UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended **March 31, 2020**

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 BIOSOLUTIONS INC.

(Exact Name of Registrant as Specified in Its Charter)

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

400 Professional Drive Suite 400
Gaithersburg, 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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T 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. (Check one):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of April 24, 2020, the registrant had 52,427,756 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 earnings and performance of Emergent BioSolutions Inc. or any of our businesses, our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management and the expected impact of the COVID-19 pandemic, are forward-looking statements. We generally identify forward-looking statements by using words like "will," "believes," "expects," "anticipates," "intends," "plans," "forecasts," "estimates" and similar expressions in conjunction with, among other things, discussions of financial performance or financial condition, growth strategy, product sales, manufacturing capabilities, product development, regulatory approvals or expenditures. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. You should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. You are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

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

- the impact of global economic conditions and public health crises and epidemics, such as the novel strain of coronavirus (SARS-CoV-2) causing COVID-19 disease, on our markets, operations and employees as well as those of our customers and suppliers;
- the availability of U.S. government (USG) funding for procurement of our products;
- our ability to perform under our contracts with the USG including the timing of and specifications relating to deliveries;
- the continued exercise of discretion by the Biomedical Advanced Research and Development Authority (BARDA) to procure additional doses of AV7909 (anthrax vaccine adsorbed with adjuvant) prior to approval by the U.S. Food and Drug Administration (FDA);
- the exercise of all options under our recently executed contract for the procurement of ACAM2000® (Smallpox (Vaccinia) Vaccine, Live);
- our ability to secure licensure of AV7909 from the FDA within the anticipated timeframe, if at all;
- our ability to secure follow-on procurement contracts for our public health threat (PHT) products that are under procurement contracts that have expired or will be expiring;
- our ability and the ability of our collaborators to enforce patents related to NARCAN Nasal Spray against potential generic entrants;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- our ability and the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices and other regulatory obligations;
- our ability to comply with the operating and financial covenants required by our Senior Secured Credit Facilities;
- our ability to obtain and maintain regulatory approvals for our product candidates and the timing of any such approvals;
- the procurement of products by USG entities under regulatory exemptions prior to approval by the 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 success of our commercialization, marketing and manufacturing capabilities and strategy; and
- the accuracy of our estimates regarding future revenues, expenses, capital requirements and needs for additional financing.

The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. 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. You should consider this cautionary statement, the risk factors identified in the section entitled "Risk Factors" in this quarterly

report on Form 10-Q and the risk factors identified in our other periodic reports filed with the Securities and Exchange Commission (SEC) when evaluating our forward-looking statements.

NOTE REGARDING COMPANY REFERENCES

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

NOTE REGARDING TRADENAMES

BioThrax® (Anthrax Vaccine Adsorbed), RSDL® (Reactive Skin Decontamination Lotion Kit), BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)), Anthrasil® (Anthrax Immune Globulin Intravenous (Human)), VIGIV (Vaccinia Immune Globulin Intravenous (Human)), Trobigard® (atropine sulfate, obidoxime chloride), ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), Vivotif® (Typhoid Vaccine Live Oral Ty21a), Vaxchora® (Cholera Vaccine, Live, Oral), NARCAN® (naloxone HCl) Nasal Spray and any and all Emergent brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent 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.

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

	March 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 181.5	$ 167.8
Restricted cash	0.2	0.2
Accounts receivable, net	162.5	270.7
Inventories	248.1	222.5
Income tax receivable, net	10.2	4.6
Prepaid expenses and other current assets	24.1	20.4
Total current assets	626.6	686.2
Property, plant and equipment, net	549.2	542.3
Intangible assets, net	708.1	712.9
In-process research and development	29.0	29.0
Goodwill	266.4	266.6
Deferred tax assets, net	17.6	13.4
Other assets	81.8	76.9
Total assets	$ 2,278.7	$ 2,327.3
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 84.2	$ 94.8
Accrued expenses	41.5	39.5
Accrued compensation	47.5	62.4
Debt, current portion	26.3	12.9
Other current liabilities	7.6	6.7
Total current liabilities	207.1	216.3
Contingent consideration, net of current portion	26.1	26.0
Debt, net of current portion	762.9	798.4
Deferred tax liability	63.9	63.9
Contract liabilities, net of current portion	85.0	85.6
Other liabilities	58.9	48.6
Total liabilities	$ 1,203.9	$ 1,238.8
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, 53.5 and 53.0 shares issued; 52.3 and 51.7 shares outstanding, respectively	0.1	0.1
Treasury stock, at cost, 1.2 common shares	(39.6)	(39.6)
Additional paid-in capital	726.2	716.1
Accumulated other comprehensive loss, net	(21.2)	(9.9)
Retained earnings	409.3	421.8
Total stockholders' equity	1,074.8	1,088.5
Total liabilities and stockholders' equity	$ 2,278.7	$ 2,327.3

See accompanying notes.

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

	Three Months Ended March 31,	
	2020	2019
Revenues:		
Product sales, net	$ 148.2	$ 153.0
Contract development and manufacturing services	21.7	15.9
Contracts and grants	22.6	21.7
Total revenues	192.5	190.6
Operating expenses:		
Cost of product sales and contract development and manufacturing services	76.9	91.8
Research and development	42.7	46.1
Selling, general and administrative	69.7	65.4
Amortization of intangible assets	14.8	14.5
Total operating expenses	204.1	217.8
Loss from operations	(11.6)	(27.2)
Other (expense) income:		
Interest expense	(8.6)	(9.6)
Other expense, net	(1.1)	(1.0)
Total other expense, net	(9.7)	(10.6)
Loss before provision for income taxes	(21.3)	(37.8)
Income tax benefit	8.8	11.8
Net loss	$ (12.5)	$ (26.0)
Net loss per common share		
Basic	$ (0.24)	$ (0.51)
Diluted	$ (0.24)	$ (0.51)
Shares used in computing loss per share		
Basic	52.0	51.2
Diluted	52.0	51.2

See accompanying notes.

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

	Three Months Ended March 31,	
	2020	2019
Net loss	$ (12.5)	$ (26.0)
Other comprehensive (loss) income, net of tax:		
Foreign currency translation	(0.1)	1.2
Unrealized losses on hedging activities, net of tax	(11.2)	—
Unrealized losses on pension benefit obligation, net of tax	—	(0.2)
Total other comprehensive (loss) income, net of tax	(11.3)	1.0
Comprehensive loss	$ (23.8)	$ (25.0)

During the three months ended March 31, 2020, there were tax benefits related to unrealized losses on hedging activities of $2.8 million and tax losses related to foreign currency translations that were de minimus. During the three months ended March 31, 2019, the tax effects of the amounts presented were de minimus.

See accompanying notes.

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

	Three Months Ended March 31,	
	2020	2019
Cash flows provided by operating activities:		
Net loss	$ (12.5)	$ (26.0)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Share-based compensation expense	6.6	6.8
Depreciation and amortization	28.2	26.6
Amortization of deferred financing costs	0.7	0.7
Deferred income taxes	(4.2)	(11.4)
Change in fair value of contingent consideration, net	0.6	1.7
Other	—	(0.1)
Changes in operating assets and liabilities:		
Accounts receivable	108.2	141.6
Inventories	(25.6)	(5.2)
Prepaid expenses and other assets	(15.3)	(16.6)
Accounts payable	(15.6)	4.2
Accrued expenses	1.1	1.7
Accrued compensation	(14.9)	(21.3)
Contract liabilities	0.5	2.1
Net cash provided by operating activities:	**57.8**	104.8
Cash flows used in investing activities:		
Purchases of property, plant and equipment and other	(24.2)	(21.4)
Net cash used in investing activities:	(24.2)	(21.4)
Cash flows used in financing activities:		
Proceeds from revolving credit facility	—	30.0
Principal payments on revolving credit facility	(20.0)	(80.0)
Principal payments on term loan facility	(2.8)	(2.8)
Proceeds from issuance of common stock upon exercise of stock options	9.1	0.9
Taxes paid on behalf of employees for equity activity	(5.6)	(6.0)
Contingent consideration payments	(0.7)	(0.5)
Net cash used in financing activities:	(20.0)	(58.4)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	0.1	—
Net increase in cash, cash equivalents and restricted cash	13.7	25.0
Cash, cash equivalents and restricted cash at beginning of period	168.0	112.4
Cash, cash equivalents and restricted cash at end of period	$ 181.7	$ 137.4
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 7.4	$ 8.9
Cash paid during the period for income taxes	$ 3.6	$ 5.0
Supplemental information on non-cash investing and financing activities:		
Purchases of property, plant and equipment unpaid at period end	$ 7.3	$ 7.1
Reconciliation of cash and cash equivalent and restricted cash at March 31, 2020 and December 31, 2019:		
Cash and cash equivalents	$ 181.5	$ 167.8
Restricted cash	$ 0.2	0.2
Total	$ 181.7	$ 168.0

See accompanying notes.

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

	$0.001 Par Value Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount		Shares	Amount			
Balance at December 31, 2019	53.0	$ 0.1	$ 716.1	(1.2)	$ (39.6)	$ (9.9)	$ 421.8	$ 1,088.5
Employee equity plans activity	0.5	—	10.1	—	—	—	—	10.1
Net income	—	—	—	—	—	—	(12.5)	(12.5)
Other comprehensive income	—	—	—	—	—	(11.3)	—	(11.3)
Balance at March 31, 2020	53.5	$ 0.1	$ 726.2	(1.2)	$ (39.6)	$ (21.2)	$ 409.3	$ 1,074.8
Balance at December 31, 2018	52.4	$ 0.1	$ 688.6	(1.2)	$ (39.6)	$ (5.5)	$ 367.3	$ 1,010.9
Employee equity plans activity	0.2	—	1.6	—	—	—	—	1.6
Net income	—	—	—	—	—	—	(26.0)	(26.0)
Other comprehensive loss	—	—	—	—	—	1.0	—	1.0
Balance at March 31, 2019	52.6	$ 0.1	$ 690.2	(1.2)	$ (39.6)	$ (4.5)	$ 341.3	$ 987.5

See accompanying notes.

1. Business

Organization and business

Emergent BioSolutions Inc. (the "Company" or "Emergent") is a global life sciences company focused on providing civilian and military populations a portfolio of innovative preparedness and response products and solutions that address accidental, deliberate and naturally occurring public health threats ("PHTs," each a “PHT”).

The Company is focused on the following six distinct PHT categories: Chemical, Biological, Radiological, Nuclear and Explosives ("CBRNE"); emerging infectious diseases ("EID"); travel health; emerging health crises; acute/emergency care, and contract development and manufacturing ("CDMO"). The Company has a product portfolio of ten products and product candidates (vaccines, therapeutics, and drug-device combination products) that contribute a substantial portion of our revenue. The Company also has two product candidates that are procured under special circumstances by certain government agencies, although they are not approved by the FDA or any health agency. The U.S. government (the "USG') is the Company's largest customer and provides the Company with substantial funding for the development of a number of its product candidates.

The Company's product portfolio includes:

Vaccines

- 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;
- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration ("FDA"), for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- Vaxchora® (Cholera Vaccine, Live, Oral), the only FDA-licensed vaccine 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.

Devices

- 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; and
- 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;

Therapeutics

- raxibacumab (Anthrax Monoclonal), 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;
- BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)), the only heptavalent antibody therapeutic licensed by the FDA and Health Canada for the treatment of botulism; and
- VIGIV (Vaccinia Immune Globulin Intravenous (Human)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination.

Product Candidates

- AV7909® (Anthrax Vaccine Absorbed with Adjuvant), is a 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 started procuring AV7909 for the Strategic National Stockpile (SNS) prior to its approval by the FDA and has been reducing its purchases of BioThrax as a result; and
- Trobigard® is a combination drug-device auto-injector product candidate that contains atropine sulfate and obidoxime chloride. It has not been approved by the FDA or any similar health regulatory body, but it is procured

by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure.

The Company also generates revenue from contract development and manufacturing services on a clinical and commercial (small and large) scale by providing such services to the pharmaceutical and biotechnology industry. These services include process development and bulk drug substance and drug product manufacturing of biologics, 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 across bacterial, viral and mammalian therapy technology platforms.

The Company operates as one operating segment.

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, 2019, 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 March 31, 2020. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Significant accounting policies

During the three months ended March 31, 2020, 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, 2019, as filed with the SEC.

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), contingent purchase consideration (level 3) and interest rate swaps arrangements (level 2) that are measured at fair value on a recurring basis (Note 7 and Note 8). As of March 31, 2020 and December 31, 2019, the Company held cash in money market accounts of $90.7 million and $52.2 million, respectively. The Company also records the assets and liabilities of acquisitions at fair value. On a non-recurring basis, the Company measures its IPR&D assets (level 3) using fair value measurements. As of March 31, 2020 and December 31, 2019, the Company had no other significant assets or liabilities that were measured at fair value.

Recently issued accounting standards

Recently Adopted

ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13")

In June 2016, the FASB issued ASU 2016-13. ASU 2016-13 provides guidance on measurement of credit losses on financial instruments that changes the impairment model for most financial assets and certain other instruments, including trade and other receivables, held-to-maturity debt securities and loans, and that requires entities to use a new, forward-looking “expected loss” model that is expected to generally result in the earlier recognition of allowances for losses. The guidance became effective for annual periods beginning after December 15, 2019, including interim periods within those years. The Company adopted the standard as of January 1, 2020 and has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

ASU 2018-13, Fair Value Measurement - Disclosure Framework (Topic 820) ("ASU 2018-13")

In August 2018, the FASB issued ASU 2018-13. ASU 2018-13 improves the disclosure requirements on fair value measurements. The updated guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted for any removed or modified disclosures. The Company adopted the standard as of January 1, 2020 which has resulted in expanded disclosures around the Company's recurring level 3 fair value measurements. The disclosures are included in note 7 of the condensed consolidated financial statements.

ASU 2018-15, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract ("ASU 2018-15")

In August 2018, the FASB issued ASU 2018-15. ASU 2018-15 clarifies the accounting for implementation costs in cloud computing arrangements. ASU 2018-15 is effective for all entities for fiscal years beginning after December 15, 2019. The Company adopted the standard as of January 1, 2020 and has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

ASU 2017-4, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment ("ASU 2017-4")

In January 2017, the FASB issued ASU 2017-4. ASU 2017-4 simplifies the subsequent measurement of goodwill and eliminates Step 2 from the goodwill impairment test. ASU 2017-4 is effective for annual and interim goodwill tests beginning after December 15, 2019. The Company's measurement period is September 30. The Company adopted the standard as of January 1, 2020 and has evaluated the effects of this standard and determined that the adoption will not have a material impact on the Company's consolidation financial statements.

Not Yet 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. Topic 848 provides relief for impacted areas as it relates to impending reference rate reform. ASC 848 contains optional expedients and exceptions for applying US GAAP to debt arrangements, contracts, hedging relationships, and other areas or transactions that are impacted by reference rate reform. This guidance is effective for upon issuance for all entities and elections of certain optional expedients are required to apply the provisions of the guidance. The Company continues to assess all potential impacts of the standard and will disclose the nature and reason for any elections that the Company makes.

ASU 2018-14, Compensation - Retirement Benefits - Defined Benefit Plans - General (Topic 715-20): Disclosure Framework - Changes to the Disclosure Requirements for Defined Benefit Plans ("ASU 2018-14")

In August 2018, the FASB issued ASU 2018-14. ASU 2018-14 modifies the disclosure requirements for defined benefit pension plans and other post-retirement plans. ASU 2018-14 is effective for all entities for fiscal years ending after December 15, 2020, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2018-14 on its consolidated financial statements.

(unaudited, in millions, except share and per share amounts)

ASU 2019-12, Simplifications to Accounting for Income Taxes ("ASU 2019-12")

In December 2019, the FASB issued ASU 2019-12. ASU 2019-12 removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including deferred taxes for goodwill and allocating taxes for members of a consolidated group. ASU 2019-12 is effective for all entities for fiscal years beginning after December 15, 2020, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2019-12 on its consolidated financial statements.

3. Inventories

The components of inventory are as follows:

	March 31, 2020	December 31, 2019
Raw materials and supplies	$ 77.7	$ 70.5
Work-in-process	114.2	89.7
Finished goods	56.2	62.3
Total inventories	$ 248.1	$ 222.5

4. Property, plant and equipment

Property, plant and equipment consisted of the following:

	March 31, 2020	December 31, 2019
Land and improvements	$ 46.6	$ 46.5
Buildings, building improvements and leasehold improvements	242.3	234.8
Furniture and equipment	340.0	334.2
Software	55.6	55.7
Construction-in-progress	86.5	81.5
Property, plant and equipment, gross	771.0	752.7
Accumulated depreciation	(221.8)	(210.4)
Total property, plant and equipment, net	$ 549.2	$ 542.3

5. Leases

The Company has operating leases for corporate offices, research and development facilities and manufacturing facilities. We determine if an arrangement is a lease at inception. Operating leases are included in right-of-use (ROU) assets and liabilities.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The Company uses an implicit rate when readily determinable. At the beginning of a lease, the operating lease ROU asset also includes any concentrated lease payments expected to be paid and excludes lease incentives. The Company's lease ROU asset may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise those options.

Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company has lease agreements with lease and non-lease components, which are accounted for separately. The Company's leases have remaining lease terms of 1 year to 15 years, some of which include options to extend the leases for up to 5 years, and some of which include options to terminate the leases within 1 year.

The components of lease expense were as follows:

	Three months ended March 31,	
	2020	2019
Operating lease cost:		
Amortization of right-of-use assets	$ 1.1	$ 0.6
Interest on lease liabilities	0.3	0.1
Total operating lease cost	$ 1.4	$ 0.7

Supplemental balance sheet information related to leases was as follows:

(In millions, except lease term and discount rate)	Balance Sheet location	March 31, 2020	December 31, 2019
Operating lease right-of-use assets	Other assets	$ 25.6	$ 24.7
Operating lease liabilities, current portion	Other current liabilities	4.2	3.6
Operating lease liabilities	Other liabilities	22.7	22.1
Total operating lease liabilities		$ 26.9	$ 25.7
Operating leases:			
Weighted average remaining lease term (years)		7.7	8.0
Weighted average discount rate		4.2%	4.2%

6. Intangible assets

The Company's intangible assets consist of products acquired via business combinations or asset acquisitions. The following tables summarize the Company's intangible assets for the periods ended March 31, 2020 and December 31, 2019:

		March 31, 2020			
(in millions)	Estimated Life	Cost	Additions	Accumulated Amortization	Net
Products	9-22 years	$ 788.0	$ 10.0	$ 96.0	$ 702.0
Customer relationships	8 years	28.6	—	23.8	4.8
Contract development and manufacturing	8 years	5.5	—	4.2	1.3
Total intangible assets		$ 822.1	$ 10.0	$ 124.0	$ 708.1

		December 31, 2019		
(in millions)	Estimated Life	Cost	Accumulated Amortization	Net
Products	9-22 years	$ 788.0	$ 82.2	$ 705.8
Customer relationships	8 years	28.6	23.0	$ 5.6
Contract development and manufacturing	8 years	5.5	4.0	$ 1.5
Total intangible assets		$ 822.1	$ 109.2	$ 712.9

During the three months ended March 31, 2020, the Company achieved a sales milestone that resulted in a $10.0 million obligation related to the Company's asset acquisition of raxibacumab in October 2017. The achievement of the milestone resulted in an increase to intangible assets with a corresponding increase in accounts payable. As of March 31, 2020 there are no remaining contractual obligations for sales milestones related to the raxibacumab acquisition.

During the three months ended March 31, 2020 and 2019, the Company recorded amortization expense for intangible assets of $14.8 million and $14.5 million, respectively. As of March 31, 2020, the weighted average amortization period remaining for intangible assets was 13.3 years.

(unaudited, in millions, except share and per share amounts)

In-process research and development (IPR&D) assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. There were no changes to the Company's IPR&D assets during the three months ended March 31, 2020.

Goodwill was $266.4 million and $266.6 million for the periods ended March 31, 2020 and December 31, 2019, respectively. The change in the balance during the period was due to foreign currency translation adjustments.

7. Contingent consideration

Contingent consideration liabilities associated with business combinations are fair value measurement items. 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 (Level 3).

The following table is a reconciliation of the beginning and ending balance of contingent considerations and is based on level 3 significant unobservable inputs.

Balance at December 31, 2019	$	29.2
Change in fair value		0.6
Settlements		(0.7)
Balance at March 31, 2020	$	29.1

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

Contingent Consideration Liability	Fair Value as of March 31, 2020	Valuation Technique	Unobservable Input	Range	Weighted Average
Revenue milestone and royalty based	$29.1 million	Discounted cash flow	Discount rate	2.5% - 8.6%	4.3%
			Probability of payment	10.0% - 40.0%	20.9%
			Projected year of payment	2020 - 2028	2022

8. Derivative instruments and hedging activities

Risk management objective of using derivatives

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

Accounting policy for derivative instruments and hedging activities

The Company entered into interest rate swaps in June 2019. The Company's interest rate swaps qualify for hedge accounting as cash flow hedges. All derivatives are recorded on the balance sheet at fair value. Hedge accounting provides for the matching of the timing of gain or loss recognition on these interest rate swaps with the recognition of the changes in interest expense on the Company's variable rate debt. For derivatives designated as cash flow hedges of interest rate risk, the gain or loss on the derivative is recorded in accumulated other comprehensive income and subsequently reclassified into interest expense in the same period during which the hedged transaction affects earnings. Amounts reported in accumulated other comprehensive income related to derivatives will be reclassified to interest

(unaudited, in millions, except share and per share amounts)

expense as interest payments are made on the Company's variable-rate debt. The cash flows from the designated interest rate swaps are classified as a component of operating cash flows, similar to interest expense. If current fair values of designated interest rate swaps remained static over the next twelve months, the Company would reclassify $5.0 million of net deferred losses from accumulated other comprehensive loss to the statement of operations over the next twelve month period. All outstanding cash flow hedges mature in October 2023.

As of March 31, 2020, the Company had the following outstanding interest rate derivatives that were designated as cash flow hedges of interest rate risk:

	Number of Instruments	Notional
Interest rate swaps	7	$ 350.0

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

	Asset Derivatives				Liability Derivatives			
	March 31, 2020		December 31, 2019		March 31, 2020		December 31, 2019	
	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	$ —	Other Current Assets	$ —	Other Current Liabilities	$ 4.8	Other Current Liabilities	$ —
	Other Assets	$ —	Other Assets	$ —	Other Liabilities	$ 11.2	Other Liabilities	$ 2.0

The valuation of the interest rate swaps is determined using widely accepted valuation techniques, including discounted cash flow analysis on the expected cash flows of each interest rate swap. This analysis reflects the contractual terms of the interest rate swaps, including the period to maturity, and uses observable market-based inputs, including interest rate curves and implied volatilities. The fair values of interest rate swaps are determined using the market standard methodology of netting the discounted future fixed cash payments (or receipts) and the discounted expected variable cash receipts (or payments). The variable cash payments (or receipts) are based on an expectation of future interest rates (forward curves) derived from observable market interest rate curves. To comply with the provisions of ASC 820, Fair Value Measurement, 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 concluded to not be significant inputs for the fair value calculations for the periods presented. In adjusting the fair value of our derivative contracts for the effect of nonperformance risk, we have considered the impact of netting and any applicable credit enhancements, such as the posting of collateral, thresholds, mutual puts and guarantees. The valuation of interest rate swaps fall into Level 2 in the fair value hierarchy.

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

Hedging derivatives	Cumulative Amount of Gain/(Loss) Recognized in OCI on Derivative, March 31,		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income, Three months ended March 31,	
	2020	2019		2020	2019
Interest Rate Swaps	$ (16.0)	$ —	Interest expense	$ —	$ —

(unaudited, in millions, except share and per share amounts)

9. Debt

The components of debt are as follows:

	March 31, 2020	December 31, 2019
Senior secured credit agreement - Term loan due 2023	$ 433.1	$ 435.9
Senior secured credit agreement - Revolver loan due 2023	353.0	373.0
2.875% Convertible Senior Notes due 2021	10.6	10.6
Other	3.0	3.0
Total debt	799.7	822.5
Current portion of long-term debt, net of debt issuance costs	(26.3)	(12.9)
Unamortized debt issuance costs	(10.5)	(11.2)
Non-current portion of debt	$ 762.9	$ 798.4

Senior secured credit agreement

In October 2018, the Company entered into a senior secured credit agreement with multiple lending institutions (the "Credit Agreement"). The terms of the credit agreement include (i) a revolving credit facility (the "Revolving Credit Facility") of $600 million with a maturity date of October 13, 2023, and (ii) a term loan with a principal amount of $450 million (the "Term Loan Facility," and together with the Revolving Credit Facility, the "Senior Secured Credit Facilities"). The Company may request incremental term loan facilities or increases in the Revolving Credit Facility (each an "Incremental Loan") as long as requirements relating to net leverage ratio will be maintained on a pro forma basis.

Borrowings under the Revolving Credit Facility and the Term Loan Facility will bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.25% to 2.00% 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 1.00%, depending on the Company's consolidated net leverage ratio. The Company is required to make quarterly payments under the 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 0.30% per annum, depending on the Company's consolidated net leverage ratio, in respect of 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 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 (unless earlier terminated) on October 13, 2023.

The 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 Credit Agreement or (b) receive cash proceeds in excess of $100 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 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 3.75 to 1.00 for the quarterly filing periods from October 1, 2019 through September 29, 2020 and 3.50 to 1.0, thereafter, which may be adjusted to 4.00 to 1.00 for a four quarter period in connection with a material permitted acquisition. Negative covenants in the 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.

(unaudited, in millions, except share and per share amounts)

2.875% Convertible senior notes due 2021

On January 29, 2014, the Company issued 2.875% convertible senior notes due 2021 (the "Notes"). The Notes bear interest at a rate of 2.875% per year, payable semi-annually in arrears on January 15 and July 15 of each year. The Notes mature on January 15, 2021.

10. Revenue recognition

The Company operates as one operating segment. Therefore, results of its operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. The Company's revenues disaggregated by the major sources were as follows:

	Three Months Ended March 31, 2020			Three Months Ended March 31, 2019		
	U.S. Government	Non-U.S. Government	Total	U.S. Government	Non-U.S. Government	Total
Product sales, net	$ 63.9	$ 84.3	$ 148.2	$ 73.3	$ 79.7	$ 153.0
Contract development and manufacturing services	—	21.7	21.7	—	15.9	15.9
Contracts and grants	22.0	0.6	22.6	20.4	1.3	21.7
Total revenues	$ 85.9	$ 106.6	$ 192.5	$ 93.7	$ 96.9	$ 190.6

Contract liabilities

When performance obligations are not transferred to a customer at the end of a reporting period, cash received associated with amounts allocated to those performance obligations is reflected as contract liabilities on the consolidated balance sheets and is deferred until control of these performance obligations is transferred to the customer. The following table presents the rollforward of the contract liability balances:

December 31, 2019	**$ 88.9**
Deferral of revenue	6.4
Revenue recognized	(5.9)
March 31, 2020	**$ 89.4**

Transaction price allocated to remaining performance obligations

As of March 31, 2020, the Company expects future revenues of approximately $555.9 million associated with performance obligations that have not been satisfied. The Company expects to recognize a majority of these revenues within the next 24 months, with the remainder recognized thereafter. However, the amount and timing of revenue recognition for unsatisfied performance obligations can materially change due to timing of funding appropriations from the USG and the overall success of the Company's development activities associated with its PHT product candidates that are then receiving development funding support from the USG under development contracts. In addition, the amount of future revenues associated with unsatisfied performance obligations excludes the value associated with unexercised option periods in the Company's contracts.

Contract assets

The Company considers unbilled accounts receivables and deferred costs associated with revenue generating contracts, which are not included in inventory or property, plant and equipment, as contract assets. As of March 31, 2020 and December 31, 2019, the Company had contract assets associated with deferred costs of $36.3 million and $34.0 million, respectively, which is reflected as a component of prepaid expenses and other current assets on the Company's consolidated balance sheets.

(unaudited, in millions, except share and per share amounts)

Accounts receivable

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

	March 31, 2020	December 31, 2019
Billed, net	$ 119.4	$ 227.3
Unbilled	43.1	43.4
Total, net	$ 162.5	$ 270.7

As of March 31, 2020 and December 31, 2019, allowances for doubtful accounts were $0.8 million and de minimis, respectively.

11. Income taxes

On March 27, 2020, the President of the United States signed into law the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The Company is currently assessing the impact of the CARES Act, but we do not expect there to be a material impact to our consolidated financial statements.

The estimated effective annual tax rate for the Company, which excludes discrete adjustments, was 26% and 27% for the three months ended March 31, 2020 and 2019. For the three months ended March 31, 2020 and 2019, the Company recorded a discrete tax benefit of $3.2 million and $1.8 million, respectively, primarily due to activity associated with equity awards.

12. Net loss per share

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

	Three Months Ended March 31,	
	2020	2019
Numerator:		
Net loss	$ (12.5)	$ (26.0)
Denominator:		
Weighted-average number of shares—basic	52.0	51.2
Dilutive securities—equity awards	—	—
Weighted-average number of shares—diluted	52.0	51.2
Net loss per share - basic	$ (0.24)	$ (0.51)
Net loss per share - diluted	$ (0.24)	$ (0.51)

Basic earnings (loss) per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed using the treasury method by dividing net 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. For the three months ended March 31, 2020 and 2019, approximately 0.7 million and 3.1 million stock options are not considered in the diluted net loss per share calculation because the exercise price of these options is greater than the average per share closing price during the three month period and their effect would be anti-dilutive.

13. Share-based compensation

During the three months ended March 31, 2020, the Company granted stock options to purchase 0.4 million shares of common stock and 0.5 million restricted and performance stock units under the Emergent BioSolutions Inc. Stock Incentive Plan. 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.

14. Commitments and contingencies

ANDA Litigation - Perrigo 4mg

On September 14, 2018, Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd. (collectively, "Adapt Pharma"), and Opiant Pharmaceuticals, Inc. ("Opiant"), received notice from Perrigo UK FINCO Limited Partnership ("Perrigo"), that Perrigo had filed an Abbreviated New Drug Application ("ANDA"), with the United States Food and Drug Administration seeking regulatory approval to market a generic version of NARCAN®(naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of U.S. Patent Nos. 9,211,253, (the "'253 Patent"), 9,468,747 (the "'747 Patent"), 9,561,177, (the "'177 Patent"), 9,629,965, (the "'965 Patent") and 9,775,838 (the "'838 Patent"). On or about October 25, 2018, Perrigo sent a subsequent notice letter relating to U.S. Patent No. 10,085,937 (the "937 Patent"). Perrigo's notice letters assert that its generic product will not infringe any valid and enforceable claim of these patents.

On October 25, 2018, Emergent BioSolutions' Adapt Pharma subsidiaries and Opiant, (collectively, the "Plaintiffs"), filed a complaint for patent infringement of the '253, '747, '177, '965, and the '838 Patents against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo's ANDA filing with the FDA. Plaintiffs filed a second complaint against Perrigo on December 7, 2018, for the infringement of the '937 Patent. On February 12, 2020, Adapt Pharma and Perrigo entered into a settlement agreement to resolve the ongoing litigation. Under the terms of the settlement, Perrigo has received a non-exclusive license under Adapt Pharma's patents to make, have made and market its generic naloxone hydrochloride nasal spray under its own ANDA. Perrigo's license will be effective as of January 5, 2033 or earlier under certain circumstances including circumstances related to the outcome of the current litigation against Teva (as defined below) or litigation against future ANDA filers. The Perrigo settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission, and entry of an order dismissing the litigation by the U.S. District Court for the District of New Jersey.

ANDA Litigation - Teva 2mg

On or about February 27, 2018, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva Pharmaceuticals Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"), that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 2 mg/spray before the expiration of U.S. Patent No. 9,480,644, (the "'644 Patent"), and U.S. Patent No. 9,707,226, (the "'226 Patent"). Teva's notice letter asserts that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '644 Patent or the '226 Patent, or that the '644 Patent and '226 Patent are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey.

ANDA Litigation - Teva 4mg

On or about September 13, 2016, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4 mg/spray before the expiration of U.S. Patent No. 9,211,253 (the "'253 Patent"). Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received additional notices from Teva relating to the '747, the '177, the '965, the '838, and the '937 Patents. Teva's notice letters assert that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '253, the '747, the '177, the '965, the '838, or the '937 Patent, or that the '253, the '747, the '177, the '965, the '838, and the '937 Patents are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant also filed complaints for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '747, the '177, the '965, and the '838 Patents. All five proceedings have been consolidated. As of the date of this filing, Adapt Pharma Inc., Adapt Pharma Operations Limited, and Opiant, have not filed a complaint related to the '937 Patent. Closing arguments took place on February 26, 2020.

In the complaints described in the paragraphs above, the Plaintiffs seek, among other relief, orders that the effective date of FDA approvals of the Teva ANDA products and the Perrigo ANDA product be a date not earlier than the expiration of the patents listed for each product, equitable relief enjoining Teva and Perrigo from making, using, offering to sell, selling, or importing the products that are the subject of Teva and Perrigo's respective ANDAs, until after the expiration of the patents listed for each product, and monetary relief or other relief as deemed just and proper by the court.

Nalox-1 Pharmaceuticals, a non-practicing entity, filed petitions with the United States Patent and Trademark Office Patent Trial and Appeal Board (the "PTAB") requesting inter parties review ("IPR") of five of the six patents listed in the Orange Book related to NARCAN® Nasal Spray 4mg/spray. In a series of decisions, the PTAB agreed to institute a review of the '253 Patent, the '747 Patent and the '965 Patent but denied review of the '177 Patent and the '838 Patent. Nalox-1 did not request review of the '937 Patent.

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, 2019. 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

We are a global life sciences company focused on providing to civilian and military populations a portfolio of innovative preparedness and response products and solutions that address accidental, deliberate and naturally occurring PHTs.

We are currently focused on the following six distinct PHT categories: CBRNE; EID; travel health; emerging health crises; acute/emergency care; and CDMO. We have a product portfolio of ten products (vaccines, therapeutics, and drug-device combination products) that contribute a substantial portion of our revenue. We also have two product candidates that are procured under special circumstances by certain government agencies, although they are not approved by the FDA or any other health agency. Additionally, we have a development pipeline consisting of a diversified mix of both pre-clinical and clinical stage product candidates (vaccines, therapeutics, devices and combination products). Finally, we have a fully-integrated portfolio of contract development and manufacturing services. We continue to pursue acquiring and developing products and solutions that provide an opportunity to serve both government and commercial (non-government) customers globally. The majority of revenue comes from the following products and product candidates:

Vaccines

- Anthrax Vaccines, including our AV7909 (Anthrax Vaccine Adsorbed with Adjuvant) 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;
- 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;
- Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever; and
- Vaxchora® (Cholera Vaccine, Live, Oral), the only FDA-licensed vaccine for the prevention of cholera.

Devices

- 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;
- 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®, a combination drug-device auto-injector product candidate that contains atropine sulfate and obidoxime chloride. It has not been approved by the FDA or any similar health regulatory body, but is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure.

Therapeutics

- raxibacumab (Anthrax Monoclonal), 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;
- BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)), the only heptavalent antibody therapeutic licensed by the FDA, as well as the governing bodies in Canada, Singapore and Ukraine for the treatment of botulism; and
- VIGIV (Vaccinia Immune Globulin Intravenous (Human)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination.

Contract Development and Manufacturing Services

We compete for CDMO service business with a number of biopharmaceutical product development organizations, contract manufacturers of biopharmaceutical products and university research laboratories. We also compete with in-house research, development and support service departments of other biopharmaceutical companies.

Highlights and Business Accomplishments for 2020

- On January 13, 2020, received agreement from the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) on the company's proposed development plan to use Serum Neutralizing Antibodies (SNA) as surrogate endpoint to predict likely clinical benefit of CHIKV VLP, the company's chikungunya virus virus-like particle (VLP) vaccine candidate, in a Phase 3 safety and immunogenicity study anticipated in late 2020.
- On January 31, 2020, received positive opinion and subsequent approval from EMA of Vaxchora® (Cholera Vaccine, Live, Oral), the company's cholera vaccine, making it the only single-dose oral vaccine indicated for active immunization against disease caused by *Vibrio cholerae* serogroup 01 in adults and children from 6 years of age across all 27 member states of the European Union and the European Economic Area countries.
- On March 10, 2020, signed a development and manufacturing agreement with Novavax, Inc. for an experimental vaccine candidate for COVID-19.
- On March 11, 2020, initiated development of two investigational plasma-derived therapies. COVID-Human Immune Globulin (COVID-HIG) is being developed as a human plasma-derived therapy candidate for potential treatment of COVID-19 in severe hospitalized and high-risk patients, and COVID-Equine Immune Globulin (COVID-EIG) is being developed as an equine plasma-derived therapy candidate for potential treatment of severe disease in humans.
- On March 18, 2020, signed a development and manufacturing agreement with Vaxart, Inc. to produce its experimental oral vaccine candidate for COVID-19.
- On March 31, 2020, signed an agreement with Novavax, Inc. to manufacture NanoFlu™, its seasonal influenza vaccine candidate.
- On April 2, 2020, announced HHS funding valued at $14.5 million to support the development of COVID-Human Immune Globulin (COVID-HIG), which will be included in one of the studies of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, evaluating potential treatments for COVID-19.
- On April 23, 2002, announced an agreement, valued at $135 million, to be U.S. manufacturing partner of Johnson & Johnson for its lead vaccine candidate for COVID-19.

Financial Operations Overview

Revenues

We generate revenues from the sale of our marketed products and product candidates which include vaccines, therapeutics and devices which have been described above. Additionally, revenue is generated from the performance of CDMO services, and our performance of research and development services under contracts and grants. The USG is the largest purchaser of our CBRNE 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. Our opioid overdose reversal product, NARCAN® Nasal Spray and our travel health products, comprising Vivotif and Vaxchora, are sold commercially through wholesalers and distributors, physician-directed or standing order prescriptions at retail pharmacies, as well as to other state and local community healthcare agencies, practitioners and hospitals.

We also generate revenue from the performance of CDMO services for third-parties. Our services include fill/finish activities as well as the production of bulk drug substances on behalf of our customers.

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 have varied, and we expect that they will continue to vary on a quarterly basis.

Critical Accounting Policies and Estimates

During the three months ended March 31, 2020, there have been no significant changes to our critical accounting policies and estimates contained in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC, (see Note 2 to the accompanying condensed consolidated financial statements).

(unaudited, amounts in millions, except share and per share amounts)

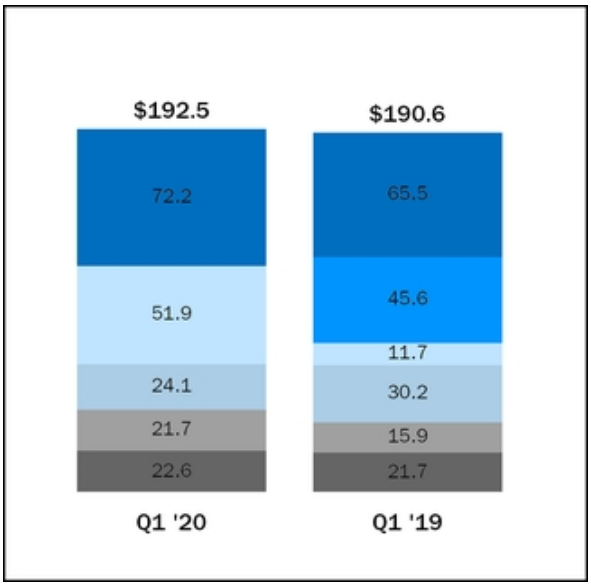
Results of Operations

	Three Months Ended March 31,			
	2020	2019	$ Change	% Change
Product sales net:				
NARCAN Nasal Spray	$ 72.2	$ 65.5	$ 6.7	10%
ACAM2000	—	45.6	(45.6)	(100%)
Anthrax vaccines	51.9	11.7	40.2	NM
Other	24.1	30.2	(6.1)	(20)%
Total product sales, net	148.2	153.0	(4.8)	(3)%
Contract development and manufacturing services	21.7	15.9	5.8	36 %
Contracts and grants	22.6	21.7	0.9	4 %
Total revenues	192.5	190.6	1.9	1 %
Operating expenses:				
Cost of product sales and contract development and manufacturing services	76.9	91.8	(14.9)	(16%)
Research and development	42.7	46.1	(3.4)	(7%)
Selling, general and administrative	69.7	65.4	4.3	7%
Amortization of intangible assets	14.8	14.5	0.3	2%
Total operating expenses	204.1	217.8	(13.7)	(6%)
Loss from operations	(11.6)	(27.2)	15.6	(57%)
Other (expense) income:				
Interest expense	(8.6)	(9.6)	1.0	(10%)
Other expense, net	(1.1)	(1.0)	(0.1)	—%
Total other expense, net	(9.7)	(10.6)	0.9	(8%)
Loss before provision for income taxes	(21.3)	(37.8)	16.5	(44%)
Income tax benefit	8.8	11.8	(3.0)	(25%)
Net loss	$ (12.5)	$ (26.0)	$ 13.5	(52%)

NM - Not meaningful

(unaudited, amounts in millions, except share and per share amounts)

Total Revenues



	NARCAN Nasal Spray		Other product sales
	ACAM2000		Contracts development and manufacturing services
	Anthrax vaccines		Contracts and Grants

Product Sales, net

NARCAN Nasal Spray

The increase in NARCAN Nasal Spray sales for the three months ended March 31, 2020 was primarily due to an increase in sales to the U.S. public interest markets slightly offset by a decrease in sales to the U.S. commercial markets.

ACAM2000

The decrease in ACAM2000 sales for the three months ended March 31, 2020 was due to timing of deliveries to the SNS between the two periods. ACAM2000 product sales are made under a long-term procurement contract. The fluctuations in ACAM2000 revenue are dictated by the timing of orders from the USG.

Anthrax Vaccines

The increase in anthrax vaccine sales for the three months ended March 31, 2020 was primarily due to the transition of SNS deliveries from BioThrax to a consistent cadence of deliveries of AV7909. There were limited sales of BioThrax during the three months ended March 31, 2019 in anticipation of the USG's transition from BioThrax to AV7909. Deliveries of AV7909 began in September of 2019.

Other Product Sales

The decrease in the Company's other product sales during the three months ended March 31, 2020 was primarily due to a decline in sales of raxibacumab, Vaxchora and Vivotif offset by an increase in sales of BAT.

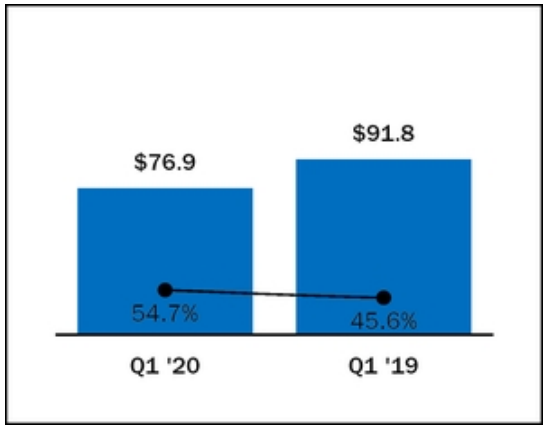
Contract Manufacturing

The increase in contract manufacturing revenue for the three months ended March 31, 2020 is largely due to increased volumes at our Camden and Winnipeg facilities partially offset by decreases at our Bayview facility.

Contracts and Grants

Contracts and grants revenue for the three months ended March 31, 2020 was consistent with the three months ended March 31, 2019.

Cost of Product Sales and Contract Development and Manufacturing Services



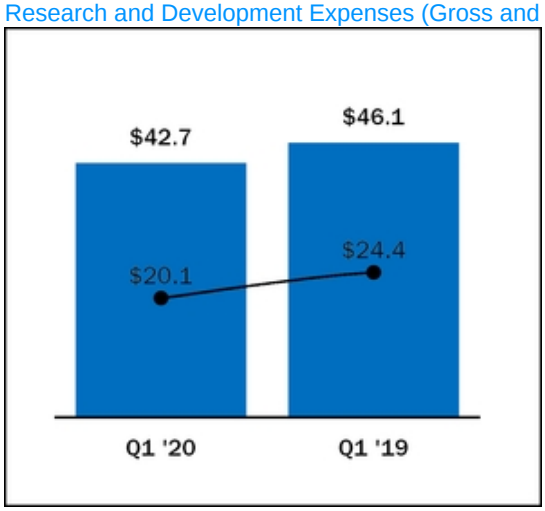
	Cost of Product Sales and Contract Manufacturing
l	Gross profit margin for product sales and contract manufacturing

Cost of product sales and contract development and manufacturing services decreased for the three months ended March 31, 2020 primarily due to decreases in

(unaudited, amounts in millions, except share and per share amounts)

sales of ACAM2000 and raxibacumab which have lower gross margins.

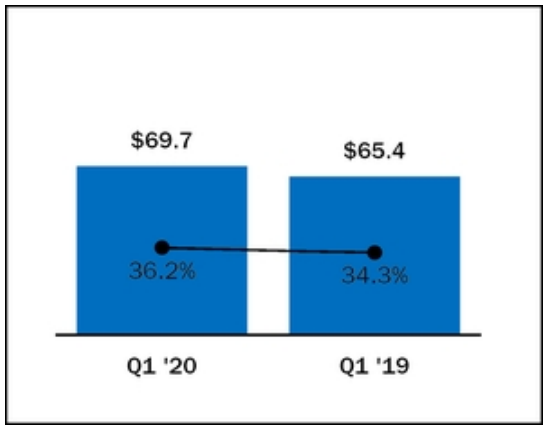
Research and Development Expenses (Gross and Net)



	Research and Development expense
l	Research and Development expense, net of contracts and grants revenue

The decrease in research and development expenses during the three months ended March 31, 2020 is consistent with the decline of contract and grant revenue following completion of developmental activities associated with our AV7909 product candidate.

Selling, General and Administrative Expenses



	Selling, General and Administrative
l	SG&A as a percentage of total revenue

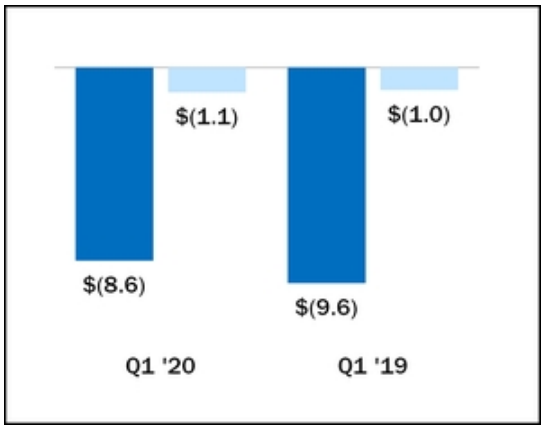
Selling, general and administrative expenses increased for the three months ended March 31, 2020 primarily due to professional services and staffing costs to support the Company's growth.

Amortization of Intangible Assets

Amortization of intangible assets for the three months ended March 31, 2020 was consistent with the three months ended March 31, 2019.

(unaudited, amounts in millions, except share and per share amounts)

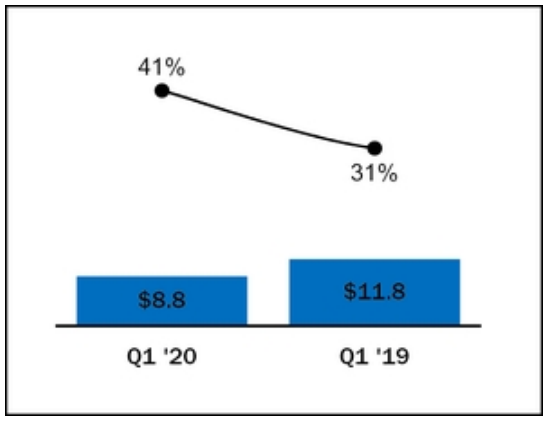
Other Expense, Net



	Interest expense
	Other income (expense)

Total other income (expense), net decreased by $0.9 million for the three months ended March 31, 2020 due primarily to a decrease in interest expense due to a decline in interest rates period over period.

Income Tax Benefit



	Income tax benefit
l	Effective tax rate

During the three months ended March 31, 2020 and 2019, the estimated effective tax rate was 26% and 27%, respectively. The actual effective tax rate includes the effects of discrete tax benefits of $3.2 million and $1.8 million during the three months ended March 31, 2020 and 2019.

(unaudited, amounts in millions, except share and per share amounts)

Liquidity and Capital Resources

Sources of Liquidity

We have historically financed our operating and capital expenditures through cash on hand, cash from operations, debt financing and 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 years through the period ended December 31, 2019. As of March 31, 2020, we had unrestricted cash and cash equivalents of $181.5 million and capacity under our revolving credit facility of $244.8 million. As of March 31, 2020, we believe that we have sufficient liquidity to fund our operations over the next 12 months.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
Net cash provided by (used in):		
Operating activities	$ 57.8	$ 104.8
Investing activities	(24.2)	(21.4)
Financing activities	(20.0)	(58.4)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	0.1	—
Net increase in cash, cash equivalents and restricted cash	$ 13.7	$ 25.0

Operating Activities

Net cash provided by operating activities of $57.8 million for the three months ended March 31, 2020 was due to net income excluding non-cash items of $19.4 million and working capital changes of $38.4 million, made up of decreases in accounts receivable offset by various other items.

Net cash provided by operating activities of $104.8 million for the three months ended March 31, 2019 was due to net losses excluding non-cash items of $1.7 million and working capital changes of $106.5 million.

The cash flows from operating activities decreased during the three months ended March 31, 2020 largely due to a decline in cash collections on accounts receivables and an increase in spend for inventory.

Investing Activities

Net cash used in investing activities was $24.2 million and $21.4 for the three months ended March 31, 2020 and 2019, respectively. The cash used in investing activities increased during the three months ended March 31, 2020 due to an increase in infrastructure and equipment investments.

Financing Activities

Net cash used in financing activities of $20.0 million for the three months ended March 31, 2020 was primarily due to $22.8 million of principal payments on the term loan and credit facility, primarily offset by cash provided by employee share-based compensation activity of $3.5 million.

Net cash used in financing activities of $58.4 million for the three months ended March 31, 2019 was primarily due to net $52.8 million of payments on the term loan and credit facility, primarily offset by cash provided by employee share-based compensation activity of $5.1 million.

The cash flows used in financing activities decreased $38.4 million during the three months ended March 31, 2020 due to a decrease in net payments on the term loan and revolving credit facility of $30.0 million and an increase in cash provided by net employee share-based compensation activity of $8.6 million.

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures, debt service requirements and any future repurchase of our common stock from the following sources:

- existing cash and cash equivalents;
- net proceeds from the sale of our products and contract development and manufacturing 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 and with the development and commercialization of our product candidates. We may seek additional external financing to provide additional financial flexibility. Our future capital requirements will depend on many factors, including (but not limited to):

- the level, timing and cost of product sales and 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 adopt a share repurchase program and repurchase shares of our common stock 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 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.

We are not restricted under the terms of the indenture governing our 2.875% Convertible Senior Notes due 2021 from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing our notes that could have the effect of diminishing our ability to make payments on our indebtedness. However, our Senior Secured Credit Facilities restricts our ability to incur additional indebtedness, including secured indebtedness.

Economic conditions, including market volatility and adverse impacts on financial markets as a result of the COVID-19 pandemic, may make it more difficult to obtain financing on attractive terms, or at all. 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 March 31, 2020 and December 31, 2019 was:

(in millions)			
Total Capacity	Outstanding Letters of Credit	Outstanding Indebtedness on Revolving Credit Facility	Unused Capacity
March 31, 2020			
$ 600.0	2.2	353.0	$ 244.8
December 31, 2019			
$ 600.0	2.2	373.0	$ 224.8

Share Repurchase Program

There were no repurchases of common stock that were made through open market transactions during the three months ended March 31, 2020. The Company previously had a share repurchase program, which expired as of December 31, 2019.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For a discussion of additional risks arising from our operations, see “Item 1A-Risk Factors” in this quarterly report.

Market Risk

We have interest rate and foreign currency market risk. We manage our interest rate risk in part by entering into interest rate swaps to swap a portion of our indebtedness that is based on variable interest rates to a fixed rate. We currently do not hedge 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. We have not used derivative financial instruments for speculation or trading purposes. 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, but any increase in market rates would likely increase the interest expense associated with our debt.

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, 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 instruments such as interest rate swap arrangements. For debt that we have not hedged through our interest rate swap arrangements increases in interest rates could therefore increase the associated interest payments that we are required to make on this debt.

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 March 31, 2020 would increase our interest expense by approximately $4.5 million annually.

Foreign Currency Exchange Rate Risk

We have exposure to foreign currency exchange rate fluctuations worldwide and primarily with respect to the Euro, Canadian dollar, Swiss franc and British pound. We manage our foreign currency exchange rate risk primarily by incurring, to the extent practicable, operating and financing expenses in the local currency in the countries in which we operate.

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 March 31, 2020. 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 March 31, 2020, 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 quarter ended March 31, 2020 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

ANDA Litigation - Perrigo 4mg

On September 14, 2018, Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd., (collectively, Adapt Pharma), and Opiant Pharmaceuticals, Inc. (Opiant), received notice from Perrigo UK FINCO Limited Partnership (Perrigo), that Perrigo had filed an Abbreviated New Drug Application, (ANDA), with the United States Food and Drug Administration, seeking regulatory approval to market a generic version of NARCAN®(naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of U.S. Patent Nos. 9,211,253, (the '253 Patent), 9,468,747 (the '747 Patent), 9,561,177, (the '177 Patent), 9,629,965, (the '965 Patent) and 9,775,838 (the '838 Patent). On or about October 25, 2018, Perrigo sent a subsequent notice letter relating to U.S. Patent No. 10,085,937 (the 937 Patent). Perrigo's notice letters assert that its generic product will not infringe any valid and enforceable claim of these patents.

On October 25, 2018, Emergent BioSolutions' Adapt Pharma subsidiaries and Opiant (collectively, Plaintiffs) filed a complaint for patent infringement of the '253, '747, '177, '965, and the '838 Patents against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo's ANDA filing with the FDA. Plaintiffs filed a second complaint against Perrigo on December 7, 2018, for the infringement of the '937 Patent. On February 12, 2020, Adapt Pharma and Perrigo entered into a settlement agreement to resolve the ongoing litigation. Under the terms of the settlement, Perrigo has received a non-exclusive license under Adapt Pharma's patents to make, have made, and market its generic naloxone hydrochloride nasal spray under its own ANDA. Perrigo's license will be effective as of January 5, 2033 or earlier under certain circumstances including circumstances related to the outcome of the current litigation against Teva (as defined below) or litigation against future ANDA filers. The Perrigo settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission, and entry of an order dismissing the litigation by the U.S. District Court for the District of New Jersey.

ANDA Litigation - Teva 2mg

On or about February 27, 2018, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva Pharmaceuticals Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, Teva) that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 2 mg/spray before the expiration of U.S. Patent No. 9,480,644, (the '644 Patent) and U.S. Patent No. 9,707,226, (the '226 Patent). Teva's notice letter asserts that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '644 Patent or the '226 Patent, or that the '644 Patent and '226 Patent are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey.

ANDA Litigation - Teva 4mg

On or about September 13, 2016, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4 mg/spray before the expiration the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received additional notices from Teva relating to the '747, the '177, the '965, the '838, and the '937 Patents. Teva's notice letters assert that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '253, the '747, the '177, the '965, the '838, or the '937 Patent, or that the '253, the '747, the '177, the '965, the '838, and the '937 Patents are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant also filed complaints for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '747, the '177, the '965, and the '838 Patents. All five proceedings have been consolidated. As of the date of this filing, Adapt Pharma Inc., Adapt Pharma Operations Limited, and Opiant, have not filed a complaint related to the '937 Patent. Closing arguments took place on February 26, 2020.

In the complaints described in the paragraphs above, the Plaintiffs seek, among other relief, orders that the effective date of FDA approvals of the Teva ANDA products and the Perrigo ANDA product be a date not earlier than the expiration of the patents listed for each product, equitable relief enjoining Teva and Perrigo from making, using, offering to sell, selling, or importing the products that are the subject of Teva and Perrigo's respective ANDAs, until after the expiration of the patents listed for each product, and monetary relief or other relief as deemed just and proper by the court.

Nalox-1 Pharmaceuticals, a non-practicing entity, filed petitions with the United States Patent and Trademark Office Patent Trial and Appeal Board ("PTAB") requesting inter parties review (IPR) of five of the six patents listed in the Orange Book related to NARCAN® Nasal Spray 4mg/spray. In a series of decisions, the PTAB agreed to institute a review of the '253 Patent, the '747 Patent and the '965 Patent but denied review of the '177 Patent and the '838 Patent. Nalox-1 did not request review of the '937 Patent.

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors in addition to the other information in this Quarterly Report on Form 10-Q when evaluating our business because these risk factors may have a significant impact on our business, financial condition, operating results or cash flows. If any of the risks described below or in subsequent reports we file with the SEC actually occur, they may materially harm our business, financial condition, operating results or cash flows. Additional risks and uncertainties that we have not yet identified or that we presently consider to be immaterial may also materially harm our business, financial condition, operating results or cash flows. Discussion of these factors is incorporated by reference into and considered an integral part of Part I, Item 2, "Management's Discussion and Analysis of Financial Conditions and Results of Operations."

GLOBAL PANDEMIC RISK

The COVID-19 coronavirus pandemic could adversely impact our business, results of operations and financial performance.

In December 2019, a novel strain of coronavirus, SARS-CoV-2, was reported to have surfaced. Since then, the SARS-CoV-2 virus has been determined to cause the disease COVID-19. COVID-19 has spread worldwide, including in United States, Canada and several European countries. The World Health Organization declared the COVID-19 coronavirus outbreak as a global pandemic on March 11, 2020. The pandemic has caused various governments, including in the United States at Federal and state levels, to impose restrictions on people and businesses, such as quarantines, closures, cancellations and travel restrictions. Depending upon the severity of the COVID-19 pandemic in the United States and elsewhere where we sell our products, we may experience significant disruptions that could severely impact our business and operations, including:

- diversion of government funding away from our primary procured products and product candidates resulting from changes in government priorities;
- limitation of company operations, including reduced productivity resulting from remote work and prolonged office closures as well as a potential adverse impact on our manufacturing operations if a significant number of our manufacturing employees contract the disease;
- potential delays or difficulties in receiving raw and other materials from third party suppliers to manufacture our products and product candidates as the pandemic has resulted in the extended shutdown of certain businesses which may in turn result in disruptions or delays to our supply chain;

- potential delays delivering products to our customers which may lead to decline in sales of our government or commercially procured products that may consequently negatively impact our revenues;
- decline to our revenues from the sales of our vaccine products that target travelers due to the significant reduction to international travel caused by the COVID-19 pandemic;
- potential delays or disruptions in our key clinical trials; and
- limitations in employee resources that would otherwise be focused on our business.

The global pandemic caused by COVID-19 continues to rapidly evolve. The extent to which the COVID-19 pandemic will impact our business, results of operations and our financial condition will depend on future developments, which are highly uncertain and cannot be predicted or reasonably estimated with confidence at this time, such as the duration of the pandemic, travel restrictions and social distancing policies and requirements 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 mitigate and treat the disease.

Due to the widespread impact of the pandemic, it is possible that our consolidated financial results for future fiscal quarters and for 2020 may be negatively impacted, including as a result of increased government regulation and introduction of mitigation and prevention measures. In addition, the COVID-19 pandemic has adversely affected, and is expected to continue to adversely affect the United States and the global economy, possibly resulting in an economic downturn and recession that could impact demand for our products. Such events that are generally outside of our control could have a material adverse impact on our business, operating results and financial conditions.

GOVERNMENT CONTRACTING RISKS

We currently derive a substantial portion of our revenue from USG procurement of AV7909, BioThrax and ACAM2000. If the USG's demand for and/or funding for procurement of AV7909, 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 and BioThrax. As AV7909 is a product development candidate, there is a higher level of risk that we may encounter challenges causing delays or an inability to deliver AV7909 than with BioThrax, 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 our BioThrax and AV7909 sales to 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 these vaccines. If priorities for the SNS change generally or with respect to our anthrax vaccines, funding to procure future doses of BioThrax or AV7909 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 options under our ACAM2000 contract our future business, financial condition, operating results and cash flows could be materially harmed.

Although a pre-EUA submission package related to AV7909 has been submitted to the FDA, we may not receive an EUA and eventual FDA licensure in a timely manner or at all. Delays in our ability to achieve a favorable outcome from the FDA could prevent us from realizing the full potential value of our BARDA contract for the advanced development and procurement of AV7909.

In collaboration with us, the CDC filed with the FDA a pre-EUA submission package related to AV7909, which enables FDA review of data in anticipation of a request for an EUA. This submission triggered BARDA to exercise its first contract option (valued at $261 million) in July 2019 to procure 10 million doses of AV7909 for inclusion into the SNS in support of anthrax preparedness.

Notwithstanding, the FDA may decide that our data are insufficient and require additional pre-clinical, clinical or other studies. If we are unsuccessful in obtaining an EUA and, ultimately, 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. Simultaneous reduction or discontinuation of funding

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 PHT-focused MCMs and is the primary source of funds for the development of most of our product candidates in our development pipeline, most notably our AV7909 product candidate. We anticipate that the USG will also be a principal customer for those MCMs that we successfully develop 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 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. For example, sales of BioThrax to be supplied under our procurement contract with the CDC are subject to the availability of funding, mostly from annual appropriations. These appropriations can be subject to political considerations, changes in priorities due to global pandemics and stringent budgetary constraints.

Additionally, our government-funded development contracts typically give the USG the right, exercisable in its sole discretion, to extend these contracts for successive option periods following a base period of performance. The value of the services to be performed during these option periods may constitute the majority of the total value of the underlying contract. For example, the September 2016 contract award from BARDA for the development and delivery to the SNS of AV7909 for post-exposure prophylaxis of anthrax disease consists of a five-year base period of performance valued at approximately $200 million. The contract award also includes options for the delivery of additional doses of AV7909 to the SNS and options for an additional clinical study and post-marketing commitments, which, if both were to be exercised in full, would increase the total contract value to up to $1.5 billion. 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 procurement contracts with the USG upon the expiration of any of our current product procurement contracts.

The majority of our revenue is substantially dependent upon product procurement contracts with the USG and foreign governments for our PHT products. Upon the expiration of a procurement contract, we may not be able to negotiate a follow-on procurement contract for the particular product for a similar product volume, period of performance, pricing or other terms, or at all. The inability to secure a similar or increased procurement contract could materially affect our revenues and our business, financial condition, operating results and cash flows could be harmed. For example, the BARDA procurement contract for raxibacumab that we acquired in our acquisition of raxibacumab from Human Genome Sciences, Inc. and GlaxoSmithKline LLC (collectively referred to as GSK), expired in November 2019. We intend to negotiate follow-on procurement contracts for most of our PHT products upon the expiration of a related procurement contract, including our procurement contract for raxibacumab, 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 products 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 issued by the government;
- the commitment of substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- 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 pursuant to competitive bidding, the potential that we may incur expenses or delays, and that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in the termination, reduction or modification of the awarded contract.

The USG may choose not to award us future contracts for either the development of our new product candidates or for the procurement of our existing products addressing PHTs 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.

There are a number of 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 business operations. Among the most significant government contracting regulations that affect our business are:

- 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 U.S. Department of Defense (DoD) government contracts;
- the Department of State Acquisition Regulation (DOSAR), 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;
- trade controls, including export and import control laws, International Traffic in Arms Regulations (ITAR), U.S. sanctions programs, and anti-boycott laws and 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 business practices and 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.

The amount we are paid under our fixed price government procurement contracts is 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 HHS and the DoD are generally fixed price contracts. We expect that future procurement contracts we successfully secure with the USG would 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. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of such a contract or cause a loss, which could harm our operating results and materially reduce our net income.

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

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

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including by imposing equitable price adjustments;
- cancel multi-year contracts and related orders, if funds for contract performance for any subsequent year become unavailable;
- 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 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 contracts, both development and procurement, 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 might not be able to prohibit third parties, including our competitors, from accessing such technology or data, including intellectual property, in providing products and services to the USG.

REGULATORY AND COMPLIANCE RISKS

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 authorities in other countries. 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 any of our future drug, biologic, or vaccine products, we will be required to submit a new drug application (NDA) or biologics license application (BLA) to the FDA. Ordinarily, the FDA requires 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.

However, many of our MCM product candidates, for example, may take advantage of a different regulatory approval pathway under the FDA's "Animal Rule." The Animal Rule provides a regulatory pathway for drug and biologic products targeting indications for which human efficacy studies are not feasible or would be unethical. Instead, 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 PHT MCM candidates under the Animal Rule. Even if we are able to proceed pursuant to the Animal Rule, it can be a very long process, and the FDA may decide that our data are insufficient to support approval and require additional preclinical, 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. For example, to the extent feasible and ethical, manufacturers of products approved pursuant to the Animal Rule must conduct post-marketing studies, such as field studies, to verify and describe the product candidate's clinical benefit and to assess its safety when used as indicated. 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 during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review process generally 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 preclinical 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.

There are many other difficulties and uncertainties inherent in pharmaceutical research and development that could significantly delay or otherwise materially delay our ability to develop future product candidates. These include, but are not limited to:

- Conditions imposed by regulators, ethics committees, or IRBs for preclinical testing and clinical trials relating to the scope or design of our clinical trials;
- Restrictions placed upon, or other difficulties with respect to, clinical trials and clinical trial sites, such as clinical holds or suspension or termination of clinical trials due to, among other things, potential safety or ethical concerns or noncompliance with regulatory requirements;
- Delayed or reduced enrollment in clinical trials, or high discontinuation rates;
- Failure by third-party contractors, contract research organizations (CROs), clinical investigators, clinical laboratories, or suppliers to comply with regulatory requirements or meet their contractual obligations in a timely manner;
- Greater than anticipated cost of or time required to complete our clinical trials; and
- Insufficient product supply or inadequate product quality.

Failure to successfully develop future product candidates for any of these or other reasons may materially adversely affect our business, financial condition, operating results and cash flows.

Once an NDA or BLA is submitted, the FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient to support approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

Unapproved and investigational products are also subject to 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 terms of approvals and ongoing regulation of our products may limit how we manufacture and market 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 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 promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our collaborators and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, were we to receive marketing approval for one or more of our product candidates, we would continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

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 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, including the requirement to implement a risk evaluation and mitigation strategy.

Certain of our products are subject to postmarketing requirements (PMRs), which we are required to conduct, and postmarketing 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 for marketing of unapproved products or unapproved uses of approved products. Violations of the Federal Food, Drug, and Cosmetic Act (FDCA) and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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 yield various results, including:

- restrictions on such products, manufacturing partners or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- 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;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

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 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 affect the prices we, or they, 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 in 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, contains the following provisions of potential importance to our business and our product candidates:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of health care fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;

- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board (IPAB), which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within the Centers for Medicare & Medicaid Services (CMS) to test innovative payment and service delivery models.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 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. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which required most Americans to carry a minimal level of health insurance, became effective on January 1, 2019. In addition, Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session. It is possible that such initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

There have been executive actions to challenge or delay implementation of the ACA. Since January 2017, there have been two Executive Orders issued designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, health care providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. In addition, the CMS has proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On May 16, 2019, CMS finalized a rule that amends the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the rule changes allow Medicare Advantage plans to use preauthorization (PA) and step therapy (ST) for six protected classes of drugs and, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs. The first change took effect in January 2020, while the second change will take effect in January 2021. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States, and members of legislative and executive branches have stated that they will address such costs through new legislative and administrative measures. While any proposed measures will require authorization through additional legislation to become effective, there may be new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly 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.

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. 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, currently set at $11,181 to $22,363 per false claim;

- 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. Similar to the U.S. federal Anti-Kickback Statute, 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 the Health Information Technology for Economic and Clinical Health Act (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, which 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), certain payments and transfers of value made to U.S. physicians and teaching hospitals, and ownership or investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and transfers of value provided to U.S. physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; 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 any governmental regulations that apply to us, 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 applicable 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 applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, 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 any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from government funded health care programs. 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.

We are committed to conducting the development, sale and marketing of our applicable products and product candidates and all our activities in compliance with all applicable laws and regulations, but certain applicable laws and regulations may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee or third party acting on our behalf violate these laws without our knowledge, a governmental authority may impose civil and/or criminal sanctions.

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;
- Expenditure of large amounts of cash on legal fees, costs and payment of damages or penalties;
- Limitations on our ability to continue some of our operations;
- Decreased demand for our products; 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 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 to retroactive rebate liability and the potential for 340B program refunds, 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 also would 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 also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to 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. The rules governing the calculation of certain reported prices are highly complex. 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 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 as well as to be purchased by certain federal agencies and certain federal 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 Public Health Service (including the Indian Health Service), and the Coast Guard-at pricing that is capped pursuant to 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. Pursuant to the VHCA, knowing provision of 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.

Under certain circumstances, we might sell unapproved MCMs to government entities. While this is permissible in some cases, the extent to which we may be able to lawfully market 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 AV7909 and Trobigard. In the United States, the Project BioShield Act of 2004 (Project BioShield) permits the Secretary of HHS to contract to purchase MCMs for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 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, may 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 we determine that we believe such activities are permissible, local enforcement authorities could disagree with our conclusion and 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 products, such as a declaration issued under the Public Readiness and Emergency Preparedness Act (the PREP Act) do not cover claims arising under non-U.S. law.

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.

In addition to the requirements and uncertainties related to pre-approval activities discussed previously, 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 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 Canadian marketed products 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 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 intend to sell certain of our products, outside the United States and received market authorization under the mutual recognition procedure to sell BioThrax in France, Italy, the Netherlands, Poland, and the United Kingdom. To market 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 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.

On January 31, 2020, the United Kingdom formally withdrew from the European Union and entered into a transition period through December 31, 2020 pursuant to a Withdrawal Agreement. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of our products or product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing product candidates in the United Kingdom and/or the European Union and could restrict our ability to generate revenue and achieve and sustain profitability. Therefore, there is a risk that we could be subject to an enforcement action if found to be in violation of such laws or regulations.

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 U.S. Foreign Corrupt Practices Act (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.

MANUFACTURING RISKS

Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture AV7909, BioThrax, ACAM2000 or our other products, as well as deliver our contract development and manufacturing services, which would harm our business, financial condition, operating results and cash flows.

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

- equipment malfunctions or failures;
- technology malfunctions;
- cyber-attacks;
- work stoppages or slowdowns;
- protests, including by animal rights activists;
- injunctions;
- damage to or destruction of the facility; and
- product contamination or tampering.

Providers of PHT countermeasures 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, including our manufacturing facilities in Winnipeg, Manitoba, Canada; other Baltimore, Maryland facilities in Camden; facilities in Canton, Massachusetts; Rockville, Maryland, Bern, Switzerland; and

Hattiesburg, Mississippi. We do not have any redundant manufacturing facilities for any of our marketed products. Accordingly, any disruption, damage, or destruction of these facilities could impede our ability to manufacture our marketed products, our product candidates and our ability to produce products for external customers, result in losses and delays, including delay in the performance of our contractual obligations or delay in our clinical trials, any of which could be costly to us and materially harm our business, financial condition, operating results and cash flows.

We may not be able to utilize the full manufacturing capacity of our manufacturing facilities, which could impact our future revenues and materially harm our business, financial condition, operating results and cash flows.

Despite our ongoing efforts to optimize the utilization of our manufacturing infrastructure (including bulk, fill/finish, support, aseptic filling, lyophilization, final packaging), we may not be able to realize full utilization, which could adversely affect our future revenues, financial condition, operating results and cash flows.

Problems may arise during the production of our marketed products and product candidates due to the complexity of the processes involved in their manufacturing and shipment. Significant delays in product manufacturing or development could cause delays in revenues, which would harm our business, financial condition, operating results and cash flows.

Several of our products, including BioThrax and ACAM2000 and many of our current product candidates, including AV7909, are biologics. Manufacturing biologic products, 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. In addition, slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation, contamination including from particulates among other things, filtration, filling, labeling, packaging, storage and shipping, potency and stability issues and other quality control testing, may result in lot failures or manufacturing shut-downs, delays in the release of lots, product recalls, spoilage or regulatory action. Such deviations may require us to revise manufacturing processes or change manufacturers. Additionally, as our equipment ages, it will need to be replaced. Replacement of equipment has the potential to introduce variations in the manufacturing process that may result in lot failures or manufacturing shut-downs, delay in the release of lots, product recalls, spoilage or regulatory action. 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 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.

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

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

Manufacturing delays, lot failures, shipping deviations, spoilage or other loss during shipping 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 potential clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

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 Centers for Disease Control (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 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.

RELIANCE ON THIRD PARTIES

The loss of any of our non-exclusive, sole-source or single source suppliers 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, including key components for NARCAN® Nasal Spray. 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 the complex nature of manufacturing processes. In addition, we may lose a sole-source supplier due to, among other things, the acquisition of such 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 an increase in the price of those materials or components could adversely affect our business, financial condition and results of operations.

Additionally, any failure by us to forecast demand for, or our suppliers to maintain an adequate supply of, the raw material and finished product for producing NARCAN® Nasal Spray could result in an interruption in the supply of NARCAN® Nasal Spray and a decline in sales of the product.

If we are unable to obtain supplies for the manufacture of our products and product candidates in sufficient quantities, at an acceptable cost and in acceptable quality, our ability to manufacture or to develop and commercialize our products and product candidates could be impaired, which could materially harm our revenues, lead to a termination of one or more of our contracts, lead to delays in clinical trials or otherwise materially harm our business.

We depend on certain single-source suppliers for key materials and services necessary for the manufacture of AV7909, BioThrax, ACAM2000, NARCAN Nasal Spray and our other products and 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 BioThrax and AV7909. We also rely on single-source suppliers for the specialty plasma in our hyperimmune

specialty plasma products and certain ingredients for ACAM2000. A disruption in the availability of such materials or services from these suppliers or in the quality of the material provided by such suppliers could require us to qualify and validate alternative suppliers. 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 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-government organizations 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 non-government organizations 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.

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. 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 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, including our acquisitions of Adapt and PaxVax. 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; and
- managing tax costs or inefficiencies associated with integrating operations.

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.

COMPETITIVE AND POLITICAL RISKS

We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.

The development and commercialization of new biopharmaceutical and medical technology products is highly competitive and subject to rapid technological advances. We may face future competition from other companies and governments, universities and other non-profit research organizations in respect to our products, any products that we acquire, our current product candidates and any products we may seek to develop or commercialize in the future. Our competitors may develop products that are safer, more effective, more convenient or less costly than any products that we may develop or market. Our competitors may have greater resources to devote to marketing or selling their products, adapt more quickly to new technologies, scientific advances or patient preferences and needs, initiate or withstand substantial price competition more successfully than we can, or more effectively negotiate 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. Many of our competitors have greater financial, technical and marketing resources than we do. Our competitors may receive patent protection that dominates, blocks or adversely affects our products or product candidates.

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.

Competition for BioThrax, ACAM2000, and our other biological products and product candidates, including AV7909, otherwise referred to as our “Biologic Products,” may be affected by follow-on biologics, or “biosimilars,” in the United States and other jurisdictions. Regulatory and legislative activity in the United States and other countries may make it easier for generic drug manufacturers to manufacture and sell biological drugs similar or identical to our Biologic Products, which might affect the profitability or commercial viability of our Biologic Products. Under the Biologics Price Competition and Innovation Act of 2010, the FDA cannot approve a biosimilar application until the 12-year exclusivity period for the innovator biologic has expired. Regulators in the European Union and in other foreign jurisdictions have already approved biosimilars. The specific regulatory framework for this biosimilar approval path and the extent to which an approved biosimilar would be substituted for the innovator biologic are not yet clear and will depend on many factors. 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.

We expect our NARCAN® Nasal Spray marketed product to face future competition from other treatments.

Our marketed product NARCAN® Nasal Spray faces potentially substantial competition from other treatments, including injectable naloxone, auto-injectors, nasal sprays or improvised nasal spray kits. In addition, other entrants may seek approval to market generic versions of NARCAN® Nasal Spray before the underlying patents expire. For example, in 2016 Teva filed, and in 2018 Perrigo filed, Abbreviated new Drug Applications with the FDA (ANDAs) which sought regulatory approval to market generic versions of NARCAN® Nasal Spray before the expiration of certain underlying patents and in April 2019, Teva received FDA approval to market its generic version of NARCAN® Nasal Spray. Perrigo recently entered into a settlement agreement with us. However, Teva may decide to sell its approved generic product in the market, although we have sued Teva and the litigation has not yet been resolved, so any market launch could subject Teva to the risk of damages for patent infringement.

Additionally, we are aware that other companies are developing other product candidates containing naloxone that, if successful, would compete with NARCAN Nasal Spray and reduce our market share. 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. Any reduction in demand for NARCAN® Nasal Spray in favor of a competing product, or unsuccessful efforts to defend underlying patents from infringement by generic entrants, could lead to a loss of market share and cause reduced revenues, margins and levels of profitability for us, which could adversely affect our business, financial condition, operating results and cash flows.

Political or social factors may delay or impair our ability to market 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 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 PHT countermeasures and thereby limit the demand for our products, which would adversely affect our business, financial condition, operating results and cash flows.

PRODUCT DEVELOPMENT AND COMMERCIALIZATION RISKS

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 effort 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 will depend on many factors, including accomplishing the following in an economical manner:

- successful development, formulation and cGMP scale-up of manufacturing that meets FDA or other foreign regulatory requirements;
- successful program partnering;
- successful completion of clinical or non-clinical development, including toxicology studies and studies in approved animal models;
- 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, whether alone or in collaboration with others;

- successful registration and maintenance of relevant patent and/or other proprietary protection; and
- acceptance of the product by potential government and other customers.

The COVID-19 product candidates we are working on may not be safe or effective and, even if they are, we may not be able to manufacture sufficient quantities to meet demand.

We are developing two product candidates for the possible prophylaxis or treatment of COVID-19 and we are also providing contract development and manufacturing services for the development and/or manufacture of three vaccine product candidates for customers. There can be no assurance that any of these product candidates will be safe or effective. There can be no assurance that any of these product candidates will receive approval or be authorized for emergency use by the FDA or any other health regulatory authority. Even if these product candidates are safe and/or effective and receive approval or authorization by a health regulatory authority, the manufacturing process for these programs are under development and will be complex. As a result, there can be no assurance that we will be able to produce any significant quantity of these products or a timely basis or at all.

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 for the marketing of our product candidates, we and our collaborative partners, where applicable, must conduct preclinical studies and clinical trials to establish proof of concept and demonstrate the safety and efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing.

Preclinical and clinical testing for certain of our product candidates addressing CBRNE threats 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. The Animal Rule permits, in certain limited 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. We have limited experience in the application of these rules to the product candidates that we are developing. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our product candidates in humans.

Under Project BioShield, the Secretary of HHS can contract to purchase MCMs for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the FDA commissioner to authorize the emergency use of medical products that have not yet been approved by the FDA under an EUA. If our product candidates are not selected under this Project BioShield authority, they generally will have to be approved by the FDA through traditional regulatory mechanisms for distribution in the United States.

We may experience unforeseen events or issues during, or as a result of, preclinical 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 of materials 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.

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. 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 research and development, 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 may also prove to be incorrect and could cause us to miss valuable opportunities.

INTELLECTUAL PROPERTY RISKS

If we are unable to protect our proprietary rights, our business, financial condition, operating results, and cash flows could be materially harmed.

Our success will depend, in large part, on our ability to obtain and maintain protection in the United States and other countries for the intellectual property incorporated into or covering our technology, products, and product candidates. Obtaining and maintaining protection of our intellectual property is very costly. The patentability of technology in the biopharmaceutical field generally is highly uncertain and involves complex legal and scientific questions.

We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may inadvertently lapse or be challenged, narrowed, invalidated, or circumvented, and such happenings could limit our ability to stop competitors from marketing similar products or limit the duration of patent protection we may have for our products. In the past, we have abandoned the prosecution and/or maintenance of patent applications related to patent families in the ordinary course of business. In the future we may choose to abandon such prosecution and/or maintenance in a similar fashion. If these patent rights are later determined to be valuable or necessary to our business, our competitive position may be adversely affected. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the United States and in other countries may diminish the value of our intellectual property, narrow the scope of our patent protection, or result in costly defensive measures. In addition, some countries do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our products or product candidates.

Changes to the U.S. patent system under the Leahy-Smith America Invents Act (the America Invents Act), affected the way patent applications are filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter parties review (IPR) post-grant review (PGR) and covered business methods review (CBM). These proceedings are conducted before the Patent Trial and Appeal Board (the PTAB) of the U.S. Patent and Trademark Office. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. In this regard, the IPR process permits any person (except a party who has been litigating the patent for more than a year) to challenge the validity of some patents on the grounds that it was anticipated or made obvious by prior art. As a result, non-practicing entities associated with hedge funds, pharmaceutical companies who may be our competitors and others have challenged certain valuable pharmaceutical U.S. patents based on prior art through the IPR process. A decision in such a proceeding adverse to our interests could result in the loss of valuable patent rights which would have a material adverse effect on our business, financial condition, results of operations and growth prospects. The America Invents Act and any other potential future changes to the U.S. patent system could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The cost of litigation to uphold the validity of patents to prevent or stop infringement or to otherwise protect or enforce our proprietary rights could be substantial and, from time to time, our patents may be subjected to opposition proceedings or validity challenges. Some of our competitors may choose to or be better able to sustain the costs of complex patent litigation. Intellectual property lawsuits are expensive and unpredictable and consume management's time and attention and other resources, even if the outcome is successful. In addition, there is a risk that a court could decide that our patents are not valid, are unenforceable, or are not infringed by a competitor product. There is also a risk that, even if the validity of a patent is upheld, a court could refuse to stop the other party from using the invention(s), including on the grounds that its

activities do not infringe the patent. If any of these events occur, our business, financial condition, operating results and cash flows could be materially and adversely affected.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend intellectual property rights in which we have an interest and, although we may have the right to assume the maintenance and defense of such intellectual property rights if these third parties do not do so, our ability to maintain and defend such intellectual property rights may be compromised by the acts or omissions of these third parties. For example, we license from Opiant Pharmaceuticals, Inc. formulations of naloxone used in our NARCAN® Nasal Spray.

We also will rely on current and future trademarks to establish and maintain recognized brands. If we fail to acquire and protect such trademarks, our ability to market and sell our products, and therefore our business, financial condition, operating results, and cash flows could be materially and adversely affected.

Third parties may choose to file patent infringement claims against us; defending ourselves from such allegations could be costly, time-consuming, distracting to management, and could materially and adversely affect our business, financial condition, operating results, and cash flows.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents and other intellectual property rights of third parties for which we do not hold sufficient licenses or other rights. Additionally, third parties may be successful in obtaining patent protection for technologies that cover development and commercialization activities in which we are already engaged. Third parties may own or control these patents and intellectual property rights in the United States and abroad. These third parties could bring claims against us that could cause us to incur substantial expenses to defend against these claims and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement or other similar suit is brought against us, we could be forced to stop or delay development, manufacturing, or sales of the product or product candidate that is the subject of the suit. Intellectual property litigation in the biopharmaceutical industry is common, and we expect this trend to continue.

As a result of patent infringement or other similar claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations. If, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms, if at all, or if an injunction is granted against us, these could materially harm our business, financial condition, operating results, and cash flows.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license and/or sue us for breach, which could cause us to not be able to market any product that is covered by the license and subject us to damages, which may be material.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

We also rely upon unpatented proprietary technology, processes, and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for all of our current products, our only other intellectual property protection for products, other than trademarks, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes, and unique starting materials. However, 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 be successful in protecting our trade secrets and confidential information.

These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known, including through a potential cyber security breach, or may be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, or if others independently develop our proprietary information or processes, competitors may be able to use this information to develop products that compete

with our products, which could materially and adversely impact our business.

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 U.S. Food, Drug and Cosmetic Act (FDCA), which renders it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process. Generic manufacturers pursuing ANDA approval are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on the innovator's data regarding safety and efficacy. Additionally, generic drug companies generally do not expend significant sums on sales and marketing activities, instead relying on pharmacists or payers to substitute the generic form of a drug for the branded form. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative pharmaceutical or biotechnology companies who have incurred substantial expenses associated with the research and development of the drug product and who must spend significant sums marketing a new drug.

The ANDA procedure includes provisions allowing generic manufacturers to challenge the innovator's patent protection by submitting "Paragraph IV" certifications to the FDA in which the generic manufacturer claims that the innovator's patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product. A patent owner who receives a Paragraph IV certification may choose to sue the generic applicant for patent infringement. If the patent owner files suit within 45 days of receiving notice from an ANDA filer, the patent owner is entitled to receive a 30 month stay on the FDA's ability to give final approval for the generic product that is the subject of the ANDA.

In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge the validity of patents listed in the FDA's Approved Drug Products List with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, on a wide array of innovative therapeutic products. We expect this trend to continue and to affect drug products with even relatively modest revenues.

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.

Further, the 2010 Patient Protection and Affordable Care Act, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA). That Act established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. As of January 15, 2020, the FDA has approved thirty six biosimilar products for use in the United States. No interchangeable biosimilars, have been approved. The FDA has issued several guidance documents outlining approaches for review and approval of biosimilars.

Under the Act, a manufacturer may apply for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

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 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 could have significant adverse consequences for our business, including:

- requiring us to dedicate a substantial portion of any cash flow from operations to payment on our debt, which would reduce the amounts available to fund 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 the risk of such increases through our hedging instruments;
- subjecting us, as under our Senior Secured Credit Facilities, to restrictive covenants that may 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 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.

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

In connection with the acquisition of Adapt, we entered into an amendment and restatement of our 2017 credit agreement to provide for new five-year syndicated Senior Secured Credit Facilities that replaced our existing facility. The Senior Secured Credit Facilities include a $450 million Term Loan and the ability to borrow up to $600 million with a revolving credit facility, of which we had outstanding borrowings of approximately $433 million and $353 million, respectively, as of March 31, 2020. We may also seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing could have significant adverse consequences for our business, including:

- the level, timing and cost of product sales and 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 common stock under any future share repurchase program; and
- the costs of commercialization activities, including product marketing, sales and distribution.

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 debt agreements could result in an event of default under those instruments. 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 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.

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 may be unable to raise capital when needed or on acceptable terms, which would harm our ability to grow our business, and our results of operations and financial condition.

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 2018, 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 8, 2021, 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 August 8, 2021, the existing shelf registration statement will expire, and we will not be able to publicly raise capital or issue debt until a new registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatically effective shelf registration statement at a future date when we may need to raise funds publicly.

If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our Senior Secured Credit Facilities, 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. We are not restricted under the terms of the indenture governing our 2.875% Convertible Senior Notes due 2021 (Senior Convertible Notes) from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that could have the effect of diminishing our ability to make payments on our indebtedness. However, our senior secured credit facilities restrict our ability to incur additional indebtedness, including secured 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 for each of the last five fiscal years, we have not been profitable for every quarter during that time. Our profitability has been substantially dependent on product sales, which historically have fluctuated significantly from quarter to quarter, and we expect that they will continue to fluctuate significantly based primarily on the timing of our fulfillment of orders from the USG. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

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.

OTHER BUSINESS RISKS

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. These declarations expire in 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, certain of our products, namely BioThrax and RSDL, are certified anti-terrorism products covered under the protections of the Support Anti-Terrorism by Fostering Effective Technology Act of 2002 (the SAFETY Act). 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 are entitled to the benefits of the SAFETY Act for BioThrax and RSDL, 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, or if the liability protections under the PREP Act and SAFETY Act are not adequate to cover all claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

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

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

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.

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. 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.

In addition, our systems are potentially vulnerable to data security breaches-whether by employee error, malfeasance or other disruption-which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property or could lead to the public exposure of personal information, including sensitive personal information, of our employees, clinical trial patients, customers and others.

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

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. 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.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

Fuad El-Hibri, executive chairman of our Board of Directors, has significant influence over us through his substantial beneficial ownership of our common stock, including an ability to influence the election of the members of our Board of Directors, or delay or prevent a change of control of us.

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his substantial beneficial ownership of our common stock. As of March 31, 2020, Mr. El-Hibri was the beneficial owner of approximately 11% of our outstanding common stock. As a result, Mr. El-Hibri could exercise substantial influence over all corporate actions requiring board or stockholder approval, including a change of control, or any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions. In addition, Mr. El-Hibri's significant beneficial ownership of our shares could present the potential for a conflict of interest.

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

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

may also prevent or frustrate attempts by our stockholders to replace or remove our management.

These provisions include:

- the classification of our directors;
- limitations on changing the number of directors then in office;
- limitations on the removal of directors;
- limitations on filling vacancies on the board;
- advance notice requirements for stockholder nominations of candidates for election to the Board of Directors and other proposals;
- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue a new series of preferred stock without stockholder approval.

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

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

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

Our Board of Directors may implement a stockholder rights plan without stockholder approval. We previously implemented a stockholder rights plan, which expired on November 14, 2016. Under our prior stockholder rights plan, we issued to each of our stockholders 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 stockholder rights plan was intended to protect stockholders 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 stockholder rights plan, which may have anti-takeover effects, potentially preventing a change in control of us in instances in which some stockholders may believe a change in control is in their best interests. This could cause substantial dilution to a person or group that attempts to acquire us on terms that our Board of Directors does not believe are in our best interests or those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

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

Our stock price has been, and is likely to continue to be, volatile. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this “Risk Factors” section, or for reasons unrelated to our operations, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as industry conditions and general financial, economic and political instability. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through April 27, 2020, our common stock has traded as high as $83.01 per share and as low as $4.17 per share. Due to fears associated with COVID-19, the stock market has recently experienced 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 BioThrax and our other products and product candidates;

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

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

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

A significant portion of our shares may be sold into the market at any time. This could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 6 million shares of our common stock outstanding as of March 31, 2020, have the right to require us to register these shares of common stock under specified circumstances.

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
10.1#†	Modification #No. 4, effective March 3, 2020, to the Award/Contract, effective September 30, 2016, from the BioMedical Advanced Research and Development Authority to Emergent Product Development Gaithersburg Inc. (the BARDA AV7909 Contract).
10.2#†	Modification #No. 5, effective April 10, 2020, to the BARDA AV7909 Contract.
31.1 #	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).
31.2 #	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).
32.1 #	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2 #	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101 #	The following financial information related to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, 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.

† Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

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

Date: April 30, 2020

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

Date: April 30, 2020

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

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P0004	See Block 16C		

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

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. EMERGENT PRODUCT DEVLOPMENT GAITHE 300 PROFESSIONAL DR # 100 GAITHERSBURG MD 208793419	X	9B. DATED *(See Item 11)*
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201600030C
		10B. DATED *(See Item 13)*
CODE 1365869 FACILITY CODE		09/30/2016

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning ____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

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

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* FAR 52.243-2 – Changes - Cost Reimbursement

E. IMPORTANT: Contractor is not, x is required to sign this document and return __2__ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
Tax ID Number: [**]
DUNS Number: [**]
The purpose of this modification is to modify ARTICLES B.5. ADVANCE UNDERSTANDINGS and G.3. KEY PERSONNEL.

Funds Obligated Prior to this Modification: $464,692,203
Funds Obligated with Mod #4: $0
Total Funds Obligated to Date: $464,692,203

Expiration Date: September 29, 2021 (unchanged)
Period of Performance: 09/30/2016 to 09/29/2021

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME OF CONTRACTING OFFICER	
Abigail Jenkins SVP Business Unit Head, Vaccines		CHRISTOPHER SCOTT	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Abigail Jenkins *(Signature of person authorized to sign)*	Mar 2, 2020	BY /s/ Christopher Scott *(Signature of Contracting Officer)*	3/3/20

NSN 7540-01-152-8070 STANDARD FORM 30 (REV. 10-83)
Previous Edition Unusable Prescribed by GSA
FAR (48 CFR) 53.243

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

m. Shipment to the Strategic National Stockpile and Storage

Emergent shall develop a delivery schedule that is in agreement with BARDA. Delivery estimates are dependent on product release. Shipping will be FOB destination.

At least [**] before each scheduled shipment by the Contractor, the Contractor shall provide the following to the Contracting Officer and COR:

i. Packing Slip

ii. Certificate(s) of Analysis

iii. Confirm the number of pallets, vials and doses to be loaded

iv. Diagram of product shipment pallet (how many vials per box, per pallet)

The Contractor will assume responsibility for the cost of shipping and transport of finished product to the SNS for long-term storage once usable product requirements have been met. The USG will assume responsibility for long-term storage of the finished product, and emergency distribution of the finished product. The USG shall incur only the storage costs while the product is held within the USG's control. The product shall be stored in compliance with cGMP at the Contractor's facility until the delivery of finished product to the SNS.

The Contractor shall ensure that vaccine delivery follows cGMPs to maintain the integrity of the product en route. The Contractor shall file the necessary documentation to the FDA/CBER for the safe movement of the product to include any protocol deviations en route.

The Contractor shall be responsible for the secure and segregated storage of held intermediates and the FDP prior to lot release and subsequent arrival at the SNS. The Contractor will agree upon a delivery schedule. [**] advance notice is required prior to shipment to the SNS. However, while the product is in long-term storage with the USG (i.e., in the SNS), the Contractor shall continue to be responsible for all quality control/quality assurance monitoring and subsequent reporting necessary to insure appropriate storage conditions of the product until said product is licensed.

The Contractor, via this contract with the USG, will be expected to comply with a written Quality Agreement (attached) as to the manner in which the product will be stored within the specific USG stockpile facility (ies) that have been identified post contract award. In addition, this Quality Agreement will outline the responsibilities of both the Contractor and the USG (i.e., SNS- Quality Control). These documents shall be drafted and signed by both parties prior to the transport and storage of the product.

BARDA will not accept considerations for stability failures/reduced shelf-life. Any lots deemed non-conforming will be placed in quarantine and must be replaced by Emergent. If there is an indication of trending stability issues then an investigation will need to be opened and deliveries suspended until resolved. **Notwithstanding anything to the contrary herein, until the Contractor receives concurrence by the FDA, the USG may accept any lots produced following Contractor's implementation of new spore dose challenge levels in [**] as part of potency release testing. Should the FDA not concur that the new spore dose challenge levels are acceptable to release and use of the material under either Emergency Use Authorization or licensure, Contractor will be responsible for replacing any such lots with new lots, acceptable to the FDA, at no cost to the USG.**

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

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

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

Name	Position
[**]	[**]
[**]	[**]
[**]	**[**]**
[**]	[**]
[**]	[**]

[**]	**[**]**
[**]	**[**]**

***Bold indicated changes in this modification**

All other terms and conditions of this contract remain unchanged.

End of Modification #4

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

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES
		1 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00005	See Block 16C		

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

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. EMERGENT PRODUCT DEVLOPMENT GAITHE 300 PROFESSIONAL DR # 100 GAITHERSBURG MD 208793419	X	9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED *(See Item 11)*
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201600030C
		10B. DATED *(See Item 13)*
CODE 1365869 FACILITY CODE		09/30/2016

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning ____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

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

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* FAR 43.103(a) (3) Mutual Agreement of the Parties

E. IMPORTANT: Contractor is not, x is required to sign this document and return __1__ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
Tax ID Number: [**]
DUNS Number: [**]
The purpose of this modification is to modify ARTICLES B.3. OPTION PRICES, B.5. ADVANCE UNDERSTANDINGS, F.3 DELIVERIES, G.1 CONTRACTING OFFICER, and G.4. INVOICE SUBMISSION.

Funds Obligated Prior to this Modification: $464,692,203
Funds Obligated with Mod #5: $0
Total Funds Obligated to Date: $464,692,203

Expiration Date: September 29, 2021 (Unchanged)
Period of Performance: 09/30/2016 to 09/29/2021

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME OF CONTRACTING OFFICER
Abigail Jenkins SVP BU HEAD, Vaccines	SABRINA J. MCINTYRE

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Abigail Jenkins *(Signature of person authorized to sign)*	Apr 10, 2020	BY /s/ Sabrina Mcintyre *(Signature of Contracting Officer)*	4/10/20

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

The purpose of this modification is to modify ARTICLES B.3 OPTION PRICES, B.5 ADVANCE UNDERSTANDINGS, F.3 DELIVERIES, G.1 CONTRACTING OFFICER, and G.4. INVOICE SUBMISSION.

ARTICLE B.3. OPTION PRICES are hereby modified as follows:

CLIN	Period of Performance	Supplies/Services	Doses	Price per Dose	Total Cost	**Additional Doses****
CLIN 0004 (Option - Funded)***	[**] - 09/29/21	Additional Surge Capacity (EUA)	[**]	[**]	[**]	**Dose number TBD**

[**].

***CLIN 0004 is funded

****Additional Doses may be delivered to BARDA as consideration under the provision in Article B.5.I. In the event that EBS delivers doses [**] (see Article B.5.I), Emergent will provide a [**]% dose-replacement equivalent of additional doses to the Government. As set forth in Article B.5.l, BARDA may accept [**] if such doses are delivered along with the appropriate number of additional doses ("Additional Doses"). Additional Doses shall be calculated as [**]% of the number of delivered [**].

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

I. Stability

BARDA understands that the stability testing is ongoing to support long-term stability of AV7909. The contractor will continue to perform ICH compliant stability studies on AV7909. While EBS and BARDA believe that a [**] will be achieved, this cannot be confirmed until FDA licensure of the vaccine.

For the agreed upon price, AV7909 will be delivered to the SNS that is [**] from the date of manufacture stamped on the vial label.

- BARDA does agree to a [**] to the [**] limitation to allow delivery of approximately [**] doses of AV7909 that were initially manufactured as PPQ material intended for qualification of a Redundant Fill Site at PAR.
- **For CLIN 0004, BARDA agrees to allow delivery of and may accept doses dated [**] if such doses are delivered along with the appropriate number of additional doses ("Additional Doses"). Additional Doses shall be calculated as [**]% of the number of delivered [**]. EBS shall provide the Additional Doses as consideration for BARDA's acceptance of [**] with a [**] for storage in the Strategic National Stockpile. The Additional Doses will be included with delivery of the [**] at no additional cost to BARDA or the US Government.**

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

Email Addresses: CO - [**]
COR - [**]

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

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

[**]
HHS/OS/ASPR/BARDA
200 C St. SW
O'Neill House Office Building
Washington, DC 20515
[**]

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

g. Invoices shall be delivered electronically to the Contracting Officer (CO), the Contracting Officer's Representative (COR), PSC, and e-Room electronically. Unless otherwise specified by the Contracting Officer, all deliverables, invoices, and reports furnished to the Government under the resultant contract shall be addressed as follows:

[**] Contracting Officer HHS/ASPR/BARDA 200 C Street, S.W. Washington, DC 20024 Email: [**]	**[**]** Contracting Officer Representative HHS/ASPR/BARDA 200 C Street, S.W. Washington, DC 20024 Email: [**]	Email invoices to: PSC_Invoices@psc.hhs.gov e-Room

All other terms and conditions of this contract remain unchanged.

End of Modification #5

EXHIBIT 31.1

CERTIFICATION

I, Robert G. Kramer, Sr., 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: April 30, 2020

/s/ROBERT G. KRAMER, SR.
Robert G. Kramer, Sr.
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Richard S. Lindahl, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: April 30, 2020

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

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert G. Kramer, Sr., 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: April 30, 2020

/s/ROBERT G. KRAMER, SR.
Robert G. Kramer, Sr.
Chief Executive Officer

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended March 31, 2020 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: April 30, 2020

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