UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

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 of Principal Executive Offices)	*(Zip Code)*

(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. x 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). x 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 x	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 x

As of April 26, 2019, the registrant had 51.4 million shares of common stock outstanding.

Emergent BioSolutions Inc.
Index to Form 10-Q

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, 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:

- appropriations for the procurement of BioThrax® (Anthrax Vaccine Adsorbed) and our other products addressing public health threats (PHTs);
- our ability to perform under our contracts with the U.S. government (USG) related to BioThrax, our AV7909 product candidate, and our other public health threat products, including the timing of and specifications relating to deliveries;
- our ability to commence deliveries based on BARDA's procurement of AV7909 (anthrax vaccine adsorbed with CPG 7909 adjuvant) for the Strategic National Stockpile (SNS), to receive Emergency Use Authorization (EUA) and eventual licensure of AV7909 from the U.S. Food and Drug Administration (FDA);
- the availability of funding for our U.S. government grants and contracts;
- our ability to secure follow-on procurement contracts for our PHTs that are under procurement contracts that have expired or will be expiring;
- our ability and the ability of our collaborators to defend underlying patents from infringement by generic naloxone entrants;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- our ability to successfully integrate and realize the benefits of our acquisitions of PaxVax Holding Company Ltd. (PaxVax) and Adapt Pharma Limited (Adapt), both of which were acquired in October 2018;
- our ability to successfully identify and respond to new development contracts with the USG, as well as successfully maintain, through achievement of development milestones, current development contracts with the USG;
- our ability and the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices and other regulatory obligations;
- the results of regulatory inspections;
- the operating and financial restrictions placed on us and our subsidiaries under 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 BioSolutions Inc. brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent BioSolutions Inc. or its subsidiaries in the United States or other countries. All other brands, products, services and feature names or trademarks are the property of their respective owners.

ITEM 1.FINANCIAL STATEMENTS

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

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 137.2	$ 112.2
Restricted cash	0.2	0.2
Accounts receivable, net	121.5	262.5
Inventories	211.0	205.8
Prepaid expenses and other current assets	58.6	40.1
Total current assets	528.5	620.8
Property, plant and equipment, net	513.4	510.2
Intangible assets, net	757.1	761.6
In-process research and development	41.0	50.0
Goodwill	267.7	259.7
Other assets	46.0	27.1
Total assets	$ 2,153.7	$ 2,229.4
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 78.6	$ 80.7
Accrued expenses	49.6	30.7
Contingent consideration, current portion	62.7	5.6
Accrued compensation	36.9	58.2
Long-term indebtedness, current portion	10.1	10.1
Other current liabilities	10.5	15.1
Total current liabilities	248.4	200.4
Contingent consideration	10.0	54.4
Long-term indebtedness	732.4	784.5
Deferred tax liability	66.4	67.5
Deferred revenue, net of current portion	64.7	62.5
Other liabilities	44.3	49.2
Total liabilities	$ 1,166.2	$ 1,218.5
Commitments and contingencies (Notes 8 & 14)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 15.0 shares authorized, no shares issued or outstanding at both 2019 and 2018	—	—
Common stock, $0.001 par value; 200.0 shares authorized, 52.6 shares issued and 51.4 shares outstanding at 2019; 52.4 shares issued and 51.2 shares outstanding at 2018	0.1	0.1
Treasury stock, at cost, 1.2 common shares at both 2019 and 2018	(39.6)	(39.6)
Additional paid-in capital	690.2	688.6
Accumulated other comprehensive loss	(4.5)	(5.5)
Retained earnings	341.3	367.3
Total stockholders' equity	987.5	1,010.9
Total liabilities and stockholders' equity	$ 2,153.7	$ 2,229.4

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

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

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Product sales, net	$ 153.0	$ 75.8
Contract manufacturing	15.9	26.1
Contracts and grants	21.7	15.9
Total revenues	190.6	117.8
Operating expenses:		
Cost of product sales and contract manufacturing	91.8	54.3
Research and development	46.1	29.1
Selling, general and administrative	65.4	40.0
Amortization of intangible assets	14.5	3.9
Total operating expenses	217.8	127.3
Loss from operations	(27.2)	(9.5)
Other income (expense):		
Interest expense	(9.6)	(0.2)
Other income (expense), net	(1.0)	0.3
Total other income (expense), net	(10.6)	0.1
Loss before benefit from income taxes	(37.8)	(9.4)
Income tax benefit	(11.8)	(4.5)
Net loss	$ (26.0)	$ (4.9)
Net loss per common share		
Basic	$ (0.51)	$ (0.10)
Diluted	$ (0.51)	$ (0.10)
Shares used in computing loss per share		
Basic	51.2	49.6
Diluted	51.2	49.6

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

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

	Three Months Ended March 31,	
	2019	2018
Net loss	$ (26.0)	$ (4.9)
Other comprehensive income (loss), net of tax:		
Foreign currency translations, net of tax	1.2	0.4
Unrealized losses on pension benefit obligation	(0.2)	—
Total other comprehensive income, net of tax	1.0	0.4
Comprehensive loss	$ (25.0)	$ (4.5)

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

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

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net Loss	$ (26.0)	$ (4.9)
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Share-based compensation expense	6.8	7.3
Depreciation and amortization	26.6	12.3
Amortization of deferred financing costs	0.7	0.1
Deferred income taxes	(11.4)	(4.5)
Change in fair value of contingent consideration	1.7	1.0
Other	(0.1)	0.1
Changes in operating assets and liabilities:		
Accounts receivable	141.6	21.8
Inventories	(5.2)	(12.4)
Prepaid expenses and other assets	(16.6)	(7.7)
Accounts payable	4.2	3.6
Accrued expenses	1.7	2.2
Accrued compensation	(21.3)	(13.4)
Deferred revenue	2.1	(6.5)
Net cash provided by (used in) operating activities:	104.8	(1.0)
Cash flows from investing activities:		
Purchases of property, plant and equipment and other	(21.4)	(11.6)
Net cash used in investing activities:	(21.4)	(11.6)
Cash flows from financing activities:		
Proceeds from revolving credit facility	30.0	—
Principal payments on revolving credit facility	(80.0)	—
Principal payments on term loan facility	(2.8)	—
Issuances of stock under share-based benefit plans	0.9	4.7
Taxes paid on behalf of employees for equity activity	(6.0)	(5.9)
Contingent consideration payments	(0.5)	(0.8)
Purchase of treasury stock	—	(0.1)
Net cash used in financing activities:	(58.4)	(2.1)
Net increase (decrease) in cash, cash equivalents and restricted cash	25.0	(14.7)
Cash, cash equivalents and restricted cash at beginning of period	112.4	179.3
Cash, cash equivalents and restricted cash at end of period	$ 137.4	$ 164.6

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

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

	$0.001 Par Value Common Stock		Additional Paid-In	Treasury Stock		Accumulated Other Comprehensive	Retained	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	Loss	Earnings	Equity
Three Months Ended March 31, 2019								
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 loss	—	—	—	—	—	—	(26.0)	(26.0)
Other comprehensive income	—	—	—	—	—	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
Three Months Ended March 31, 2018								
Balance at December 31, 2017	50.6	$ 0.1	$ 618.3	(1.2)	$ (39.5)	$ (3.7)	$ 337.1	$ 912.3
Adoption of new revenue accounting standard (ASC 606), net of tax	—	—	—	—	—	—	(32.5)	(32.5)
Balance at January 1, 2018	50.6	0.1	618.3	(1.2)	(39.5)	(3.7)	304.6	879.8
Employee equity plans activity	0.4	—	6.1	—	—	—	—	6.1
Treasury stock	—	—	—	—	(0.1)	—	—	(0.1)
Net loss	—	—	—	—	—	—	(4.9)	(4.9)
Other comprehensive income	—	—	—	—	—	0.4	—	0.4
Balance at March 31, 2018	51.0	$ 0.1	$ 624.4	(1.2)	$ (39.6)	$ (3.3)	$ 299.7	$ 881.3

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

1. Business

Emergent BioSolutions Inc. is a global life sciences company focused on providing specialty products for civilian and military populations that address accidental, deliberate and naturally occurring PHTs.

The Company is focused on innovative preparedness and response products and solutions addressing the following four distinct PHT categories: Chemical, Biological, Radiological, Nuclear and Explosives (CBRNE); emerging infectious diseases (EID); travelers' diseases; and opioids. The U.S. Government (USG) is the Company's largest customer and provides the Company with substantial funding for the development of a number of the Company's product candidates.

The majority of the Company's revenue comes from a product portfolio that includes:

- **Vaccines and Anti-Infectives** - BioThrax® (Anthrax Vaccine Adsorbed), ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), Vaxchora® (Cholera Vaccine, Live, Oral), and Vivotif® (Typhoid Vaccine, Live, Oral Ty21a).
- **Devices** - NARCAN® (naloxone HCl) Nasal Spray for opioid overdose, RSDL® (Reactive Skin Decontamination Lotion Kit), and the Trobigard® (atropine sulfate, obidoxime chloride a nerve agent countermeasure) auto-injector.
- **Antibody Therapeutics** - raxibacumab (Anthrax Monoclonal antibody therapeutic for anthrax), Anthrasil®(Anthrax Immune Globulin Intravenous (Human)), BAT®(Botulism Antitoxin Heptavalent), and VIGIV (Vaccinia Immune Globulin Intravenous (Human) therapeutic) for complications from smallpox vaccinations.

The Company also generates revenue from contract development and manufacturing services including pharmaceutical product process development, manufacturing and filling services for injectable and other sterile products, inclusive of process design, technical transfer, manufacturing validations, laboratory analytical development support, aseptic filling, lyophilization, final packaging and accelerated and ongoing stability studies, as well as manufacturing of vial and pre-filled syringe formats, bulk drug products and finished units of clinical and commercial drugs.

We operate 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 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 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, 2018, 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, 2019. 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, 2019, 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, 2018, as filed with the SEC, except for recently adopted accounting standards.

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 contingent consideration liabilities that are measured at fair value on a recurring basis (Note 8). The Company also records the assets and liabilities of acquitions at fair value (Note 3). As of March 31, 2019 and 2018, the Company had no other significant assets or liabilities that were measured at fair value on a non-recurring basis.

Recently Adopted Accounting Pronouncements

Leases

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) *2016-02*, which increases transparency and comparability among organizations by requiring the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements for both lessees and lessors. The Company adopted the new standard effective January 1, 2019 using the modified retrospective approach. As a result, the Company recorded the transition provisions at the beginning of the period of adoption. Total right of use assets increased $13.4 million, while total operating lease liabilities increased 14.0 million as of January 1, 2019. There was no adjustment to the opening balance of retained earnings as of January 1, 2019. The standard will not materially affect the Company's consolidated net earnings. The Company continues to apply the legacy guidance from the old lease accounting standard, including its disclosure requirements, in the comparative periods presented. The Company did not reassess existing contracts for lease classification or the classification of existing leases or associated costs. The Company will not reflect leases with an initial term of 12 months or less as a right of use asset or liability, but it will recognize those lease payments in the consolidated statements of operations on a straight-line basis over

the lease term. In addition, the Company will account for non-lease components of the arrangement separate from lease components.

SEC Simplification

In August 2018, the SEC issued Final Rule Release No. 33-10532, *Disclosure Update and Simplification*, which makes a number of changes meant to simplify interim disclosures. The new rule requires a presentation of changes in stockholders' equity and noncontrolling interest in the form of a reconciliation, for the current and comparative year-to-date interim periods. The Company adopted the new disclosure requirements in its Form 10-Q for the period ended March 31, 2019 and included these disclosures in the condensed consolidated statements of changes in stockholders equity. The additional elements of this release did not have a material impact on the Company's overall condensed Consolidated Financial Statements.

Tax Effects from Accumulated Other Comprehensive Income

In February 2018, the FASB issued ASU 2018-02, *Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* (ASU 2018-02). ASU 2018-02 provides the option to reclassify certain income tax effects related to the Tax Cuts and Jobs Act passed in December of 2017 between accumulated other comprehensive income and retained earnings and also requires additional disclosures. ASU 2018-02 is effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. There was no impact for the adoption of ASU 2018-02 on the Company's condensed consolidated financial statements.

New Accounting Pronouncements

Financial Instruments - Credit Losses

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 result in the earlier recognition of allowances for losses. The guidance is effective for annual periods beginning after December 15, 2019, including interim periods within those years, but early adoption is permitted. The Company is currently evaluating the effect that the pronouncement will have on the Company's consolidated financial statements.

Goodwill

In January 2017, the FASB issued ASU 2017-04, *Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* (ASU 2017-04). ASU 2017-04 simplifies the subsequent measurement of goodwill and eliminates Step 2 from the goodwill impairment test. ASU 2017-04 is effective for annual and interim goodwill tests beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates on or after January 1, 2017. The Company is currently evaluating the impact that the adoption of this standard will have on its condensed consolidated financial statements.

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

Fair Value Measurements

In August 2018 the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. This new standard modifies certain disclosure requirements on fair value measurements. This new standard will be effective for the Company on January 1, 2020. The Company does not expect that the adoption of this new standard will have a material impact on the Company's disclosures.

Compensation - Retirement Benefits - Defined Benefit Plans

In August 2018, the FASB issued ASU 2018-14. ASU 2018-14 modifies the disclosure requirements for defined benefit pension plans and other postretirement 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.

There are no other recently issued accounting pronouncements that are expected to have a material impact on the Company's financial position, results of operations or cash flows.

3. Acquisitions

Adapt

On October 15, 2018, the Company acquired Adapt, a company focused on developing new treatment options and commercializing products addressing opioid overdose and addiction. Adapt's NARCAN® (naloxone HCl) Nasal Spray marketed product is 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. This acquisition includes approximately 50 employees, located in the U.S., Canada, and Ireland, including those responsible for supply chain management, research and development, government affairs, and commercial operations. The products and product candidates within Adapt's portfolio are consistent with the Company's mission and expands the Company's core business of addressing public health threats.

Under the acquisition method of accounting, the assets and liabilities of Adapt have been recorded as of October 15, 2018, the acquisition date, at their respective fair values, and combined with those of the Company. As the Company continues to finalize the fair value of assets acquired and liabilities assumed, purchase price adjustments have been recorded and additional purchase price adjustments may be recorded during the measurement period. The Company reflects measurement period adjustments in the period in which the adjustments occur. The adjustments for the three months ended March 31, 2019 resulted from the receipt of additional financial information associated with certain acquired contract assets and the value of associated contingent purchase consideration. These adjustments did not impact the Company's statements of operations. As of March 31, 2019, certain fair value estimates relating to intangible assets (including acquired in-process research and development (IPR&D)) acquired and income taxes are subject to further adjustment.

The total purchase price, revised for adjustments is summarized below:

	October 15, 2018
Cash	$ 581.5
Equity	37.7
Fair value of contingent purchase consideration	48.0
Preliminary purchase consideration	667.2
Adjustments	1.5
Updated purchase consideration	$ 668.7

The Company issued 733,309 shares of common stock at $60.44 per share, the closing price of Emergent's common stock on October 15, 2018, with a total value of $44.3 million. The $44.3 million value of the common shares issued has been adjusted to a fair value of $37.7 million considering a discount for lack of marketability due to a two-year lock-up period beginning on October 15, 2018. The remaining contingent consideration payable for the acquisition consists of up to $100 million in cash based on the achievement of certain sales milestones through 2022, which the Company has determined had a fair value of $48.0 million as of March 31, 2019 and for the payment of additional consideration based on the collectibility of identified acquired contract assets. The fair value of the contingent purchase consideration is based on management's assessment of the potential future realization of the contingent purchase consideration

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

payments. This assessment is based on inputs that have no observable market (Level 3). The obligation is measured using a discounted cash flow model.

The table below summarizes the preliminary allocation of the purchase price based upon estimated fair values of assets acquired and liabilities assumed at October 15, 2018 updated for measurement period adjustments recorded through March 31, 2019.

	October 15, 2018	Measurement Period Adjustments	Updated October 15, 2018
Estimated fair value of tangible assets acquired and liabilities assumed:			
Cash	$ 17.7	$ —	$ 17.7
Accounts receivable	21.3	—	21.3
Inventory	41.4	—	41.4
Prepaid expenses and other assets	7.8	3.0	10.8
Accounts payable	(32.2)	—	(32.2)
Accrued expenses and other liabilities	(50.4)	—	(50.4)
Deferred tax liability, net	(62.4)	(0.5)	(62.9)
Total estimated fair value of tangible assets acquired and liabilities assumed	(56.8)	2.5	(54.3)
Acquired in-process research and development	41.0	—	41.0
Acquired intangible assets	534.0	—	534.0
Goodwill	149.0	(1.0)	148.0
Total purchase price	$ 667.2	$ 1.5	$ 668.7

The Company determined the estimated fair value of the intangible asset using the income approach. The preliminary estimated fair value of the intangible asset acquired for Adapt's marketed product NARCAN® Nasal Spray is valued at $534.0 million. The Company has determined the useful life of the NARCAN® Nasal Spray intangible asset to be 15 years. The Company estimated the fair value of the NARCAN® Nasal Spray intangible asset using the income approach which is based on the present value of future cash flows with a present value discount rate of 10.5%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of Adapt. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value these intangible assets. The projected cash flows from the NARCAN® Nasal Spray intangible asset were based on key assumptions including: estimates of revenues and operating profits, and risks related to the viability of and potential alternative treatments in any future target markets. The fair value measurements are based on significant unobservable inputs that are developed by the Company using estimates and assumptions of the respective market and market penetration of the acquired company's products.

The intangible asset associated with the IPR&D acquired from Adapt is related to a product candidate. Management determined that the estimated acquisition-date fair value of intangible assets related to IPR&D was $41.0 million. The estimated fair value was determined using the income approach, which discounts expected future cash flows to present value. The Company estimated the fair value using a present value discount rate of 11.0%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of Adapt and IPR&D assets at a similar stage of development as the product candidate. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value the IPR&D. The projected cash flows for the product candidate were based on key assumptions including: estimates of revenues and operating profits, the stage of development of pipeline programs on the acquisition date; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate, such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential for alternative treatments in any future target markets. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts (see Note 7).

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

The Company determined the fair value of inventory using the comparative sales method, which estimates the expected sales price reduced for all costs expected to be incurred to complete/dispose of the inventory with a profit on those costs.

The Company has recorded $148.0 million in goodwill related to the Adapt acquisition, which is calculated as the purchase price paid in excess of the fair value of the tangible and intangible assets acquired representing the future economic benefits the Company expects to receive as a result of the acquisition. The goodwill created from the Adapt acquisition is associated with early stage pipeline products. Substantially all of the goodwill generated from the Adapt acquisition is not expected to be deductible for tax purposes due to the legal structure of the transaction.

PaxVax

On October 4, 2018, the Company completed the acquisition of PaxVax, a company focused on developing, manufacturing, and commercializing specialty vaccines that protect against existing and emerging infectious diseases. This acquisition includes Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever, Vaxchora® (Cholera Vaccine, Live, Oral), the only FDA-licensed vaccine for the prevention of cholera, and clinical-stage vaccine candidates targeting chikungunya and other emerging infectious diseases, European-based current good manufacturing practices (cGMP) biologics manufacturing facilities, and approximately 250 employees including those in research and development, manufacturing, and commercial operations with a specialty vaccines salesforce in the U.S. and in select European countries. The products and product candidates within PaxVax's portfolio are consistent with the Company's mission and will expand the Company's core business of addressing PHTs. In addition, the acquisition expands the Company's manufacturing infrastructure and related capabilities.

The Company paid cash consideration of $273.1 million for PaxVax. As of the date of this filing, the accounting for the PaxVax acquisition is preliminary due to the Company's need to gather data to assess the fair value of property, plant and equipment, intangible assets and accounting for taxes. The table below summarizes the preliminary allocation of the purchase price based upon estimated fair values of assets acquired and liabilities assumed at October 4, 2018 updated for measurement period adjustments recorded through March 31, 2019.

	October 4, 2018	Measurement Period Adjustments	Updated October 4, 2018
Estimated fair value of tangible assets acquired and liabilities assumed:			
Cash	$ 9.0	$ —	$ 9.0
Accounts receivable	4.1	—	4.1
Inventory	19.7	—	19.7
Prepaid expenses and other assets	12.2	—	12.2
Property, plant and equipment	57.8	—	57.8
Deferred tax assets	3.8	—	3.8
Accounts payable	(3.5)	—	(3.5)
Accrued expenses and other liabilities	(33.6)	—	(33.6)
Total estimated fair value of tangible assets acquired and liabilities assumed	69.5	—	69.5
Acquired in-process research and development	9.0	(9.0)	—
Acquired intangible assets	133.0	—	133.0
Goodwill	61.6	9.0	70.6
Total purchase price	$ 273.1	$ —	$ 273.1

The preliminary estimated fair value of the intangible assets acquired for PaxVax's marketed products is a total of $133.0 million. The Company determined the estimated fair value of the intangible assets using the income approach, which is based on the present value of future cash flows. The fair value measurements are based on significant unobservable inputs that are developed by the Company using estimates and assumptions of the respective market and market penetration of the acquired Company's products. The Company has determined that the weighted average useful lives of the intangible assets to be 19 years. The Company estimated the fair value of the Vivotif and Vaxchora intangible

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

assets using a present value discount rate of 14.5% and 15.0%, respectively, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of PaxVax. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value these intangible assets. The projected cash flows from these intangible assets were based on key assumptions, including: estimates of revenues and operating profits, and risks related to the viability of and potential alternative treatments in any future target markets.

The intangible asset associated with the IPR&D acquired from PaxVax is related to a product candidate. The Company has adjusted the provisional amounts recognized at the acquisition date to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the measurement of the amounts recognized as of that date. The Company estimates the fair value based on the income approach.

The Company determined the fair value of the inventory using the comparative sales method, which estimates the expected sales price reduced for all costs expected to be incurred to complete/dispose of the inventory with a profit on those costs.

The Company determined the fair value of the property, plant and equipment utilizing both the cost approach and the sales comparison approach. The cost approach is determined by establishing replacement cost of the asset and then subtracting any value that has been lost due to economic obsolescence, functional obsolescence, or physical deterioration. The sales comparison approach determines an asset is equal to the market price of an asset of comparable features such as design, location, size, construction, materials, use, capacity, specification, operational characteristics and other features or descriptions.

The Company recorded approximately $70.6 million in goodwill related to the PaxVax acquisition, calculated as the purchase price paid in the acquisition that was in excess of the fair value of the tangible and intangible assets acquired representing the future economic benefits the Company expects to receive as a result of the acquisition. The goodwill created from the PaxVax acquisition is associated with early stage pipeline products along with potential contract manufacturing services. The majority of the goodwill generated from the PaxVax acquisition is expected to be deductible for tax purposes based upon the structure used in the acquisition.

Impact of Business Acquisitions

The operations of each of the two business acquisitions discussed above were included in the consolidated financial statements as of each of their respective acquisition dates. The following table presents their revenue and earnings as reported within the consolidated financial statements.

	March 31, 2019
Revenue	$ 74.9
Operating loss	(3.8)

4. Inventories

The components of inventory are as follows:

	March 31, 2019	December 31, 2018
Raw materials and supplies	$ 57.3	$ 51.8
Work-in-process	112.7	103.2
Finished goods	41.0	50.8
Total inventories	$ 211.0	$ 205.8

5. Property, plant and equipment

Property, plant and equipment consisted of the following:

	March 31, 2019	December 31, 2018
Land and improvements	$ 44.3	$ 44.6
Buildings, building improvements and leasehold improvements	223.4	216.2
Furniture and equipment	316.8	293.9
Software	55.5	55.2
Construction-in-progress	57.2	71.8
Property, plant and equipment, gross	697.2	681.7
Less: Accumulated depreciation and amortization	(183.8)	(171.5)
Total property, plant and equipment, net	$ 513.4	$ 510.2

In the table presented above, construction-in-progress includes costs related to construction and equipment purchases.

6. Lease liabilities

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 operating lease right-of-use (ROU) reflected as a component of other current liabilities and other liabilities in our condensed consolidated balance sheets.

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:

	March 31, 2019
Operating lease cost:	
Amortization of right-of-use assets	$ 0.6
Interest on lease liabilities	0.1
Total operating lease cost	$ 0.7

Supplemental balance sheet information related to leases was as follows:

(In millions, except lease term and discount rate)	March 31, 2019
Operating lease right-of-use assets	$ 12.9
Other current liabilities	2.0
Operating lease liabilities	11.6
Total operating lease liabilities	$ 13.6
Operating leases:	
Weighted Average Remaining Lease Term	9.3
Weighted Average Discount Rate	4.27%

7. Intangible assets

The Company's intangible assets consist of CBRNE, travelers' and opioid products acquired via business combinations or asset acquisitions. The following table summarizes the carrying amount of the Company's intangible assets and goodwill, net of accumulated amortization:

	March 31, 2019						
	Estimated Life (years)	Cost	Measurement Period	Additions	Gross Total	Accumulated Amortization	Net

		Adjustment					
Intangible assets, net	5-22	$ 818.4	—	$ 10.0	$ 828.4	$ (71.3)	$ 757.1
IPR&D	indefinite	50.0	(9.0)	—	41.0	—	41.0
Goodwill	indefinite	259.7	8.0	—	267.7	—	267.7

		December 31, 2018					
	Estimated Life (years)	Cost	Measurement Period Adjustment	Additions	Gross Total	Accumulated Amortization	Net
Intangible assets, net	5-22	$ 151.4	—	667.0	$ 818.4	$ (56.8)	$ 761.6
IPR&D	indefinite	50.0	—	—	50.0	—	50.0
Goodwill	indefinite	49.1	—	210.6	259.7	—	259.7

During the three months ended March 31, 2019 and 2018, the Company recorded amortization expense for intangible assets of $14.5 million and $3.9 million, respectively. As of March 31, 2019, the weighted average amortization period remaining for intangible assets was 14.3 **years. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts.**

8. 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 if future events occur or conditions are met. These liabilities 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 and achieving regulatory milestones, which are inputs that have no observable market (Level 3). The Company also has contingent consideration associated with its asset acquisitions. These liabilities are accrued when milestones have been achieved. The following table is a reconciliation of the beginning and ending balance of contingent considerations and is based on level 3 significant unobservable inputs for the three months ended March 31, 2019.

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

Balance at December 31, 2018	$ 60.0
Milestone achievement - asset acquisition	10.0
Measurement period adjustment	1.5
Change in fair value	1.7
Settlements	(0.5)
Balance at March 31, 2019	$ 72.7

During the three months ended March 31, 2019, a contingent milestone was achieved related to the Company's acquisition of raxibacumab in October 2017. The acquisition of raxibacumab was accounted for as an asset acquisition and therefore the achievement of the $10.0 million milestone resulted in an increase to the contingent consideration liability with a corresponding increase in intangible assets.

9. 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, 2019			Three Months Ended March 31, 2018		
	U.S Government	Non-U.S. Government	Total	U.S Government	Non-U.S. Government	Total
Product sales	$ 73.3	$ 79.7	$ 153.0	$ 66.0	$ 9.8	$ 75.8
Contract manufacturing	—	15.9	15.9	—	26.1	26.1
Contracts and grants	20.4	1.3	21.7	14.8	1.1	15.9
Total revenues	$ 93.7	$ 96.9	$ 190.6	$ 80.8	$ 37.0	$ 117.8

Contract liabilities

When performance obligations are not transferred to a customer at the end of a reporting period, the amount allocated to those performance obligations is reflected as deferred revenue 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 deferred revenue contract liability balances:

December 31, 2018	$ 73.1
Deferral of revenue	4.9
Revenue recognized	(2.8)
March 31, 2019	$ 75.2

Transaction price allocated to remaining performance obligations

As of March 31, 2019, the Company had expected future revenues associated with performance obligations that have not been satisfied of approximately $510.8 million. 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 government 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 (which are not performance obligations as of March 31, 2019).

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, 2019 and December 31, 2018, the Company had contract assets associated with deferred costs of $1.3 million and $1.2 million, respectively, which is included in prepaid expenses and other current assets on the Company's consolidated balance sheets.

Accounts receivable

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

	March 31, 2019	December 31, 2018
Billed, net	$ 89.6	$ 234.0
Unbilled	31.9	28.5
Total, net	$ 121.5	$ 262.5

As of March 31, 2019 and December 31, 2018, allowance for doubtful accounts were de minimis.

10. Income taxes

The estimated effective annual tax rate for the Company, which excludes discrete adjustments, was 27% and 26% for the three months ended March 31, 2019 and 2018, respectively. The increase in the estimated effective annual tax rate is primarily due to the impact of the acquisitions of Adapt and PaxVax on state taxes and changes in fair value of the Apapt contingent consideration which is non-deductible. For the three months ended March 31, 2019 and 2018, the Company recorded a discrete tax benefit of $1.8 million and $2.3 million, respectively, primarily associated with equity awards activity during the quarters.

11. Earnings per share

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

	Three Months Ended March 31,	
(in millions, except share and per share data)	2019	2018
Numerator:		
Net loss	$ (26.0)	$ (4.9)
Denominator:		
Weighted-average number of shares—basic	51.2	49.6
Dilutive securities—equity awards	—	—
Weighted-average number of shares—diluted	51.2	49.6
Net loss per share - basic	$ (0.51)	$ (0.10)
Net loss per share - diluted	$ (0.51)	$ (0.10)

For the three months ended March 31, 2019 and 2018, basic earnings per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period.

For the three months ended March 31, 2019 and 2018, diluted earnings 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. No adjustment for the potential dilutive effect of dilutive securities is reported as the effect would have been anti-dilutive for the three months ended March 31, 2019 and 2018 due to the Company's net loss. For the three months ended March 31, 2019 and 2018, approximately 3.1 million and 3.2 million, respectively, of equity awards were excluded from the calculation of diluted earnings per share.

12. Equity

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

During the three months ended March 31, 2019, the Company granted stock options to purchase 0.3 million shares of common stock and 0.3 million restricted stock units under the Emergent BioSolutions Inc. Stock Incentive Plan (the Plan). The grants vest over three equal annual installments beginning on the day prior to the anniversary of the grant date.

13. Defined benefit plan

The Company sponsors a defined benefit pension plan covering eligible employees in Switzerland (the Swiss Plan). Under the Swiss Plan, the Company and certain of its employees with annual earnings in excess of government determined amounts are required to make contributions into a fund managed by an independent investment fiduciary. Employer contributions must be in an amount at least equal to the employee's contribution. The Swiss Plan assets are comprised of an insurance contract that has a fair value consistent with its contract value based on the practicability exception using level 3 inputs. The entire liability is listed as non-current, because plan assets are greater than the expected benefit payments over the next year. The Company recognized pension expense related to the Swiss Plan of $$0.3 million, reflected as a component of selling, general and administrative for the three months ended March 31, 2019.

The measurement date used for the Swiss Plan is December 31, annually. The expense components of the Swiss Plan consisted of the following:

	Three Months Ended March 31, 2019
Net service cost	$ 0.3
Expected return on plan assets, net of expenses	(0.1)
Total	$ 0.2

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 FDA, 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. As a result of timely filing the first lawsuit in accordance with the Hatch-Waxman Act, a 30-month stay of approval will be imposed by the FDA on Perrigo's ANDA, which is expected to remain in effect until March 2021 absent an earlier judgment, unfavorable to the Plaintiffs, by the Court.

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 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.

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.

Shareholder Class Action Lawsuit filed July 19, 2016

On July 19, 2016, Plaintiff William Sponn (Sponn), filed a putative class action complaint in the United States District Court for the District of Maryland on behalf of purchasers of the Company's common stock between January 11, 2016 and June 21, 2016, inclusive (the Class Period), seeking to pursue remedies under the Exchange Act against the Company and certain of its senior officers and directors (collectively, the Defendants). The complaint alleged, among other things, that the Defendants made materially false and misleading statements about the government's demand for BioThrax and expectations that the Company's five-year exclusive procurement contract with the U.S. Department of Health and Human Services (HHS) would be renewed, and omitted certain material facts. Sponn sought unspecified damages, including legal costs. On October 25, 2016, the court added City of Cape Coral Municipal Firefighters' Retirement Plan and City of Sunrise Police Officers' Retirement Plan as plaintiffs and appointed them Lead Plaintiffs and Robbins Geller Rudman & Dowd LLP as Lead Counsel. On December 27, 2016, the Plaintiffs filed an amended complaint that cited the same class period, named the same defendants and made similar allegations to the original complaint. The Defendants filed a Motion to Dismiss on February 27, 2017. The Plaintiffs filed an opposition brief on April 28, 2017. The Defendants' Motion to Dismiss was heard and denied on July 6, 2017. The Defendants filed an answer on July 28, 2017. The parties then engaged in the discovery process. The Plaintiffs filed an amended motion for class certification and appointment of Lead Plaintiffs, Sponn, and Geoffrey L. Flagstad (Flagstad) as Class Representatives on December 20, 2017. A hearing on that motion was heard on May 2, 2018. On June 8, 2018 the Court granted class certification with a shortened class period, from May 5, 2016 to June 21, 2016. In that same order, the court appointed Flagstad as Class Representative and Robbins Geller Rudman & Dowd LLP as Class Counsel. The Defendants have denied, and continue to deny, any and all allegations of fault, liability, wrongdoing, or damages. However, recognizing the risk, time, and expense of litigating any case to trial, on August 27, 2018, the Defendants reached an agreement in principle with Plaintiffs to settle all of the related claims of any individual plaintiff that purchased or acquired Company stock from January 11, 2016 to June 21, 2016, for $6.5 million, an amount that was paid by the Company's insurance carrier. The settlement required no payment by any of the Defendants. The Defendants continue to deny any and all liability. The parties executed the settlement agreement on October 16, 2018 and filed the agreement with the court on October 17, 2018. The court granted preliminary approval of the settlement on October 18, 2018, issued an amended preliminary approval of the settlement on October 25, 2018, and scheduled a hearing regarding final approval for January 22, 2019. At the time of the final approval hearing on January 22, 2019, there were no objections to the settlement, but there were two shareholders who had submitted opt-outs so that they could be excluded from the settlement. On January 25, 2019, the court issued an order and final judgment approving the settlement. The time to file a notice of appeal has passed. Defendants continue to believe that the allegations in the complaint are without merit.

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

15. Supplemental Information

The following table provides a reconciliation of cash, cash equivalents and restricted cash:

	March 31, 2019	December 31, 2018
Cash and cash equivalents	$ 137.2	$ 112.2
Restricted cash	0.2	0.2
Total cash, cash equivalents and restricted cash	$ 137.4	$ 112.4

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this quarterly report on Form 10-Q. 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.

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 focused on the following four distinct PHT categories: CBRNE; EID; travelers' diseases; and opioids. We have a product portfolio of eleven products (vaccines, antibody therapeutics, and drug-device combination products) that generate a majority of our revenue. We also have a development pipeline consisting of a diversified mix of both pre-clinical and clinical stage product candidates (vaccines, antibody therapeutics, and drug-device 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.

Our product portfolio includes:

Vaccines and Anti-Infectives

- **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 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® (atropine sulfate, obidoxime chloride), an auto-injector device designed for intramuscular self-injection of atropine sulfate and obidoxime chloride, as a nerve agent countermeasure. This product is not currently approved or cleared by the FDA or any similar regulatory body, and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.**

Antibody 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.

Highlights and Business Accomplishments for 2019

- On April 16, 2019, we announced results from an interim analysis of our Phase 2 clinical study evaluating the safety and immunogenicity of the Company's chikungunya virus virus-like particle vaccine candidate across a series of dosing regimens. The interim analysis has shown that with a single dose administered, up to 98% of study participants produced a neutralizing antibody response against the chikungunya virus by day 7. Further, the immune response was shown to be persistent through the six-month visit, including in the one-dose regimen.
- On March 19, 2019, we announced the initiation of a Phase 3 trial to evaluate the lot consistency, immunogenicity, and safety of AV7909 (anthrax vaccine adsorbed with CPG 7909 adjuvant) following a two-dose schedule administered intramuscularly in healthy adults. AV7909 is being developed for post-exposure prophylaxis of disease resulting from suspected or confirmed Bacillus anthracis exposure.
- On February 28, 2019, we announced that we have signed an indefinite-delivery, indefinite-quantity contract with the U.S. Department of State to establish a long-term, reliable, and stable supply chain for medical countermeasures that address the treatment prosed by chemical warfare agents. The contract is comprised of a five-year base period of performance along with five one-year option periods with a total contract value of a minimum of approximately $7 million to a maximum of $100 million over the contract's period of performance. We will be supplying two of our current medical countermeasures addressing chemical threats; Trobigard® auto-injector and RSDL®kit.

Financial Operations Overview

Revenues

We generate revenues from the sale of our eleven marketed products, the performance of contract development and manufacturing services, and our performance of research and development services under contracts and grants that we receive from the USG and others. The USG is the largest purchaser of our CBRNE products and primarily purchases our products for the U.S. Strategic National Stockpile (SNS), a national repository of medical countermeasures including critical antibiotics, vaccines, chemical antidotes, antitoxins, and other critical medical supplies. The USG primarily purchases our products under long-term firm fixed price procurement contracts. The majority of our historical product sales were derived from BioThrax purchases by the USG.

Our opioid overdose treatment, NARCAN® Nasal Spray, is sold commercially through physician-directed or standing order prescriptions at retail pharmacies, as well as to state health departments, local law enforcement agencies, community-based organizations, substance abuse centers, and federal agencies. Our travelers' disease products, comprising Vivotif and Vaxchora, are sold to wholesalers and distributors, as well as directly to healthcare practitioners. We sell Vivotif and Vaxchora to private travel clinics, retail pharmacies and integrated hospital networks.

We also generate revenue from the performance of contract development and manufacturing 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 related to programs addressing certain CBRNE threats and emerging infectious disease.

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, 2019, 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, 2018, as filed with the SEC, except for the adoption of the new lease standard (see Note 2 to the accompanying condensed consolidated financial statements).

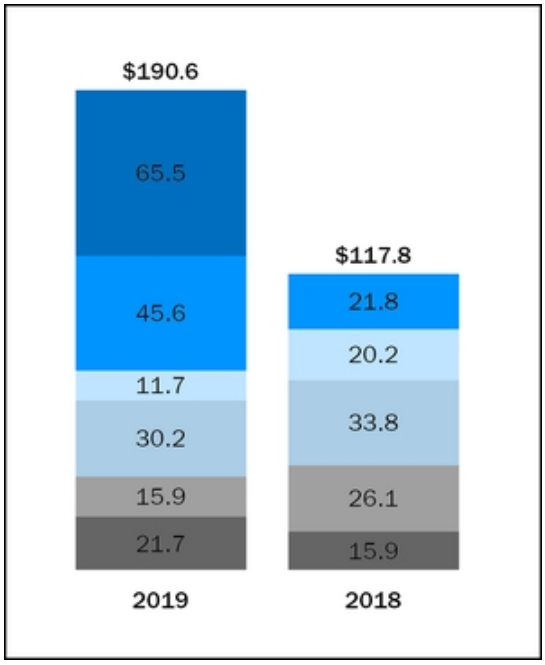
(amounts in millions, except share and per share amounts)

Results of Operations

	Three Months Ended March 31,			
	2019	2018	Change	% Change
Product sales net:				
NARCAN Nasal Spray	$ 65.5	$ —	$ 65.5	NM
ACAM2000	45.6	21.8	23.8	109%
BioThrax	11.7	20.2	(8.5)	(42%)
Other	30.2	33.8	(3.6)	(11)%
Total product sales, net	153.0	75.8	77.2	102 %
Contract manufacturing	15.9	26.1	(10.2)	(39)%
Contracts and grants	21.7	15.9	5.8	36 %
Total revenues	190.6	117.8	72.8	62 %
Operating expenses:				
Cost of product sales and contract manufacturing	91.8	54.3	37.5	69%
Research and development	46.1	29.1	17.0	58%
Selling, general and administrative	65.4	40.0	25.4	64%
Amortization of intangible assets	14.5	3.9	10.6	NM
Total operating expenses	217.8	127.3	90.5	71%
Loss from operations	(27.2)	(9.5)	(17.7)	NM
Other income (expense):				
Interest expense	(9.6)	(0.2)	(9.4)	NM
Other income (expense), net	(1.0)	0.3	(1.3)	NM
Total other income (expense), net	(10.6)	0.1	(10.7)	NM
Loss before benefit from income taxes	(37.8)	(9.4)	(28.4)	NM
Income tax benefit	(11.8)	(4.5)	(7.3)	NM
Net loss	$ (26.0)	$ (4.9)	$ (21.1)	NM

NM - Not meaningful

Product Sales, net



NARCAN Nasal Spray

NARCAN Nasal Spray was acquired in October 2018 in connection with the Company's acquisition of Adapt resulting in an increase in product sales in the current period.

ACAM2000

The increase in ACAM2000 sales for the three months ended March 31, 2019 **was primarily due to the number of ACAM2000 deliveries to the SNS during the** three months ended March 31, 2019 **as compared to the three months ended March 31, 2018. Substantially all of the ACAM2000 product sales revenues during the three months ended March 31, 2019 and 2018 were made to the USG under a long-term procurement contract at a consistent value per dose. The fluctuations in ACAM2000 revenue are related to changes in volume depending on when the product qualifies for release. Delivery obligations under this long-term procurement contract were fully satisfied during the** three months ended March 31, 2019**.**

BioThrax

The decrease in BioThrax sales for the three months ended March 31, 2019 was primarily due to the number of BioThrax deliveries to the SNS during the period as compared to the three months ended March 31, 2018. These decreases were slightly offset by inflationary increases in per unit pricing. Substantially all of the BioThrax product sales revenues are made to the USG under a long-term procurement contract. The fluctuations in BioThrax revenue are largely related to changes in volume depending on when the USG requests delivery. The USG delivery schedule varies based on funding and management of the SNS inventory.

Contract Manufacturing

The decrease in contract manufacturing revenue for the three months ended March 31, 2019 was primarily due to a contract to perform design, construction and validation of manufacturing capability for a third party at our Lansing, Michigan site during the first quarter of 2018 for which no similar services were provided during the three months ended March 31, 2019.

Contracts and Grants

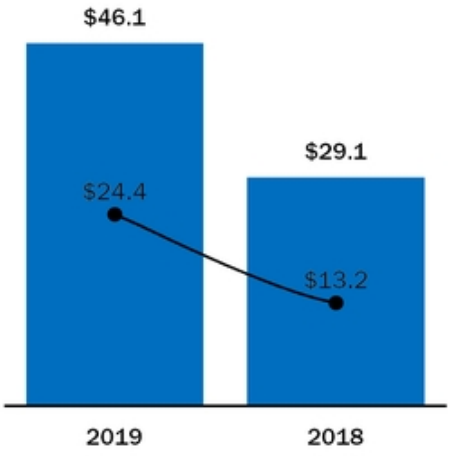
The increase in contracts and grants revenue for the three months ended March 31, 2019 primarily reflects research and development activities related to development funding for AV7909 for clinical trial activities and manufacturing. These increases were partially offset by a reduction in development funding for ACAM2000 for stability testing which were recorded during the **three months ended March 31, 2018** for which no similar services were provided in current period.

Cost of Product Sales and Contract Manufacturing

Cost of Product Sales and Contract Manufacturing
Cost of Sales as a Percentage of Product Sales and Contract Manufacturing Revenue

Cost of product sales and contract manufacturing increased $37.5 million, or 69% primarily due to the acquisition of Adapt and PaxVax, both acquired in October 2018, along with increased sales of ACAM 2000.

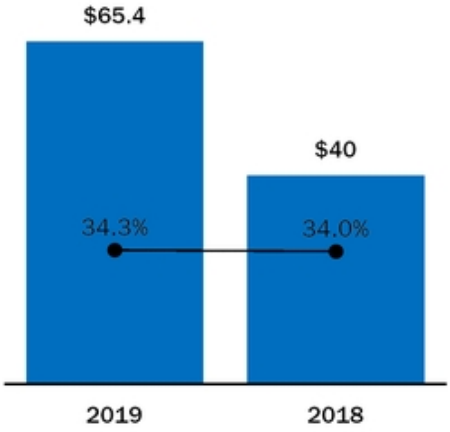
Research and Development Expenses (Gross and Net)



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

Research and development expenses increased $17.0 million, or 58%, for the three months ended March 31, 2019, primarily due to the acquisitions of Adapt and PaxVax, both acquired in October 2018. Increases also resulted from the **timing of manufacturing development activities for our AV7909 product candidate. These increases were offset** by decreases in technology transfer expenses for raxibacumab. While spending for the technology transfer has been consistent, these costs have been capitalized as a contract asset following the modification of the Center for Innovation Advanced Development and Manufacturing (CIADM) contract during the third quarter of 2018. Prior to the contract modification, technology transfer costs were expensed.

Selling, General and Administrative Expenses



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

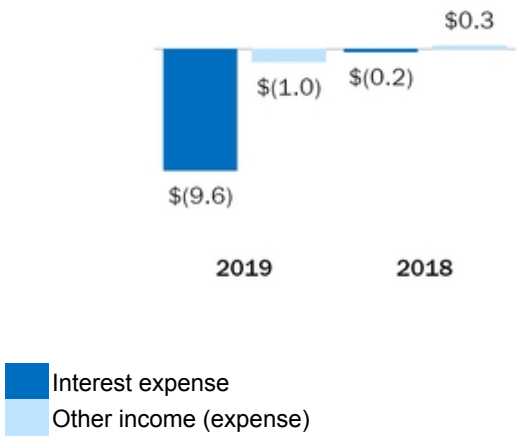
Selling, general and administrative expenses increase by $25.4 million, or 64%, for the three months ended March 31, 2019, primarily due to $20.5 million in expenses related to Adapt and PaxVax, both acquired in October 2018. The remaining increase is due to an increase in professional services to support our strategic growth initiatives.

Amortization of intangible Assets

The increased in amortization of intangible assets for the three months ended March 31, 2019 was primarily due to the acquisitions of Adapt and PaxVax.

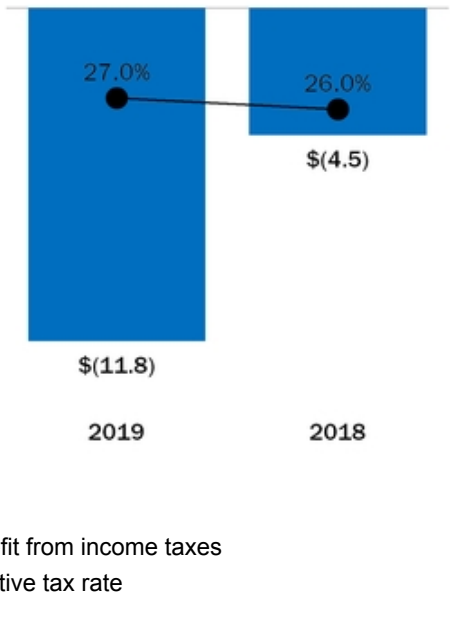
(amounts in millions, except share and per share amounts)

Total Other Income (Expense), Net



Total other income (expense), net decreased by $10.7 million, for the three months ended March 31, 2019, due to an increase in **interest expense for borrowings on our senior secured credit facilities established in October 2018 to fund our acquisitions of Adapt and PaxVax.**

Benefit from Income Taxes



Benefit from income taxes increased by $7.3 million, for the three months ended March 31, 2019**, due to a 1% increase in effective tax rate and an increase in pre-tax losses of $28.4 million, partially offset by a decrease in the discrete tax benefit associated with equity awards activities during the quarter.**

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 for the period ended December 31, 2018. As of March 31, 2019, we had cash and cash equivalents of $137.2 million. As of March 31, 2019, 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, 2019 and 2018:

	Three months ended March 31, 2019	
	2019	2018
Net cash provided by (used in):		
Operating activities(i)	$ 104.8	$ (1.0)
Investing activities	(21.4)	(11.6)
Financing activities	(58.4)	(2.1)
Net increase (decrease) in cash and cash equivalents	$ 25.0	$ (14.7)

(i) Includes the effect of exchange rates on cash and cash equivalents.

Operating Activities

Net cash provided by operating activities of $104.8 million for the three months ended March 31, 2019 was primarily due to changes in working capital which resulted in a net cash inflow of $106.5 million related primarily to the timing of collection of amounts billed to the USG for BioThrax, partially offset by the payment of 2018 annual bonuses reflected as accrued compensation.

Net cash used by operating activities of $1.0 million for the three months ended March 31, 2018 was primarily due to our net loss excluding non-cash items of $11.4 million and changes in working capital which resulted in a net cash outflow of $12.4 million. Cash outflows include the timing of collection of accounts receivables related to amounts billed (primarily to the CDC), partially offset by an increase in inventories primarily due to the timing of deliveries of BioThrax and ACAM2000 to the CDC, a decrease in accrued compensation primarily related to the payment of 2017 annual bonuses, a decrease from prepaid expenses and other assets primarily due to upfront payments for raw materials, and a decrease in deferred revenue primarily related to our contract with PAR Pharmaceutical.

Investing Activities

Net cash used in investing activities of $21.4 million for the three months ended March 31, 2019 reflects software, infrastructure and equipment investments.

Net cash used in investing activities of $11.6 million for the three months ended March 31, 2018 reflects infrastructure and equipment investments, including construction at our Baltimore CIADM manufacturing facility.

Financing Activities

Net cash used in financing activities of $58.4 million for the three months ended March 31, 2019 was primarily due to the net $52.8 million of payments on our revolving credit facility, and $6.0 million associated with the taxes paid on behalf of employees for equity activity.

Net cash used in financing activities of $2.1 million for the three months ended March 31, 2018 was primarily due to the $5.9 million associated with the taxes paid on behalf of employees for equity activity and $0.8 million in contingent obligation payments, partially offset by $4.7 million in proceeds from the issuance of common stock pursuant to our employee equity awards plan.

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 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 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 our authorized share repurchase program; and
- the costs of commercialization activities, including product marketing, sales and distribution.

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements.

If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt

financing, if available, may involve agreements that include covenants, like those contained in our senior 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 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.

Share Repurchase Program

In March 2018, our board of directors authorized our management to repurchase from time to time of up to an aggregate of $50 million of our common stock under a board-approved share repurchase program. The term of the board authorization of the repurchase program is until December 31, 2019. Any repurchased shares will be available for use in connection with our stock plans and for other corporate purposes. As of March 31, 2019, we have not made any repurchases under this program.

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 Risks

Our exposure to market risk is currently confined to our cash and cash equivalents. We currently do not hedge interest rate exposure or 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. 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, 2019, would increase our interest expense by approximately $7.0 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, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act, 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, 2019, 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, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's assessment of and conclusion on the effectiveness of disclosure controls and procedures and internal controls over financial reporting did not include the internal controls related to the operations acquired in the acquisition of PaxVax Holding Company Ltd. and Adapt Pharma Limited, which are included in our unaudited condensed consolidated financial statements for the three months ended March 31, 2019**, and which constituted $1.1 billion and $905.4 million of total assets and net assets, respectively as of March 31, 2019 and $74.9 million and $3.8 million of revenues and operating loss, respectively, for the quarter then ended.**

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. and Opiant Pharmaceuticals, Inc., received notice from Perrigo UK FINCO Limited Partnership that Perrigo had filed an ANDA with the FDA, seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of the '253 Patent, the '747 Patent, the '177 Patent, the '965 Patent, and the '838 Patent. On or about October 25, 2018, Perrigo sent a subsequent notice letter relating to 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. As a result of timely filing the first lawsuit in accordance with the Hatch-Waxman Act, a 30-month stay of approval will be imposed by the FDA on Perrigo's ANDA, which is expected to remain in effect until March 2021 absent an earlier judgment, unfavorable to the Plaintiffs, by the Court.

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., 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 the '644 Patent, and 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 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.

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.

Shareholder Class Action Lawsuit filed July 19, 2016

On July 19, 2016, Plaintiff William Sponn (Sponn), filed a putative class action complaint in the United States District Court for the District of Maryland on behalf of purchasers of the Company's common stock between January 11, 2016 and June 21, 2016, inclusive, seeking to pursue remedies under the Exchange Act against the Company and certain of its senior officers and directors (collectively, the Defendants). The complaint alleged, among other things, that the Defendants made materially false and misleading statements about the government's demand for BioThrax and expectations that the Company's five-year exclusive procurement contract with HHS would be renewed, and omitted certain material facts. Sponn sought unspecified damages, including legal costs. On October 25, 2016, the court added City of Cape Coral Municipal Firefighters' Retirement Plan and City of

Sunrise Police Officers' Retirement Plan as plaintiffs and appointed them Lead Plaintiffs and Robbins Geller Rudman & Dowd LLP as Lead Counsel. On December 27, 2016, the Lead Plaintiffs filed an amended complaint that cited the same class period, named the same defendants and made similar allegations to the original complaint. The Defendants filed a Motion to Dismiss on February 27, 2017. The Plaintiffs filed an opposition brief on April 28, 2017. The Defendants' Motion to Dismiss was heard and denied on July 6, 2017. The Defendants filed an answer on July 28, 2017. The parties then engaged in the process of exchanging discovery. The Plaintiffs filed an amended motion for class certification and appointment of Lead Plaintiffs, Sponn, and Geoffrey L. Flagstad as Class Representatives on December 20, 2017. A hearing on that motion was heard on May 2, 2018. On June 8, 2018 the Court granted class certification with a shortened class period, May 5, 2016 to June 21, 2016. In that same order, the court appointed Flagstad as Class Representative and Robbins Geller Rudman & Dowd LLP as Class Counsel. The Defendants have denied, and continue to deny, any and all allegations of fault, liability, wrongdoing, or damages. However, recognizing the risk, time, and expense of litigating any case to trial, on August 27, 2018, the Defendants reached an agreement in principle with Plaintiffs to settle all of the related claims of any individual plaintiff that purchased or acquired Company stock from January 11, 2016 to June 21, 2016, for $6.5 million, an amount that was paid by the Company's insurance carrier. The settlement required no payment by any of the Defendants. The Defendants continue to deny any and all liability. The parties executed the settlement agreement on October 16, 2018 and filed the agreement with the court on October 17, 2018. The court granted preliminary approval of the settlement on October 18, 2018, issued an amended preliminary approval of the settlement on October 25, 2018, and scheduled a hearing regarding final approval for January 22, 2019. At the time of the final approval hearing on January 22, 2019, there were no objections to the settlement, but there were two shareholders who had submitted opt-outs so that they could be excluded from the settlement. On January 25, 2019, the court issued an order and final judgment approving the settlement. The time to file a notice of appeal has passed. Defendants continue to believe that the allegations in the complaint are without merit.

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."

GOVERNMENT CONTRACTING RISKS

We currently derive a substantial portion of our revenue from sales of BioThrax to our largest customer, the USG. If the USG's demand for and/or funding for procurement of BioThrax 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 sales of BioThrax, our anthrax vaccine licensed by the FDA to the USG. In December 2016, we signed a follow-on procurement contract with the CDC for the delivery of approximately 29.4 million doses of BioThrax for placement into the SNS over a five-year period ending in September 2021. The potential value of this contract is approximately $911 million if all procurement options are exercised.

The procurement of doses of BioThrax by the CDC is subject to the availability of funding. We have no certainty that funding will be made available for the procurement of doses under the CDC contract. If the SNS priorities change, funding to procure doses of BioThrax may be limited or not available, and our business, financial condition and operating results and cash flows would be materially harmed. The success of our business and our future operating results are significantly dependent on funding for the procurement of BioThrax and the terms of our BioThrax sales to the USG, including the price per dose, the number of doses and the timing of deliveries.

Our pre-EUA submission package related to AV7909 may not be accepted and we may not receive EUA and eventual FDA licensure may not be approved by the FDA 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 September 2016, we entered into a contract with HHS, through BARDA for the advanced development and procurement of AV7909, our next generation anthrax vaccine candidate. The contract, as modified in March 2017, is valued at up to approximately $1.5 billion.

In collaboration with us, the Centers for Disease Control and Prevention recently filed with the FDA a pre-EUA submission package related to AV7909, and although there can be no assurances, we currently anticipate that BARDA could begin procuring AV7909 for

delivery into the SNS as early as this year. The FDA may decide that our data are insufficient to accept the pre-EUA submission package and require additional pre-clinical, clinical or other studies. If we are unsuccessful in obtaining acceptance of the pre-EUA submission package for AV7909, and EUA and eventual 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.

In addition, if priorities for the SNS change, funding to procure any future doses of AV7909 may be limited or not available, and our future business, financial condition, operating results and cash flows could be materially harmed.

Our USG procurement and development contracts require ongoing funding decisions by the USG. Reduced or discontinued 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 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 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 CDC procurement contract for ACAM2000 that we acquired in our acquisition of the ACAM2000 business from Sanofi expired on March 31, 2018. 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, will expire in November 2019. Our CDC procurement contract for BioThrax expires in 2021. We intend to negotiate follow-on procurement contracts for each of our PHT products upon the expiration of a related procurement contract, including our procurement contract for ACAM2000, 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.

Laws and regulations affecting government contracts make it costlier and more difficult for us to successfully conduct our business. Failure to comply with these laws could result in significant civil and criminal penalties and materially damage our reputation and relationship with the USG, 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;**
- **export and import control laws and regulations, including but not limited to International Traffic in Arms Regulations; and**
- **laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.**

We may be subject to government investigations of 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 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.

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 (Naloxone API, along with the vial, stopper and device). Where a particular single-source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation of materials prior to use in our products, and 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.

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 their development, including testing, manufacture, recordkeeping, storage and approval, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Except under limited circumstances related to certain government sales, failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate.

In the United States, to obtain approval from the FDA to market any of our future biologic products, we will be required to submit a biologics license application (BLA) to the FDA. Ordinarily, the FDA requires a company to support a BLA with substantial evidence of the product candidate's safety and efficacy in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase 3 safety and efficacy trials conducted in patients with the disease or condition being targeted.

However, AV7909 and 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 AV7909 or any of our PHT MCM candidates under the Animal Rule. Even if we are able to proceed pursuant to the Animal Rule, 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.

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.

Healthcare legislature reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act (ACA) was enacted, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. However, some provisions of the ACA have yet to be fully implemented and certain provisions have been subject to legal and political challenges, as well as efforts by the Trump Administration to repeal or replace certain aspects of the ACA. For example, since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing penalties as of

January 1, 2019 for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. We continue to evaluate how the ACA and recent efforts to repeal and replace or limit the implementation of the ACA will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2 percent per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken.

Additionally, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical 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. These new laws and initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our future customers and accordingly, our financial operations.

If we fail to comply with foreign, federal, state and local healthcare 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 "antikickback" 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 and our employees 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 healthcare 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 healthcare providers or other entities, among other activities;**

- **federal civil and criminal false claims, including the federal False Claims Act, and false statement laws and civil monetary penalty laws, which impose criminal and civil penalties, including through civil whistleblower or qui tam actions, on individuals or entities for, among other things,**

knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal health care programs that are false or fraudulent or knowingly making any materially false statement in connection with the delivery or payment for healthcare benefits, items or services;

- **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 healthcare 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 healthcare 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, healthcare 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 (HITECH), and their respective implementing regulations mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare 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 requires 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 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 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 healthcare 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 healthcare 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 U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge 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.

We are committed to conducting the sales and marketing of our applicable products and all our activities in compliance with the healthcare fraud and abuse and antitrust laws, but certain applicable laws 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 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/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 you 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 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, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We intend to transfer the manufacturing of raxibacumab, which we acquired from GSK, to our bulk and fill finish facilities in Baltimore, Maryland, and this transfer of manufacturing operations requires FDA approval.

Under our arrangements with GSK for our acquisition of the raxibacumab product, we will continue to purchase product from GSK to satisfy deliveries to the SNS under the current BARDA contract, which expires in November 2019. We intend to seek FDA approval to transfer the manufacturing of raxibacumab to our Baltimore, Maryland bulk and fill finish manufacturing facilities and currently anticipate FDA approval of this technology transfer in 2020. Approval of this technology transfer may involve complications or may not be secured on a timely basis or at all. Any delay in the approval of this anticipated technology transfer would delay our expected benefits and synergies from this product acquisition and could materially harm our revenues and our business, financial condition, operating results and cash flows could be harmed. Until approval of this technology transfer, we must rely on GSK to supply product to us to satisfy deliveries to the SNS under the BARDA contract, and GSK may fail to meet delivery obligations, which could result in our inability to satisfy requirements under the BARDA contract.

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

Any vaccine, therapeutic product or medical device for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to 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, 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.

Our regulators enforce cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect domestic manufacturing facilities without prior notice at reasonable times and in a reasonable manner. Health Canada may conduct similar inspections of our 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. 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 drugs for "off-label" uses (*i.e.,* uses that are not described in the product's labeling and that differ from those approved by the applicable regulatory agencies). A company that is found to have improperly promoted off-label uses 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 "off-label" marketing of any of our products, 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.

One or more of our products could be subject to early generic competition.

One or more of our products is approved 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 physicians 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 applicability 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.

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 U.K. To market our products in foreign jurisdictions under normal circumstances, we may 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. 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 international operations increase our risk of exposure to potential claims of bribery and corruption.

As we continue to expand our commercialization activities outside of the United States, we are subject to an increased risk of inadvertently conducting activities in a manner that violates the U.S. Foreign Corrupt Practices Act (the FCPA), the U.K. Bribery Act, Canada's Corruption of Foreign Public Officials Act, or 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. In the course of establishing and expanding our commercial operations and seeking regulatory approvals outside of the United States, we will need to establish and expand business relationships with various third parties and will interact more frequently with foreign officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be foreign officials under the FCPA or similar foreign laws. If our business practices are found to be in violation of the FCPA or similar foreign laws despite our training and compliance efforts, we and our senior management may be subject to significant civil and criminal penalties, potential debarment from public procurement and reputational damage, which could have a material adverse effect on our business, financial condition, operating results, cash flows and growth prospects.

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 receivables 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 may materially impact our operating results.

MANUFACTURING RISKS

Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture BioThrax 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 PHT countermeasures 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 slow-downs;**
- **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; 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.

BioThrax, raxibacumab, ACAM2000, Anthrasil, BAT, VIGIV, Vivotif, Vaxchora, 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.

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.

We are required to obtain FDA approval prior to the release of each lot of BioThrax and ACAM2000, which may not be obtained on a timely basis or at all.

FDA approval is required for the release of each lot of BioThrax and ACAM2000. We are not able to sell any lots that fail to satisfy the release testing specifications. For example, we must provide the FDA with the results of certain tests, including potency tests, before lots are released for sale. Potency testing of each lot of BioThrax and each lot of ACAM2000 is performed against qualified control lots that we maintain. We continually monitor the status of our reference lots and periodically produce and qualify a new reference lot to replace the existing reference lot. If we are not able to produce and qualify a new reference lot or otherwise satisfy the FDA's requirements for release of BioThrax or ACAM2000, our ability to sell BioThrax or ACAM2000 would be impaired until such time as we become able to meet the FDA's requirements, which would materially harm our business, financial condition, operating results and cash flows.

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 BioThrax 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, and currently rely on a single-source supplier to manufacture raxibacumab. We also rely on single-source suppliers for the sponge applicator device and the active ingredient used to make RSDL as well as 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.

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

Our operations involve the use of hazardous materials, including chemicals, bacteria and viruses, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf, are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. Under the Federal Select Agent Program, pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act, we are required to register with and be inspected by the CDC and the Animal and Plant Health Inspection Service if we have in our possession, or if we use or transfer, select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires stringent safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel and establishes a comprehensive national database of registered entities. We are also subject to a variety of environmental and occupational health and safety laws. Compliance with current or future laws and regulations 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.

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, raxibacumab, ACAM2000, Anthrasil, BAT, VIGIV, Vivotif and Vaxchora 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 and improvised or other 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, ANDAs which seek 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 and Teva may decide to launch its generic version at risk even if the ongoing litigation we instituted against Teva is still proceeding.

Additionally, in January 2019, the FDA released new proposed template Drug Facts Labels to assist sponsors of investigation 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, whether CBRNE or EID, 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.

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. 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. Absent an applicable exception, our MCM product candidates generally will have to be approved by the FDA or other regulatory authorities 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 marketing 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) may 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.

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.

For certain of our product candidates addressing CBRNE threats, we 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 depend on third parties to conduct 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 do not have the ability to independently conduct the clinical and non-clinical trials required to obtain regulatory approval for our product candidates. 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.

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.

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 that 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:

- Pfizer, Inc. an oligonucleotide adjuvant, CPG 7909, for use in our AV7909 (anthrax vaccine adsorbed with CPG 7909 adjuvant) anthrax vaccine product candidate.

- **Opiant Pharmaceuticals, Inc. formulations of naloxone, for use in our NARCAN® Nasal Spray.**
- **Pharma Consult GmbH autoinjectors, including the autoinjector used for our Trobigard® (atropine sulfate, obidoxime chloride) autoinjector.***

Trobigard® is not currently approved or cleared by the FDA or any similar regulatory body and is only distributed to authorized government buyers for use outside the US. This product is not distributed in the US.

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.

FINANCIAL RISKS

Servicing our debt requires a significant amount of cash, and 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;**
- **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 debt instruments 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 instrument and a cross default and acceleration under other debt instruments, 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 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 a $600 million revolver, of which we had outstanding borrowings of $444 million and $298 million, respectively, as of March 31, 2019. 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 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 our authorized 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 instruments 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 instrument and a cross default and acceleration under other debt instruments, 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.

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. For example, we incurred a net loss in the second quarter of 2016 and in each of the first quarters of 2019, 2018, 2015, 2014 and 2013.

Our profitability has been substantially dependent on BioThrax 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 SPIN-OFF OF OUR BIOSCIENCES BUSINESS

If the spin-off distribution on August 1, 2016 of all of the outstanding shares of Aptevo Therapeutics Inc. common stock to our stockholders does not qualify as a tax-free transaction for U.S. federal income tax purposes, we and our stockholders could be subject to significant tax liabilities.

It was our intention that our distribution on August 1, 2016 of all of the outstanding shares of Aptevo common stock to our stockholders (the Distribution), together with certain related transactions, qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Internal Revenue Code of 1986, as amended (the Code). In anticipation of the Distribution, we received a favorable private letter ruling from the Internal Revenue Service (the IRS), regarding certain U.S. federal income tax matters relating to the Distribution and certain related transactions and an opinion of counsel substantially to the effect that, for U.S. federal income tax purposes, the Distribution, together with certain related transactions, will qualify as a transaction described under Sections 355 and 368(a)(1)(D) of the Code. A "private letter ruling," is a written statement issued to a taxpayer by an Associate Chief Counsel Office of the Office of Chief Counsel that interprets and applies the tax laws to a specific set of facts. Our private letter ruling is based on certain facts and representations submitted by us to the IRS and the opinion of counsel was based upon and relied on, among other things, the IRS private letter ruling and certain facts and assumptions, as well as certain representations and covenants of us and Aptevo contained in a tax matters agreement and certain representations contained in representation letters provided by us, Aptevo and certain stockholders to such counsel, including representations and covenants relating to the past and future conduct of us, Aptevo and such stockholders. If any of these facts, assumptions, representations, or covenants are, or become, inaccurate or incomplete, the IRS private letter ruling and/or the opinion of counsel may be invalid and the conclusions reached therein could be jeopardized and, as a result, the Distribution, together with certain related transactions, could fail to qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code for U.S. federal income tax purposes.

In addition, the IRS private letter ruling only addresses certain limited matters relevant to

determining whether the Distribution, together with certain related transactions, qualifies as a transaction described under Sections 355 and 368(a)(1)(D) of the Code, and the opinion of counsel only represents the judgment of such counsel, which is not binding on the IRS or any court. Accordingly, notwithstanding the IRS private letter ruling and the opinion of counsel, there can be no assurance that the IRS will not assert that the Distribution, together with certain related transactions, should be treated as a taxable transaction for U.S. federal income tax purposes or that a court would not sustain such a challenge.

If the Distribution, together with certain related transactions, fails to qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code, for U.S. federal income tax purposes, in general, (i) we would recognize taxable gain on the Distribution equal to the amount by which the fair market value of the Aptevo shares distributed to our stockholders exceeded our tax basis in the Aptevo shares and (ii) each of our stockholders who received Aptevo shares in the Distribution would be treated as receiving a taxable distribution equal to the fair market value of the Aptevo shares received by such stockholder.

Under the tax matters agreement that we entered into with Aptevo in connection with the spin-off, Aptevo may be required to indemnify us against any tax liabilities and related expenses resulting from the failure of the Distribution, together with certain related transactions, to qualify as a transaction described under Sections 355 and 368(a)(1)(D) of the Code to the extent that the failure to so qualify is attributable to actions, events or transactions relating to Aptevo's stock, assets or business, or a breach of the relevant representations or covenants made by Aptevo in the tax matters agreement or the IRS private letter ruling or in the representation letters provided to our counsel for purposes of their opinion. Any such indemnity obligations could be material, and there can be no assurance that Aptevo will be able to pay any such indemnification.

To preserve the tax-free treatment of the Distribution, together with certain related transactions, and in addition to Aptevo's indemnity obligation, the tax matters agreement, which expired on August 2, 2018, restricted Aptevo from taking any action that prevents such transactions from being tax-free for U.S. federal income tax purposes. In particular, for the two-year period following the Distribution, Aptevo was restricted from taking certain actions (including restrictions on share issuances, business combinations, sales of assets, amendments to organizational documents and similar transactions) that could cause the Distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes. There can be no assurance that Aptevo adequately complied with these restrictions. If a finding is made by the IRS through a tax audit that Aptevo failed to satisfy its obligations, this could have a substantial impact on our tax obligations, consolidated financial condition and cash flows.

In connection with Aptevo's separation from us, Aptevo agreed to indemnify us for certain matters. This indemnity may not be sufficient to hold us harmless from the full amount of losses that we may incur in connection with these matters, and Aptevo may not be able to satisfy its indemnification obligations to us.

Pursuant to the agreements that we entered into with Aptevo at the time of Aptevo's separation from us, Aptevo agreed to indemnify us for certain matters, including liabilities related to Aptevo's business or for which Aptevo otherwise agreed to be responsible in the separation. This indemnity from Aptevo may not be sufficient to protect us against the full amount of losses that we may incur in connection with these matters, including if third parties assert claims against us for liabilities that were allocated to Aptevo in the separation. Moreover, Aptevo may dispute its indemnification obligation to us or have insufficient resources to satisfy its indemnification obligations to us. Even if we ultimately succeed in recovering from Aptevo the amount of any losses that we incur in connection with these matters, the recovery could take a substantial amount of time and we may be required to bear these losses ourselves while we seek recovery. Each of these risks could negatively affect our business, operating results, financial condition and cash flows.

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. 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 indemnification under the PREP Act and SAFETY Act is 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 April 26, 2019, 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 26, 2019, our common stock has traded as high as $73.89 per share and as low as $4.40 per share. The stock market in general as well as the market for biopharmaceutical companies in particular has 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 April 26, 2019, 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#	Amendment No. 2 to License Agreement, dated as of December 15, 2014, by and between Opiant Pharmaceuticals, Inc. (formerly known as Lightlake Therapeutics Inc.) and Adapt Pharma Operations Limited, effective March 18, 2019.
10.2	Form of 2019-2021 Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K, filed on February 12, 2019).
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. INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Calculation Linksbase Document.
101.DEF	XBRL Taxonomy Definition Linksbase Document.
101.LAB	XBRL Taxonomy Label Linksbase Document.
101.PRE	XBRL Taxonomy Presentation Linksbase Document.

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language):

(i) Condensed Consolidated Statements of Operations for the three months ended March 31, 2019 and 2018;
(ii) Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2019 and 2018;
(iii) Condensed Consolidated Balance Sheets at March 31, 2019 and December 31, 2018;
(iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2019 and 2018; and
(v) Condensed Consolidated Statement of Changes in Stockholders' Equity for the three months ended March 31, 2019 and 2018; and
(vi) Notes to Condensed Consolidated Financial Statements.

Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

EMERGENT BIOSOLUTIONS INC.

By: /s/ROBERT G. KRAMER, SR.
Robert G. Kramer, Sr.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 8, 2019

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

Date: May 8, 2019

AMENDMENT NO. 2 TO LICENSE AGREEMENT

This Amendment No. 2 to License Agreement (this "**Amendment**") is made as of March 18, 2019, by and between Opiant Pharmaceuticals Inc. (formerly known as Lightlake Therapeutics Inc.), a Delaware corporation ("**Opiant**"), and Adapt Pharma Operations Limited, an Irish limited company ("**Adapt**"). Opiant and Adapt are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**". Capitalized terms used but not defined herein have the meanings given to them in the License Agreement (as defined below).

RECITALS

WHEREAS, the Parties entered into a License Agreement, dated as of December 15, 2014 (including the exhibits and schedules thereto, and as amended by that certain Amendment No. 1 to License Agreement, dated December 6, 2016, the "**License Agreement**"), pursuant to which Opiant licenses to Adapt certain intellectual property rights to develop and commercialize Products in accordance with the terms and conditions set forth therein;

WHEREAS, Section 11.9 of the License Agreement provides that no amendment or modification to the License Agreement shall be binding upon the Parties unless in writing and duly executed by authorized representations of both Parties;

WHEREAS, Adapt has entered into an agreement with a Third Party, titled Exclusive Patent License Agreement and dated February 27, 2018, a copy of which has been provided to Opiant's counsel (the "**Third Party License**"), pursuant to which Adapt has made, and expects to make, certain payments to such Third Party;

WHEREAS, the Parties wish to memorialize their agreement regarding the treatment under the License Agreement of such payments pursuant to the Third Party License; and

WHEREAS, in connection with such agreement, the Parties desire to amend the License Agreement in the manner specified in this Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

1. Third Party License. The Parties agree that, anything to the contrary contained in the License Agreement or otherwise notwithstanding, Adapt shall be entitled to make the following deductions from royalties payable pursuant to Section 5.4 of the License Agreement and, as applicable pursuant to the sub-paragraphs below, the unpaid Annual Net Sales-Based Milestone Payment under Section 5.3.1 of the License Agreement, after the date of this Amendment:

(a) Adapt shall deduct six million five hundred thousand dollars ($6,500,000) (the "**Initial Deductible Amount**") from royalties payable pursuant to Section 5.4 of the License Agreement after the date of this Amendment; provided, however, that (i) Adapt shall not deduct more than two million dollars ($2,000,000) from the royalty payment in respect of any single Calendar Quarter, and (ii) if the Annual Net Sales-Based Milestone Payment of fifteen million dollars ($15,000,000) due upon

achievement of Net Sales of two hundred million dollars ($200,000,000) becomes payable in accordance with Section 5.3.1 of the License Agreement before the full Initial Deductible Amount has been deducted from royalty payments, the remaining balance of the Initial Deductible Amount shall be deducted from such Annual Net Sales-Based Milestone Payment.

(b) Adapt shall deduct an additional two million five hundred thousand dollars ($2,500,000) (the "**Additional Deductible Amount**") upon the Annual Net Sales-Based Milestone Payment of fifteen million dollars ($15,000,000) due upon achievement of Net Sales of two hundred million dollars ($200,000,000) becoming payable by Adapt in accordance with Section 5.3.1 of the License Agreement. The Additional Deductible Amount shall be deducted from such Annual Net Sales-Based Milestone Payment made by Adapt.

(c) Adapt agrees that no deductions other than the Initial Deductible Amount and the Additional Deductible Amount will be taken after the date of this Amendment from payments made by Adapt under the License Agreement in relation to payments made under or in respect of the Third Party License. With respect to the initial deduction, in the amount of six million two hundred fifty thousand ($6,250,000), from the Annual Net Sales-Based Milestone paid to Opiant on or about February 28, 2018, based on the initial payment under the Third Party License (the "**Initial Deduction**"), Opiant, for itself and on behalf of its Affiliates, predecessors, successors, and assigns (i) accepts such Initial Deduction and (ii) irrevocably waives and foregoes any actual or potential objection or claim related to such Initial Deduction, including, without limitation any actual or potential claim that such Initial Deduction constituted or constitutes a breach of the License Agreement.

2. Omnibus Amendment to the License Agreement. Each instance of "Sublicense" in the License Agreement is hereby deleted and replaced with "sublicense". In addition, the row containing "Sublicense" in the cross-reference table at the end of Article I of the License Agreement is hereby deleted.

3. Amendment to Section 1.30 of the License Agreement. Section 1.30 of the License Agreement is hereby deleted in its entirety and replaced with the following:

"**1.30** "**Generic Product**" means, with respect to a Product, any intranasal product in an intranasal device that (i) is sold by a Third Party under an (A) Abbreviated New Drug Application (ANDA) in the United States; (B) in the European Union, pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision), or (C) in any other country or jurisdiction, pursuant to all equivalents of such provisions; (ii) contains naloxone as the primary active ingredient; and (iii) is approved in reliance, in whole or in part, on the prior approval of such Product. A Product licensed or produced by Adapt or its Affiliates or Commercial Sublicensees (i.e., an authorized generic product) will not constitute a Generic Product."

4. Amendment to Section 1.45 of the License Agreement. The first paragraph of Section 1.45 of the license agreement (ending with a colon) is hereby deleted and replaced with the following:

"**1.45 "Net Sales"** means, with respect to a Product for any period, the total amount billed or invoiced on sales of such Product during such period by Adapt, its Affiliates, or Sublicensees on behalf of Adapt or its Affiliates to Third Parties, and the total amount of money or other consideration received by Adapt or its Affiliates from sales of such Product (including sales of Product as an authorized generic product) or Generic Product by Sublicensees or Specified Sublicensee, less the following normal and customary bona-fide deductions and allowances actually taken:"

5. Amendment to Section 1.61 of the License Agreement. Section 1.61 of the License Agreement is hereby deleted in its entirety and replaced with the following:

"**1.61** "**Sublicensee**" means a Person, other than an Affiliate, that is granted a sublicense by Adapt, or an Affiliate of Adapt, under the license granted in Section 4.1, but excluding Specified Sublicensees."

6. Amendment to Article I of the License Agreement. Article I of the License Agreement is hereby amended by adding the following immediately following Section 1.60 of the License Agreement:

"**1.60A** "**Specified Sublicensee**" means a Third Party that Adapt or an Affiliate grants a non-exclusive sublicense, a covenant not to sue, or other right, under any Patent in furtherance of any settlement, compromise or other resolution of any claim by Adapt or its Affiliate that such Third Party has infringed any Patent."

7. Amendments to Section 4.3.1 of the License Agreement.

(a) Section 4.3.1 of the License Agreement is hereby amended by adding the words "or Specified Sublicensees" immediately following the words "tiers of Sublicensees" in the first sentence thereof.

(b) Section 4.3.1 of the License Agreement is hereby further amended by adding the words "to a Sublicensee" immediately after the words "With respect to any such Sublicense," in the fourth sentence thereof.

8. Amendment to Section 4.3.2 of the License Agreement. Section 4.3.2 of the License Agreement is hereby amended by adding the following to the end thereof:

"provided, however, that notwithstanding the foregoing, any sublicense granted by Adapt to a Specified Sublicensee shall survive termination of this Agreement in accordance with the terms of the applicable agreement with such Specified Sublicensee"

9. Amendment to Section 4.6.1 of the License Agreement. Section 4.6.1 of the License Agreement is hereby amended by adding the following at the end thereof:

"provided, however, that the foregoing shall not limit or preclude Adapt or its Affiliate from granting a sublicense to any Specified Sublicensee"

10. Amendment to Section 10.3 of the License Agreement. Section 10.3 of the License Agreement is hereby amended by adding the words "or Specified Sublicensee" after each occurrence of the word "Sublicensee" in the final sentence thereof.

11. Amendment to Section 10.6.1 of the License Agreement. Section 10.6.1 of the License Agreement is hereby amended by adding the words "subject to Section 4.3.2," at the beginning thereof.

12. Amendment to Section 5.5 of the License Agreement. Section 5.5 of the License Agreement is hereby deleted in its entirety and replaced with the following:

"**5.5 Third Party Licenses**.

5.5.1 If, during the Term, Adapt elects, in its sole discretion, to seek a license under any Patent of a Third Party that (i) Adapt reasonably determines would be infringed by the Exploitation, in any part of the Territory, of any Product then under Development or being Commercialized by Adapt, its Affiliates or its Sublicensees, or that Adapt determines could be listed in the FDA's Orange Book in respect of one or more Products (including Products in Development), or that claims an invention that Adapt determines

could facilitate the Development of one or more new Product(s) (any of the foregoing, "**Core IP**") or (ii) that Adapt otherwise reasonably determines is necessary or desirable for Adapt, its Affiliates or Sublicensees to Exploit the Products, then, in either case, Adapt shall be solely responsible for the negotiation and execution of the corresponding license agreement (a "**Third Party License Agreement**").

5.5.2 Adapt may, but shall not be obligated to, provide Opiant with a copy of any Third Party License Agreement before entering into such agreement, in which event Adapt shall concurrently notify Opiant in writing if Adapt regards any Patent(s) to be licensed under such Third Party License Agreement as Core IP. In the event that Adapt provides Opiant with a copy of any Third Party License Agreement, the Parties will discuss the same in good faith for a period of up to ten (10) Business Days from the date on which such Third Party License Agreement is provided to Opiant. Not later than fifteen (15) Business Days after the date on which such Third Party License Agreement is provided to Opiant, Opiant shall notify Adapt in writing (a) whether or not, in Opiant's good faith determination, the license contemplated thereby would meet the criteria set forth in either or both of clause (i) or clause (ii) of Section 5.5.1, (b) if Adapt has notified Opiant that it regards one or more of the Patent(s) subject to such license as Core IP, whether or not, in Opiant's good faith determination, such Patent(s) constitute Core IP, and (c) whether and to what extent, in Opiant's good faith determination, payments that would be owing by Adapt to the Third Party under the Third Party License Agreement constitute Eligible Payments within the meaning of Section 5.5.3. If Opiant notifies Adapt within such fifteen (15) Business Day period that it agrees that the license contemplated by such Third Party License Agreement would meet the criteria set forth in either or both of clause (i) or clause (ii) of Section 5.5.1, or if Opiant fails to provide its written determination to Adapt within such fifteen (15) Business Day period, the applicable Third Party License Agreement, in the form provided to Opiant, shall be deemed an "**Accepted Third Party License Agreement**". If Opiant notifies Adapt within such fifteen (15) Business Day period that payments that would be owing by Adapt to the Third Party under the Third Party License Agreement constitute Eligible Payments, then fifty percent (50%) of such Eligible Payments explicitly identified by Opiant as appropriate shall be deemed "**Accepted Section 5.5 Deductions**." If Opiant fails to provide its written determination to Adapt within such fifteen (15) Business Day period, then fifty percent (50%) of all Eligible Payments under such Third Party License shall be deemed Accepted Section 5.5 Deductions. If Opiant further indicates in such notice that it agrees that one or more of the Patent(s) subject to such license constitute Core IP, or if Adapt has notified Opiant that Adapt regards one or more of the Patent(s) subject to such license as Core IP and Opiant fails to notify Adapt within such fifteen (15) Business Day period, whether or not it agrees that such Patent(s) constitute Core IP, then such Patent(s) shall be deemed "**Accepted Core IP**". For the sake of clarity, Opiant's determination as to whether or not any license proposed by Adapt meets the criteria of either or both of clause (i) or clause (ii) of Section 5.5.1 shall not affect in any way Adapt's right to enter into any agreement in respect of such license, except that under no circumstances shall Adapt make any deductions from payments owed to Opiant in relation to any Third Party License Agreement except as expressly provided for in Section 5.5.3 below.

5.5.3 Any amounts due under any Third Party License Agreement will be borne

by Adapt; provided, however, that (i) if such Third Party License Agreement is an Accepted Third Party License Agreement with Accepted Section 5.5 Deductions, Adapt shall be entitled to deduct such Accepted Section 5.5 Deductions paid to such Third Party from the Regulatory Milestones payable by Adapt pursuant to Section 5.2, the Sales-Based Milestones payable by Adapt pursuant to Section 5.3 and the royalties payable by Adapt pursuant to Section 5.4, or (ii) either (A) if such Third Party License Agreement is in furtherance of a settlement of a Patent infringement claim against Adapt or its Affiliates as evidenced by a written claim of infringement received by a Third Party, or (B) to the extent that royalty payments are made by Adapt under such Third Party License Agreement based on sales of Products, Adapt shall be entitled to deduct up to fifty percent (50%) of all Eligible Payments made to such Third Party under such Third Party License Agreement and referred to in this clause (ii) from the Regulatory Milestones payable by Adapt pursuant to Section 5.2, the Sales-Based Milestones payable by Adapt pursuant to Section 5.3 and the royalties payable by Adapt pursuant to Section 5.4. "**Eligible Payments**" means any one-time license fee payment that serves as the exclusive source of monetary consideration, upfront payment, milestones or royalties paid to the applicable Third Party under a Third Party License Agreement on account of rights relating to Products. For the avoidance of doubt, with respect to Accepted Third Party License Agreements that do not fall within clause (ii) of this Section 5.5.3, Adapt shall only be entitled to deduct Accepted Section 5.5 Deductions. Also for the avoidance of doubt, the term "milestone(s)" as used in this Section 5.5.3 refers to development, regulatory, launch or sales events or achievements relating to and on account of the Products that trigger a payment under the Third Party License Agreement. To the extent that, in any Calendar Quarter with respect to a royalty payment or with respect to milestone payment in the event of a milestone, Adapt was not able to deduct the entire amount of the above percentage of any and all amounts paid to such Third Party in such Calendar Quarter or from such regulatory or sales-based milestone payment, Adapt shall be entitled to carry forward such remaining amounts and deduct them from the royalties due in subsequent Calendar Quarters or a subsequent regulatory or sales-based milestone payment; provided that in no event shall reductions pursuant to this Section 5.5.3 result in royalties on Product of less than (x) one and one half percent (1.5%) of Net Sales in any Calendar Quarter in the case of reductions associated with Accepted Core IP or reductions associated with payments contemplated by clause (ii) of this Section 5.5.3 in respect of Core IP or (y) two and one half percent (2.5%) of Net Sales in any Calendar Quarter in the case of reductions associated with any other license contemplated by this Section 5.5."

5.5.4. To the extent that Adapt enters into a Third Party License Agreement that it has not provided to Opiant in advance of execution under Section 5.5.2 above and that is anticipated to result in deductions under clause (ii) of Section 5.5.3 above, Adapt shall provide Opiant with a copy of the Third Party License Agreement within ten (10) Business Days of execution of the Third Party License Agreement.

13. Amendment to Section 11.8.2 of the License Agreement. Section 11.8.2 of the License Agreement is hereby amended by replacing the address for notice of Opiant set forth therein with the following:

If to Opiant, to:

Opiant Pharmaceuticals, Inc.

201 Santa Monica Blvd., Suite 500

Santa Monica, CA 90401

Attention: CEO and CFO

With a copy (which shall not constitute notice) to:

Wilson Sonsini Goodrich & Rosati, P.C.

12235 El Camino Real

San Diego, CA 92130-3002

Attention: Martin J. Waters

Facsimile: 1-858-350-2399

14. References in the License Agreement. All references in the License Agreement to "this Agreement" shall mean the License Agreement as amended by this Amendment.

15. Limitation of Amendment and Affirmation of License Agreement. Except as expressly provided herein, this Amendment shall not be deemed to be a waiver or modification of any term, condition or covenant of the License Agreement. Any conflict between the terms herein and in the License Agreement shall be governed by the terms of this Amendment. Except as expressly amended hereby, all terms and conditions set forth in the License Agreement are hereby affirmed by the Parties and shall remain in full force and effect.

16. Incorporation by Reference. The provisions of Sections 11.3.1, 11.4, 11.5, 11.6, 11.7, 11.8, 11.10, 11.11, 11.12, 11.13, 11.14, 11.16 and 11.18 of the License Agreement are hereby incorporated by this reference, *mutatis mutandis*, as if the provisions were fully set forth herein.

[*Signature page follows*]

IN WITNESS WHEREOF, this Amendment is hereby executed by the authorized representatives of the Parties as of the date first written above.

OPIANT PHARMACEUTICALS, INC.

By: */s/ David D. O'Toole*
Name: David D O'Toole
Title: Chief Financial Officer

ADAPT PHARMA OPERATIONS LIMITED

By: */s/ David Brabazon*
Name: David Brabazon
Title: Chief Financial Officer

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: May 8, 2019

/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: May 8, 2019

/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, 2019 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: May 8, 2019

/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, 2019 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: May 8, 2019

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