128.1 million for the nine months ended September 30, 2022 was primarily due proceeds from our revolving credit facility of \$238.0 million, partially offset by repurchases of stock of \$81.9 million and payments on debt of \$25.3 million.

Net cash used in financing activities of \$31.0 million for the nine months ended September 30, 2021 was primarily due to payments on debt of \$27.5 million.

The increase of \$159.1 million of cash provided by financing activities is largely due proceeds from our revolving credit facility of \$238.0 million, partially offset by an increase in cash used for repurchases of stock of \$81.9 million.

### Funding requirements

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

- existing cash and cash equivalents;
- net proceeds from the sale of our products and CDMO services;
- development contracts and grants funding; and
- our Senior Secured Credit Facilities and any other lines of credit we may establish from time to time.

There are numerous risks and uncertainties associated with product sales, delivery of CDMO services and 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 cost of contract development and manufacturing 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 additional shares of our common stock under our current share repurchase program; 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 or collaboration and licensing arrangements.

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

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

### Unused credit capacity

Available room under the revolving credit facility for the periods ended September 30, 2022 and December 31, 2021 was:

Total Capacity	Outstanding Letters of Credit	Outstanding Indebtedness on Revolving Credit Facility	Unused Capacity
September 30, 2022			
\$600.0	1.3	238.0	\$360.7
December 31, 2021			
\$600.0	2.3	—	\$597.7

### 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. Floating rate debt carries interest based generally on the eurocurrency rate, as defined in our Amended Credit Agreement, plus an applicable margin. We manage the impact of interest rate changes on our variable debt through derivative interest rate swap arrangements. Increases in interest rates could result in an increase in interest payments for debt that we have not hedged through our interest rate swap arrangements. See Note 9, "Debt", in Part I, item 1, of this Quarterly Report on Form 10-Q.

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 September 30, 2022 would increase our interest expense by approximately \$2.6 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 chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. 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 September 30, 2022, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

#### 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 September 30, 2022 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 15, "Commitments and contingencies" 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 AV7909 and/or BioThrax or ACAM2000 and discontinuation of funding of our other USG procurement and development contracts.
- Inability to receive FDA licensure of AV7909 and realize the full value of our contract for development and procurement of AV7909.

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

- Our inability to maintain quality and manufacturing compliance at our manufacturing facilities has hindered and could continue to hinder our ability to produce products and product candidates for our CDMO customers.
- Disruption at, damage to or destruction of our development and/or manufacturing facilities and supply chain disruption, including lower availability of plasma, 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:

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

Due to numerous factors, the COVID-19 coronavirus pandemic could have a material adverse impact on our business, results of operations and financial performance, including:

- Changes in government priorities resulting from the pandemic and continuing supply chain shortages could impact our overall business.
- COVID-19 may impede our workers ability to work and may result in reduced production of products or services.
- The evolving nature of COVID-19 and related vaccines and treatments and resulting changes in demand for such product candidates may impact sales of related services offered by our CDMO business.

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 is currently subject to generic competition and may be subject to additional branded and generic competition and generic products rather than branded products are often dispensed where a generic version is available.
- 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 defense or enforcement of our intellectual property rights including against current or potential infringers.
- Potential discrepancies or challenges with respect to third party 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 expiry 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 third parties upon which we rely to conduct many of our clinical trials and other work do not perform as contractually required or as expected, we may not be able to obtain regulatory approval for or commercialize our product candidates or honor customer obligations.

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

- Unfavorable results of legal proceedings and government investigations could adversely impact our business, financial condition and results of operations.
- Our work on PHTs has exposed us to criticism and may expose us to further criticism, from the media, government personnel and others, which could further harm our reputation, negatively affect our share price, operations, and our ability to attract and retain talent.
- The potential for cyber security incidents to harm our ability to operate our business effectively in light of our heightened risk profile.
- Inherent product liability exposure due to our unique business.

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.
- Our ability to comply with the covenants under our Senior Secured Credit Facilities and other debt agreements and to refinance the Senior Secured Credit Facilities.

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

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

There are a number of 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 AV7909 and ACAM2000 and have historically derived a substantial portion of our revenue from USG procurement of BioThrax. If the USG's demand for and/or funding for procurement of AV7909 and/or BioThrax or ACAM2000 is substantially reduced, our business, financial condition, operating results and cash flows would be materially harmed.*

We derive a substantial portion of our current and expected future revenues from USG procurement of AV7909. As AV7909 is a product candidate, there is a higher level of risk that we may encounter challenges causing delays or an inability to deliver AV7909 than with BioThrax, an approved product, which may have a material effect on our ability to generate and recognize revenue.

The success of our business and our future operating results are significantly dependent on anticipated funding for the procurement of our anthrax vaccines and the terms of such procurement by the USG, including the price per dose, the number of doses and the timing of deliveries. We have no certainty that funding will be made available for the procurement of our anthrax vaccines. If priorities for the SNS change generally, or as a result of the conclusion of the USG's audit of the Strategic National Stockpile ("SNS"), or with respect to the level of procurement of our anthrax vaccines, funding to procure future doses of AV7909 or BioThrax may be delayed, limited or not available, BARDA may never complete the anticipated full transition to stockpiling AV7909 in support of anthrax preparedness, and our future business, financial condition, operating results and cash flows could be materially harmed.

In addition, we currently derive a substantial portion of our revenues from sales of ACAM2000 to the USG. If priorities for the SNS change with respect to ACAM2000 or the USG decides not to exercise additional options under our ACAM2000 contract, our future business, financial condition, operating results and cash flows would be materially harmed.

*We may not receive FDA licensure of AV7909 in a timely manner or at all. Delays in our ability to achieve a*

*favorable outcome from the FDA, or lack of approval from the FDA, could prevent us from realizing the full potential value of our BARDA contract for the advanced development and procurement of AV7909.*

In collaboration with us, the Centers for Disease Control and Prevention (the "CDC") filed with the FDA a pre-Emergency Use Authorization ("EUA") submission package related to AV7909, which enables FDA review of data in anticipation of a request for an EUA. Following this submission, BARDA began procuring AV7909, exercising its first contract option in July 2019 to procure 10 million doses of AV7909 and its second contract option in July 2020 and, most recently, funded another procurement commitment in October 2021 for inclusion of additional doses into the SNS in support of anthrax preparedness.

In April 2022, we completed the rolling submission of a Biologics License Application ("BLA") filing with the FDA related to AV7909 and the application has been accepted for review. There can be no guarantee that our submission will be approved by the FDA. The FDA may decide that our initial data are insufficient and require additional pre-clinical, clinical or other studies. If we are unsuccessful in obtaining FDA licensure, in a timely manner or at all, we may not be able to realize the full potential value of the contract, which could have a material adverse effect on our future business, financial condition, operating results and cash flows. Furthermore, prior to FDA licensure, if we obtain an EUA, the EUA could be terminated if the emergency determination underlying the EUA terminates.

*Our USG procurement and development contracts require ongoing funding decisions by the USG. Any reduction or discontinuation of funding of any of these contracts could cause our business, financial condition, operating results and cash flows to suffer materially.*

The USG is the principal customer for our Medical Countermeasures ("MCMs") and the primary source of funds for the development of most of our product candidates in our development pipeline, most notably our AV7909 procured product candidate. We anticipate that the USG will also be a principal customer for any MCMs that we successfully develop from within our existing product development pipeline, as well as those we acquire in the future. Additionally, a significant portion of our revenue comes from USG development contracts and grants. Over its lifetime, a USG procurement or development program, such as for AV909 under our development and procurement contract with BARDA, may be implemented through the award of many different individual contracts and subcontracts. The funding for such government programs is subject to Congressional appropriations,

generally made on a fiscal year basis, even for programs designed to continue for several years. These appropriations can be subject to a number of uncertainties, including political considerations, changes in priorities due to global pandemics, the results of elections and stringent budgetary constraints.

Additionally, our government-funded development contracts typically give the USG the right, exercisable in its sole discretion, to extend these contracts for successive option periods following a base period of performance. The value of the services to be performed during these option periods may constitute the majority of the total value of the underlying contract. For example, the September 2016 contract award from BARDA for the development and delivery to the SNS of AV7909 for post-exposure prophylaxis of anthrax disease consisted of a five-year base period of performance and includes options for the delivery of additional doses of AV7909 to the SNS and options for an additional clinical study and post-marketing commitments. This contract was extended in September 2021 through 2025, and provides for additional procurement of AV7909 for the SNS over 18 months. In addition, the September 2019 contract award from the USG for the supply of ACAM2000 to the SNS included a one-year base period of performance and includes nine options for additional years of performance, the first two of which were exercised by the USG. 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. For example, in November 2019, the BARDA procurement contract for raxibacumab that we acquired in our 2017 acquisition of the product from GlaxoSmithKline LLC was completed. We intend to negotiate a follow-on procurement contract for raxibacumab and other 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 and product candidates procured under special circumstances 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 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 and Human Services ("HHS") and the U.S. Department of Defense ("DoD") are typically 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 or no reason;
- unilaterally reduce or modify contracts or subcontracts;
- decline, in whole or in part, to exercise an option to purchase product under a procurement contract or to fund additional development under a development contract;

- decline to renew a procurement contract;
- claim certain rights to facilities or to products, including intellectual property, developed under the contract;
- require repayment of contract funds spent on construction of facilities in the event of contract default;
- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- suspend or debar the contractor from doing business with the government or a specific government agency;
- pursue civil or criminal remedies under acts such as the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

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

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

## MANUFACTURING RISKS

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

The FDA conducts periodic inspections of our manufacturing facilities for compliance with cGMP requirements relating to quality control. For example, on August 10, 2022, the FDA issued a warning letter to the Company with respect to its Camden manufacturing facility in Baltimore, Maryland. The warning letter cited two areas of deficiencies: (i) systems for cleaning and maintenance of equipment to prevent contamination of drug product, specifically related to particulates from the metal trays, and (ii) processes and practices surrounding aseptic processing. In addition, the FDA recommended the Company review and assess its Quality Management System and engage a consultant with respect to Current Good Manufacturing Practices. The Company has retained a third party for additional review of the facility and to provide additional oversight of processes for product release.

The Company's failure to regain or maintain compliance with cGMP standards at our manufacturing facilities has hindered and could continue to hinder our ability to continue manufacturing for CDMO customers, which could adversely affect our business, financial condition, operating results and cash flows.

*Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture anthrax vaccines, ACAM2000 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;
- 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);

- work stoppages or slowdowns due to the potential resurgence of new COVID-19 variants;
- civil unrest and protests, including by animal rights activists;
- injunctions;
- damage to or destruction of one or more facilities;
- FDA facility inspection findings/recommendations; and
- product contamination or tampering.

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.

The factors listed above could also cause disruptions at our other 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, 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.

*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. 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. In addition, 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.

As our equipment ages, it will need to be replaced, which has the potential to result in similar consequences. Success rates can also vary dramatically at different stages of the manufacturing process, which can reduce yields and increase costs. From time to time, we may experience deviations in the manufacturing process that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation or regulatory action against us, including the issuance of Forms FDA 483, warning letters and other restrictions on the marketing or manufacturing of a product, or cause the FDA to cease releasing product until the deviations are explained and corrected, any of which could be costly to us, damage our reputation and negatively impact our business. For example, in April 2021, we temporarily stopped manufacturing bulk drug substance material for Johnson & Johnson's COVID-19 vaccine at our Baltimore Bayview facility after issues were identified in a viral vaccine drug substance batch.

Additionally, 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.

In addition, we may not be able to ramp up our manufacturing processes to meet the rapidly changing demand or specifications of our customers on the desired timeframe, if at all. For example, we have not previously had to ramp our organization for a commercial launch of any product or manufacture any

product for our CDMO customers at the pace required to address treatments related to COVID-19 and doing so in a pandemic environment with an urgent, critical global need creates unique manufacturing challenges, challenges related to distribution channels, and the need to establish teams of people with the relevant skills. Our inability to ramp up manufacturing to meet the demand or specifications of our customers 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.*

Our products and product candidates procured by the USG and other customers require us to perform tests for and meet certain potency and lot release standards prescribed by the FDA and other agencies, which may not be met on a timely basis or at all. We are unable to sell any products and product candidates that fail to satisfy such testing specifications. For example, we must provide the FDA with the results of certain tests, including potency tests, before certain lots are released for sale. Potency testing of each applicable lot is performed against qualified control lots that we maintain. We continually monitor the status of such reference lots for FDA compliance and periodically produce and qualify a new reference lot to replace the existing reference lot. If we are unable to satisfy USG requirements for the release of our products or product candidates, our ability to supply such products and product candidates to authorized buyers would be impaired until such time as we become able to meet such requirements, which could materially harm our future business, financial condition, operating results and cash flows.

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

Our operations involve the use of hazardous materials, including chemicals, bacteria and viruses, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf, are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. Under the Federal Select

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

## PRODUCT DEVELOPMENT AND COMMERCIALIZATION RISKS

*The COVID-19 product candidates we are manufacturing 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 are providing CDMO services for the development and/or manufacture of multiple therapeutic product candidates. There can be no assurance that any of these product candidates will be safe or effective. There can also be no assurance that any of these product candidates will be authorized for emergency use or approved by the FDA or any other health regulatory authority. Even if these product candidates are safe and/or effective and receive authorization or approval by a health regulatory authority, the manufacturing processes for our CDMO COVID-19 programs are under development and are complex. There can be no assurance that we will be able to produce any significant quantity of these

product candidates in a timely basis or at all, or negotiate further commitments under our existing CDMO contracts, which could adversely affect our business, financial condition, operating results and cash flows.

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

We have invested significant 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 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 from the FDA and equivalent foreign regulatory authorities;
- establishment of commercial manufacturing processes and product supply arrangements;
- training of a commercial sales force for the product;
- successful registration and maintenance of relevant patent and/or other proprietary protection;
- competitive pricing and market access; and
- acceptance of the product by potential government and other customers.

*Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. We must invest substantial amounts of time and financial resources in these trials, which may not yield viable*

*products. Failure to obtain regulatory approval for product candidates, particularly in the United States, could materially and adversely affect our financial resources, which would adversely affect our business, financial condition, operating results and cash flows.*

Before obtaining regulatory approval 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 or 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 preclinical studies or 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. We therefore 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 studies, such as field studies, to verify and describe the drug's clinical benefit and to assess its safety when used as indicated. It is possible that results from 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.

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

#### **GLOBAL PANDEMIC RISK**

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



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

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

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

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

*The continually evolving nature of the COVID-19 pandemic and the resulting public health response, including the changing demand for various COVID-19 vaccines and treatments from both patients and governments around the world, may affect the demand for COVID-19 product candidates manufactured by our CDMO business.*

Through our CDMO business, we provide services for a variety of product candidates intended for the prevention or treatment of COVID-19 and its symptoms and effects. These services include product development and drug product fill and finish services.

None of the COVID-19-related product candidates we develop and manufacture have yet to receive full regulatory approval from any regulatory authority, although some are being offered and sold pursuant to an EUA from the FDA or the equivalent authorization from non-U.S. regulatory authorities. Should the facilities producing these product candidates be denied an EUA or one or more of these COVID-19-related product candidates be denied an EUA (or equivalent) or be denied full regulatory approval by the FDA or other major non-U.S. regulatory authority, the demand for such product candidates could decrease significantly and therefore decrease customer orders for additional CDMO services for such product candidates. Additionally, the need for continued manufacture and supply of vaccines (including “booster” doses) and therapies to address the COVID-19 pandemic, including new and developing variants of COVID-19, is highly uncertain and subject to various political, economic, regulatory and other factors that are outside of our control. For example, in the first quarter of 2022, Johnson and Johnson suspended its COVID-19 vaccine sales guidance due to global supply surplus and demand uncertainty. Should the United States or other major regions worldwide determine that additional manufacturing of COVID-19 vaccines, boosters, or therapies is no longer necessary, or necessary to a lesser degree, it could adversely affect our revenue and financial condition and our ability to grow our CDMO business in the near term. In addition, highly-public political and social debates relating to the need for, efficacy of, or side effects related to one or more specific COVID-19 vaccines could contribute to changes in public perception of COVID-19 vaccines manufactured by us, which could decrease demand for a COVID-19 related product candidate we develop or manufacture (in whole or in part).

*The impact of working remotely may increase our cybersecurity risk profile and potentially impact productivity.*

One of the significant areas of impact of COVID-19 on our business has been a shift in company policy to hybrid work arrangements. We have recently implemented a hybrid work model through which our administrative workforce may choose a mixture of in-office and remote work, continue to work entirely on a remote basis or return to the office full time. Although we have allowed all employees to return to the office, a significant number of administrative employees have chosen to continue to work remotely either on a part-time or full-time basis. Working remotely could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. In addition, our on-site staff conducting R&D may not be able to access our laboratories if government-mandated lockdowns return, due to a resurgence in COVID-19 variants and new state and local restrictions.

## 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. Our status as a USG contractor means that we are subject to various statutes and regulations, including:

- the Federal Acquisition Regulation ("FAR") and agency-specific regulations supplemental to FAR, which comprehensively regulate the award, formation, administration and performance of government contracts;
- the Defense Federal Acquisition Regulations ("DFARs") and agency-specific regulations supplemental to DFARs, which comprehensively regulate the award, formation, administration and performance of DoD government contracts;
- the Department of State Acquisition Regulation which regulates the relationship between a Department of State organization and a contractor or potential contractor;

- business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act, the Procurement Integrity Act, the False Claims Act and the Foreign Corrupt Practices Act (the "FCPA");
- export and import control laws and regulations, including but not limited to International Traffic in Arms Regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

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, as well as oversight by other regulatory agencies in the United States and by comparable foreign regulatory authorities. This includes, but is not limited to, laws and regulations governing product development, including testing, manufacturing, record keeping, storage and approval, as well as advertising and promotion. In limited circumstances, governments may procure products that have not obtained regulatory approval. In all other

circumstances, failure to obtain regulatory approval for a product candidate will prevent us from selling and commercializing the product candidate.

In the United States, to obtain approval from the FDA to market and sell any of our future drug, biologic, or vaccine products, we will be required to submit a New Drug Application ("NDA") or BLA to the FDA. Ordinarily, the FDA will require a company to support an NDA or BLA with substantial evidence of the product candidate's effectiveness, safety, purity and potency in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase 3 trials conducted in patients with the disease or condition being targeted. Once an NDA or BLA is submitted, the FDA has substantial discretion and may refuse to accept any application or may decide that our data are insufficient to support approval and require additional pre-clinical, clinical or other studies.

However, many of our MCM product candidates, for example, may take advantage of a different regulatory approval pathway under the FDA's "Animal Rule." Under the Animal Rule, efficacy must be demonstrated, in part, by utilizing animal models rather than testing in humans. We cannot guarantee that the FDA will permit us to proceed with licensure of any of our 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 rejection of an application. There is a high rate of failure inherent in this process, and potential products that appear promising at early stages of development may fail for a number of reasons, and positive results from pre-clinical studies may not be predictive of similar results in human clinical trials. Similarly, promising results from earlier clinical trials of a product candidate may not be replicated in later clinical trials.

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. Therefore, there is a risk that we could be subject to enforcement actions if found to be in violation of such laws or regulations.

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

Once approval has been granted, an approved product and its manufacturer and marketer remain subject to ongoing review and extensive regulation.

We and our collaborators must therefore comply with post-approval regulatory requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to FDA-regulated products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to sell any products we develop for indications or uses for which they are not approved.

If we and our collaborators are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market 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.

Any product candidate for which we or our collaborators obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine.

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

The FDA and other agencies, including the U.S. Department of Justice ("DOJ") and the HHS Office of Inspector General ("OIG"), closely regulate and monitor the pre-approval and post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA, DOJ, and OIG impose stringent restrictions on manufacturers' communications regarding unapproved products and unapproved uses of approved products and if we market unapproved products or market our approved products for unapproved indications, we may be subject to enforcement action. Violations of the Federal Food, Drug, and Cosmetics Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- refusal to approve pending applications or supplements to approved applications that are submitted;
- 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.

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.

In addition, other legislative changes have been proposed and adopted in the United States since the

ACA was enacted that may negatively impact us. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031 under the Coronavirus Aid, Relief and Economic Security Act, or CARES Act. These Medicare sequester reductions were suspended through the end of March 2022, and a 1% sequester cut was in effect from April 2022 through June 2022, with the full 2% cut resuming thereafter.

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. For example, the last Presidential administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers.

For example, 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, but at least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada with the intent of developing SIPs for review and approval by the FDA.

Further, on July 9, 2021, the President signed an Executive Order that focuses on, among other things, the price of pharmaceuticals. The Order directed HHS to create a plan within 45 days to combat "excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the

prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging." On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers; (b) improve and promote competition throughout the prescription pharmaceutical industry; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

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 and CMS and the issuance of final regulations implementing those changes has affected and could further affect our 340B "ceiling price" calculations. Because we participate in the Medicaid rebate program, we are required to report average sales price ("ASP"), information to CMS for certain categories of drugs that are paid for under Part B of the Medicare program. Future statutory or regulatory changes or CMS binding guidance could affect the ASP calculations for our products and the resulting Medicare payment rate and could negatively impact our results of operations.

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

In addition, if we are found to have made a misrepresentation in the reporting of ASP, we are subject to civil monetary penalties for each such price misrepresentation and for each day in which such price misrepresentation was applied. If we are found to have knowingly submitted false AMP or "best price" information to the government, we may be liable for civil monetary penalties per item of false information. Any refusal of a request for information or knowing provision of false information in connection with an AMP survey verification would also subject us to civil monetary penalties. In addition, our failure to submit monthly/quarterly AMP or "best price" information on a timely basis could result in a civil monetary penalty per day for each day the information is late beyond the due date. Such failure 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 assure that our submissions will not be found by CMS to be incomplete or incorrect.

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

To be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we also must participate in the DVA FSS pricing program. To participate, we are required to enter into an FSS contract with the DVA, under which we must make our innovator "covered drugs" available to the "Big Four" federal agencies—the DVA, the DoD, the 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 circumstances, MCMs may be procured by government entities prior to approval by the FDA or other regulatory authorities, a practice which we follow in connection with certain MCMs, including AV7909 and TROBIGARD, in the United States. In the United States, Project BioShield permits the Secretary of HHS to contract to purchase MCMs for the SNS prior to FDA approval of the relevant MCM in specified circumstances. Project BioShield and the PAHPRA also allow the FDA Commissioner to authorize the emergency use of medical products that have not yet been approved by the FDA under an EUA. An EUA terminates when the emergency determination underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product. Absent an applicable exception, our MCM product candidates generally will have to be approved by the FDA or other regulatory authorities in the relevant country through traditional pathways before we can sell those products to governments. Additionally, the laws in certain jurisdictions regarding the ability of government entities to purchase unapproved product candidates are ambiguous, and the permissibility of exporting unapproved products from the United States and importing them to foreign countries may be unclear. Nevertheless, government bodies, such as U.S. federal

entities other than HHS, state and local governments within the United States, and foreign governments have sought and may further seek to procure our MCM product candidates that are not yet approved. If so, we would expect to assess the permissibility and liability implications of supplying our product candidates to such entities on a case-by-case basis, which presents certain challenges, both in the case of U.S. and foreign governments, and particularly under emergency conditions. In addition, agencies or branches of one country's government may take different positions regarding the permissibility of such sales than another country's government or even other agencies or branches of the same government. If local enforcement authorities disagree with our conclusion that such activities are permissible, they may take enforcement action against us.

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

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

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

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

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. 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. In addition, various state laws require that companies that manufacture and/or distribute drug products within the state obtain and maintain a manufacturer or distributor license, as appropriate. Because of the breadth of these laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Government regulators enforce cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect domestic and foreign manufacturing facilities without prior notice at reasonable times and in a reasonable manner. Health Canada may conduct similar inspections of our domestic and foreign facilities where 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 and other communications;
- product seizure or withdrawal of the product from the market;
- restrictions on the marketing or manufacturing of a product;
- suspension or withdrawal of regulatory approvals or refusal to approve pending applications or supplements to approved applications;

- fines or disgorgement of profits or revenue; and
- injunctions or the imposition of civil or criminal penalties.

Similar action may be taken against us should we fail to comply with regulatory requirements, or later discover previously unknown problems with our products or manufacturing processes. For instance, our products are tested regularly to determine if they satisfy potency and stability requirements for their required shelf lives. Failure to meet potency, stability or other specification requirements could result in delays in distributions, recalls or other consequences. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or sold or to the conditions of approval. Regulatory approval may also contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. If we experience any of these post-approval events, our business, financial condition, operating results and cash flows could be materially and adversely affected.

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

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

We currently sell certain of our products outside the United States and intend to expand the countries in which we sell our products and have received market authorization under the mutual recognition procedure to sell BioThrax in France, Italy, the Netherlands, Poland, and the United Kingdom. To market 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), or 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 and require us to develop and implement costly compliance programs.*

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

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

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

Various laws, regulations and executive orders also restrict the use and dissemination outside of the

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

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

### **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 face and will continue to face future competition from other companies and governments, universities and other non-profit research organizations in respect of 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 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 drugs are “highly similar”, but close enough in duplication, to accomplish the same therapeutic and clinical result. Biologic Products in our current pipeline include AV7909, BioThrax, and ACAM2000. If a biosimilar version of one of our Biologic Products were approved, it could have a material adverse effect on the sales and gross profits of the affected Biologic Product and could adversely affect our business, financial condition, operating results and cash flows.

*NARCAN® (naloxone HCl) Nasal Spray 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 filed an 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.

On December 22, 2021, Teva commenced the launch of its generic naloxone nasal spray. NARCAN may face additional generic competition from other parties, including from Perrigo UK FINCO Limited Partnership (Perrigo), who filed their own ANDA in 2018. Emergent settled with Perrigo on February 12, 2020 providing for a license effective upon the Teva litigation decision.

Sales of generic versions of NARCAN at prices lower than our branded product or the version 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.

NARCAN may also face branded competition. For example, on April 30, 2021, the FDA approved Kloxxado™, a branded product developed by Hikma Pharmaceuticals, Inc. which delivers a higher dose naloxone nasal spray. In addition, Orexo AB and Harm Reduction Therapeutics both have development programs for novel naloxone nasal spray formulations intended for use in opioid overdose reversal.

Additional branded competition may correspond to other injectable naloxone, auto-injectors and improvised nasal kits including Amphastar Pharmaceuticals, Inc.’s naloxone injection product and Kaléo’s EVZIO™ (naloxone HCl injection) Auto-Injector.

*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, 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 the EMA 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 product for the same therapeutic indication for that time period. The applicable period is seven years in the United States.

In order for the FDA to grant orphan drug exclusivity to one of our products, the agency must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity 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 an orphan drug is approved, 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. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

## 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, third parties may have the first right to maintain or defend intellectual property rights in which we have an interest, or may pursue strategies that are divergent to the interest of our Company.

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

Claims by third parties of alleged patent infringement could delay 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 THIRD PARTIES**

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

We purchase certain supplies used in our manufacturing processes from non-exclusive or single sources due to quality considerations, costs or constraints resulting from regulatory requirements. We depend on certain single-source suppliers for key materials and services necessary to manufacture the majority of our products and certain product candidates. For example, we rely on a single-source supplier to provide us with Alhydrogel in sufficient quantities to meet our needs to manufacture AV7909 and BioThrax and the specialty plasma in our hyperimmune specialty plasma products and certain ingredients for ACAM2000. We also rely on single-source suppliers for the materials necessary to produce NARCAN, 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 impact of COVID-19 on such supplier, the acquisition of a supplier by a competitor (which may cause the supplier to stop selling its products to us) or the bankruptcy of such a supplier, which may cause the supplier to cease operations. Any reduction or interruption by a sole-source supplier of the supply of materials or key components used in the manufacturing of our products or product candidates, a reduction in quality or an increase in the price of those materials or components could adversely affect us. If we are unable to locate or establish alternative suppliers, our ability to manufacture our products and product candidates could be adversely affected and could harm our revenues, cause us to fail to satisfy contractual commitments, lead to a termination of one or more of our contracts or lead to delays in our clinical trials, any of which could be costly to us and otherwise materially harm our business, financial condition, operating results and cash flows.

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

We depend on third parties, such as independent clinical investigators, contract research organizations and other third-party service providers to conduct the clinical and non-clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical and non-clinical trials, but do not exercise day-to-day control over their activities. Our reliance on these service providers does not relieve us of our regulatory responsibilities, including ensuring that our trials are conducted in accordance with good clinical practice regulations and the plan and protocols contained in the relevant regulatory application. In addition, these organizations may not complete these activities on our anticipated or desired timeframe. We also may experience unexpected cost increases that are beyond our control. Problems with the timeliness or



quality of the work of a contract research organization or other third party may lead us to seek to terminate the relationship and use an alternative service provider, which may prove difficult, costly and result in a delay of our trials. Any delay in or inability to complete our trials could delay or prevent the development, approval and commercialization of our product candidates.

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

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

#### LEGAL AND REPUTATIONAL RISKS

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

We are subject to various claims, legal proceedings and government investigations that have not yet been fully resolved, including shareholder 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 shareholder 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.

In addition, we have received inquiries and subpoenas to produce documents 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, Senator Murray of the Committee on Health, Education, Labor and Pensions, the Financial Industry Regulatory Authority, the Department of Justice), the SEC, the Maryland Attorney General's Office, and the New York Attorney General's Office. We are producing and have produced documents as required in response and will continue to cooperate with these government inquiries.

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 also have contracted with the USG and pharmaceutical companies, which has raised our security profile, and heightened potential risks that malicious actors may seek to disrupt our systems or misappropriate our information. The size and complexity of our computer systems make them potentially vulnerable to interruption, invasion, computer viruses, destruction, malicious intrusion and additional related disruptions, which may result in the impairment of production and key business processes. Our systems are also potentially vulnerable to data security breaches through employee error, phishing scams and malfeasance, which may expose sensitive data to unauthorized persons. No system of protection is adequate to protect against all such threats, even if they are deemed to be industry standard, and there can be no assurance that we will be able to repel any such attacks. Data security breaches could lead to the loss of trade secrets or other intellectual property or the public exposure of personal information, including sensitive personal information, of our employees, clinical trial patients, customers and others. Responding to any such threats may also be expensive and time-consuming.

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

*Our work on PHTs has exposed us to criticism and may expose us to further criticism, from the media, government personnel, and others, that can negatively affect our share price, reputation, operations, and our ability to attract and retain talent and secure new customer contracts.*

Our work on PHTs, including manufacturing issues at our Baltimore Bayview facility, has exposed us to criticism and may expose us to additional potential criticism, from the media, government personnel, and others. In addition, our work on PHTs has exposed us

to governmental inquiries and investigations, including by Congress and other government agencies. For example, a joint panel of the U.S. House of Representatives launched an investigation into, among other things, the cause of the previously mentioned cross-contamination issues identified in a viral vaccine drug substance batch at the Baltimore Bayview facility. Such criticism can be particularly acute during a public health emergency like the COVID-19 pandemic. The unfavorable media coverage and increased government scrutiny, including the Congressional inquiry, could further harm our reputation, distract management's attention from our operations, and impact our ability to attract and retain talent and result in further declines to our share price. We have already incurred significant legal costs to respond to government inquiries and are likely to incur additional costs. Any adverse actions by government authorities may result in significant civil or criminal fines or penalties, all of which could adversely impact our financial condition, operating results and cash flows.

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

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

One measure of protection against such lawsuits is coverage under the PREP Act, which was signed into law in December 2005. The PREP Act creates liability protection for manufacturers of biodefense countermeasures when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is meant to provide liability protection from all claims under federal or state law for loss arising out of the administration or use of a covered countermeasure under a government contract. The Secretary of HHS has issued PREP Act declarations identifying certain of our products, namely BioThrax, ACAM2000, raxibacumab, Anthrasil, BAT and VIGIV, as covered countermeasures, which expire on December 31, 2022. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct or for cases brought in non-U.S. tribunals or under non-U.S. law. We cannot predict whether the Secretary of HHS will renew the declarations when they expire, whether Congress will fund the relevant PREP Act compensation programs, or whether the necessary prerequisites for immunity would be triggered with respect to our products or product candidates.

Additionally, BioThrax and RSDL have been certified as anti-terrorism products under the SAFETY Act and applications for continued coverage under the SAFETY Act are currently pending. The SAFETY Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. Although we have been entitled to the benefits of the SAFETY Act for BioThrax and RSDL, such benefits may not be renewed and even if they are renewed, the SAFETY Act may not provide adequate protection from claims made against us.

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

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

The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. Further product liability insurance may be difficult and expensive to obtain. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy all potential liabilities. For example, we may not have sufficient insurance against potential liabilities associated with a possible large-scale deployment of BioThrax as a countermeasure to a bioterrorism threat. We rely on PREP Act protection for BioThrax, raxibacumab, ACAM2000, Anthrasil, BAT and VIGIV, and possible continuation of SAFETY Act protection for BioThrax and RSDL in addition to our insurance coverage to help mitigate our product liability exposure for these products. Additionally, potential product liability claims related to our commercial products, including NARCAN, Vivotif and Vaxchora, may be made by patients, health care providers or others who sell or consume these products. Such claims may

be made even with respect to those products that possess regulatory approval for commercial sale. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition, operating results and cash flows.

## FINANCIAL RISKS

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

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

- requiring us to dedicate a substantial portion of cash flows from operations to payment on our debt, which would reduce available funds for other corporate initiatives;
- increasing the amount of interest that we have to pay on debt with variable interest rates, if market rates of interest increase, to the extent we are unable to offset such risk through our hedging instruments;
- subjecting us, as under our Senior Secured Credit Facilities and the indenture governing the 3.875% Senior Unsecured Notes due 2028 (the "Senior Unsecured Notes"), to restrictive covenants that reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing;
- requiring us to pledge our assets as collateral, which could limit our ability to obtain additional debt financing;
- limiting our flexibility in planning for, or reacting to, general adverse economic and industry conditions; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

We may not have sufficient funds or be able to obtain additional financing to pay the amounts due under our indebtedness. In addition, failure to comply with the covenants under our Senior Secured Credit Facilities and other debt agreements, including the maintenance of a specified consolidated net leverage ratio and debt service coverage ratio under our Senior Secured Credit Facilities, could result in an event of default under those agreements. An event of default could result in the acceleration of amounts due under a particular debt agreement and a cross default and acceleration under other debt agreements, and we may not have sufficient funds to pay or be able to obtain additional financing to make any accelerated payments. Under these circumstances, our lenders could seek to enforce security interests in our assets securing our indebtedness.

Additionally, as of September 30, 2022, there was \$238.0 million outstanding under the Revolving Credit Facility and \$371.3 million outstanding under the Term Loan Facility that matures in October 2023, which is within one year of the date that the consolidated financial statements are issued for the quarter ended September 30, 2022. The Company determined that there is substantial doubt about the Company's ability to continue as a going concern as a result. Any delay in or inability to refinance these Senior Secured Credit Facilities on favorable terms, or at all, could adversely affect our results of operations and financial condition.

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

The Senior Secured Credit Facilities include a \$450 million Term Loan Facility which had an outstanding principal balance of \$371.3 million as of September 30, 2022, and the ability to borrow up to \$600 million under our Revolving Credit Facility, of which we had \$238 million in borrowings as of September 30, 2022. On August 7, 2020, we completed an offering of \$450 million aggregate principal amount of Senior Unsecured Notes, of which \$353 million of the net proceeds were used to pay down our Revolving Credit Facility. We may also seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing can have significant adverse consequences for our business, including:

- the level, timing and cost of product sales and CDMO services;
- the extent to which we acquire or invest in and integrate companies, businesses, products or technologies;

- the acquisition of new facilities and capital improvements to new or existing facilities;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
- the extent to which we repurchase additional shares of common stock under our current share repurchase program; and
- the costs of commercialization activities, including product marketing, sales and distribution.

*Our hedging program is subject to counterparty default risk.*

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

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

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 (which



include, among other things, the timely filing of our reports under the Exchange Act and maintenance of at least \$700 million of public float or issuing an aggregate amount of \$1 billion of non-convertible securities, other than common stock, in registered offerings for cash during the past three years), this shelf registration statement, effective until August 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 shelf registration statement (whether by lapse of time or due to us no longer qualifying as a "well-known seasoned issuer"), the existing shelf registration statement will expire, and we will not be able to publicly raise capital or issue debt until a new registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatically effective shelf registration statement at a future date when we may need to raise funds publicly.

If we raise funds by issuing equity securities, our shareholders 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 profitability on a quarterly basis or sustain or increase profitability on an annual basis.

*The expansion of our international operations increases our risk of exposure to credit losses.*

As we continue to expand our business activities with foreign governments in certain countries that have experienced deterioration in credit and economic conditions or otherwise, our exposure to uncollectible accounts will rise. Global economic conditions and liquidity issues in certain countries have resulted and may continue to result in delays in the collection of accounts receivable and may result in credit losses. Future governmental actions and customer specific actions may require us to re-evaluate the collectability of our accounts receivable and we may potentially incur credit losses that materially impact our operating results.

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

In July 2017, the Financial Conduct Authority, the authority that regulates the London Inter-bank Offered Rate ("LIBOR") announced that it intended to stop compelling banks to submit rates for the calculation of LIBOR after 2021.

On December 31, 2021, the International Exchange ("ICE") Benchmark Association, which administrates LIBOR, ceased (i) entering into new contracts that use LIBOR as a reference rate and (ii) publication of two LIBOR rates (one-week and two-month) and announced that the remaining LIBOR rates (overnight, one-month, three-month, six-month and 12-month) will be retired on June 30, 2023. It is unclear if LIBOR will cease to exist at that time or if new methods of calculating LIBOR will be established such that it continues to exist after 2023. We have certain financial contracts, including the amended credit agreement related to our Senior Secured Credit Facilities and our interest rate swaps, that are indexed to LIBOR. Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness. Any transition process may involve, among other things, increased volatility or illiquidity in markets for instruments that rely on LIBOR, reductions in the value of certain instruments or the effectiveness of related

transactions such as hedges, increased borrowing costs, uncertainty under applicable documentation, or difficult and costly consent processes. The transition away from LIBOR may result in increased expenses, may impair our ability to refinance our indebtedness or hedge our exposure to floating rate instruments, or may result in difficulties, complications or delays in connection with future financing efforts, any of which could adversely affect our financial condition and results of operations.

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

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

Our business strategy includes growing our business through acquisition and in-licensing transactions. 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 or 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.

## 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 shareholders 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 shareholders may consider favorable, including transactions in which shareholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts by our shareholders 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 shareholder nominations of candidates for election to the Board of Directors and other proposals;
- the inability of shareholders to act by written consent;
- the inability of shareholders 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 shareholder 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 shareholder, 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 shareholder, 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 shareholder rights plan without shareholder approval, which could prevent a change in control of us in instances in which some shareholders may believe a change in control is in their best interests.*

Our Board of Directors may implement a shareholder rights plan without shareholder approval. We previously implemented a shareholder rights plan, which expired on November 14, 2016. Under our prior shareholder rights plan, we issued to each of our shareholders one preferred stock purchase right for each outstanding share of our common stock. Each right, when exercisable, would have entitled its holder

to purchase from us a unit consisting of one one-thousandth of a share of series A junior participating preferred stock at a purchase price of \$150 in cash, subject to adjustments. Our shareholder rights plan was intended to protect shareholders in the event of an unfair or coercive offer to acquire us and to provide our Board of Directors with adequate time to evaluate unsolicited offers.

Our Board of Directors may implement a new shareholder rights plan, which may have anti-takeover effects, potentially preventing a change in control of us in instances in which some shareholders 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 shareholders and may discourage, delay or prevent a merger or acquisition that shareholders may consider favorable, including transactions in which shareholders 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 November 1, 2022, our common stock has traded as high as \$137.61 per share and as low as \$4.17 per share. Due to fears associated with current world events, current historically high levels of inflation and the possible resurgence of COVID-19, the stock market has been experiencing extreme volatility and the market for biopharmaceutical companies has generally experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including, among others:

- contracts, decisions and procurement policies by the USG affecting our anthrax vaccines and our other products and product candidates;
- CDMO contracts related to COVID-19 with collaboration partners;

- the success of competitive products or technologies;
- results of clinical and non-clinical trials of our product candidates;
- announcements of acquisitions, financings or other transactions by us;
- litigation or legal proceedings;
- public concern as to the safety of our products;
- termination or delay of a development program;
- the recruitment or departure of key personnel;
- variations in our product revenue and profitability; and
- the other factors described in this “Risk Factors” section.

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

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

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

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

**GENERAL RISKS**

*The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. A material weakness in our internal control over financial reporting could have an adverse effect on our business and financial results and our ability to meet our reporting obligations could be negatively affected, each of which could negatively affect the trading price of our common stock.*

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

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

Our system of internal controls, however well-designed, can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting, or the internal controls of other companies we may acquire, are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial reporting, and the trading price of our common stock could be negatively affected.

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

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel (including quality and manufacturing personnel). If we are unable to retain the services of one or more of the principal members

of senior management or other key employees, our ability to implement our business strategy could be materially harmed. We face intense competition for qualified employees from biopharmaceutical companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. We believe part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including equity incentive awards. If we cannot offer a competitive compensation package to attract and retain the qualified personnel necessary for the continued development of our business, we may not be able to maintain our operations or grow our business.

**ITEM 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**

Not applicable.

**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
31.1 #	<a href="#">Certification of the Chief Executive Officer, pursuant to Exchange Act Rule 13a-14(a).</a>
31.2 #	<a href="#">Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).</a>
32.1 #	<a href="#">Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2 #	<a href="#">Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101 #	The following financial information related to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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 Income, (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.

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/ROBERT G. KRAMER

Robert G. Kramer  
President, Chief Executive Officer and Director  
(Principal Executive Officer)

Date: November 8, 2022

By: /s/RICHARD S. LINDAHL

Richard S. Lindahl  
Executive Vice President, Chief Financial Officer and Treasurer  
(Principal Financial and Accounting Officer)

Date: November 8, 2022

## CERTIFICATION

I, Robert G. Kramer, 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: November 8, 2022

/s/ROBERT G. KRAMER

Robert G. Kramer  
Chief Executive Officer

## 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: November 8, 2022

/s/RICHARD S. LINDAHL

Richard S. Lindahl  
Chief Financial Officer

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

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert G. Kramer, 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: November 8, 2022

/s/ROBERT G. KRAMER

Robert G. Kramer  
Chief Executive Officer

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

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended September 30, 2022 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: November 8, 2022

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