UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended **June 30, 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. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

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

As of July 26, 2019, the registrant had approximately 51.6 million shares of common stock outstanding.

Emergent BioSolutions Inc.
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PART I. FINANCIAL INFORMATION

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q and the documents we incorporate by reference include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding the future earnings and performance of Emergent BioSolutions Inc. or any of our businesses, our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, 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);
- the exercise of discretion by the Biomedical Advanced Research and Development Authority (BARDA) to procure AV7909 (anthrax vaccine adsorbed with CPG 7909 adjuvant) in reliance on the U.S. Food and Drug Administration (FDA) review and acceptance of the company's pre-Emergency Use Authorization (pre-EUA) submission;
- 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), and to receive eventual licensure of AV7909 from the FDA;
- the availability of funding for our USG 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 brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent or its subsidiaries in the United States or other countries. All other brands, products, services and feature names or trademarks are the property of their respective owners.

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

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 177.4	$ 112.2
Restricted cash	0.2	0.2
Accounts receivable, net	218.1	262.5
Inventories	232.0	205.8
Prepaid expenses and other current assets	65.0	40.1
Total current assets	692.7	620.8
Property, plant and equipment, net	520.5	510.2
Intangible assets, net	742.4	761.6
In-process research and development	41.0	50.0
Goodwill	268.3	259.7
Other assets	56.4	27.1
Total assets	$ 2,321.3	$ 2,229.4
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 124.5	$ 80.7
Accrued expenses	54.8	30.7
Contingent consideration, current portion	54.6	5.6
Accrued compensation	44.7	58.2
Debt, current portion	10.1	10.1
Other current liabilities	12.5	15.1
Total current liabilities	301.2	200.4
Contingent consideration	10.4	54.4
Debt	830.4	784.5
Deferred tax liability	65.6	67.5
Deferred revenue	77.0	62.5
Other liabilities	47.8	49.2
Total liabilities	$ 1,332.4	$ 1,218.5
Commitments and contingencies (Notes 8 & 16)		
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, 52.7 shares issued and 51.6 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	(39.7)	(39.6)
Additional paid-in capital	701.8	688.6
Accumulated other comprehensive loss	(5.0)	(5.5)
Retained earnings	331.7	367.3
Total stockholders' equity	988.9	1,010.9
Total liabilities and stockholders' equity	$ 2,321.3	$ 2,229.4

See accompanying notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Product sales, net	$ 183.5	$ 180.1	$ 336.5	$ 255.8
Contract manufacturing	18.7	23.6	34.6	49.8
Contracts and grants	41.0	16.5	62.8	32.4
Total revenues	243.2	220.2	433.9	338.0
Operating expenses:				
Cost of product sales and contract manufacturing	100.8	85.3	192.7	139.4
Research and development	63.9	24.7	110.0	53.8
Selling, general and administrative	70.8	39.5	136.4	79.7
Amortization of acquisition-related intangible assets	14.7	3.9	29.2	7.8
Total operating expenses	250.2	153.4	468.3	280.7
(Loss) income from operations	(7.0)	66.8	(34.4)	57.3
Other income (expense):				
Interest expense	(9.5)	(1.0)	(19.0)	(1.2)
Other income, net	1.4	—	0.4	0.3
Total other expense, net	(8.1)	(1.0)	(18.6)	(0.9)
(Loss) income before income taxes	(15.1)	65.8	(53.0)	56.4
Income tax (benefit) expense	(5.6)	15.7	(17.4)	11.2
Net (loss) income	$ (9.5)	$ 50.1	$ (35.6)	$ 45.2
Net (loss) income per common share				
Basic	$ (0.18)	$ 1.00	$ (0.69)	$ 0.91
Diluted	$ (0.18)	$ 0.98	$ (0.69)	$ 0.89
Shares used in computing (loss) income per share				
Basic	51.5	49.9	51.3	49.7
Diluted	51.5	51.2	51.3	51.0

See accompanying notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net (loss) income	$ (9.5)	$ 50.1	$ (35.6)	$ 45.2
Other comprehensive (loss) income, net of tax:				
Foreign currency translations, net of tax	0.7	(1.2)	1.7	(0.7)
Derivatives	(1.2)	—	(1.2)	—
Total other comprehensive (loss) income, net of tax	(0.5)	(1.2)	0.5	(0.7)
Comprehensive (loss) income	$ (10.0)	$ 48.9	$ (35.1)	$ 44.5

See accompanying notes.

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

	Six Months Ended June 30,	
	2019	2018
Cash flows provided by (used in) operating activities:		
Net (loss) income	$ (35.6)	$ 45.2
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Share-based compensation expense	14.9	11.7
Depreciation and amortization	55.1	24.7
Amortization of deferred financing costs	1.5	—
Deferred income taxes	(1.3)	8.5
Change in fair value of contingent consideration, net	5.5	1.7
Other	2.9	1.2
Changes in operating assets and liabilities:		
Accounts receivable	44.6	(46.2)
Inventories	(26.1)	3.4
Prepaid expenses and other assets	(44.9)	(9.3)
Accounts payable	42.6	(4.4)
Accrued expenses	6.9	5.6
Accrued compensation	(13.5)	(8.6)
Deferred revenue	16.4	0.1
Net cash provided by operating activities:	**69.0**	33.6
Cash flows used in investing activities:		
Purchases of property, plant and equipment and other	(35.5)	(25.2)
Milestone payment from prior asset acquisition	(10.0)	—
Proceeds from sale of assets	—	2.6
Net cash used in investing activities:	(45.5)	(22.6)
Cash flows provided by (used in) financing activities:		
Proceeds from revolving credit facility	130.0	—
Principal payments on revolving credit facility	(80.0)	—
Principal payments on term loan facility	(5.6)	—
Issuances of stock under share-based benefit plans	4.6	8.5
Taxes paid on behalf of employees for equity activity	(6.3)	(6.0)
Contingent consideration payments	(1.0)	(1.3)
Purchase of treasury stock	—	(0.1)
Net cash provided by financing activities:	41.7	1.1
Effect of exchange rate changes on cash, cash equivalents and restricted cash	—	(0.1)
Net increase in cash, cash equivalents and restricted cash	65.2	12.0
Cash, cash equivalents and restricted cash at beginning of period	112.4	179.3
Cash, cash equivalents and restricted cash at end of period	$ 177.6	$ 191.3

See accompanying notes.

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

	$0.001 Par Value Common Stock		Additional Paid-In	Treasury Stock		Accumulated Other Comprehensive	Retained	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	Loss	Earnings	Equity
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	0.3	—	13.2	—	(0.1)	—	—	13.1
Net loss	—	—	—	—	—	—	(35.6)	(35.6)
Other comprehensive income	—	—	—	—	—	0.5	—	0.5
Balance at June 30, 2019	52.7	$ 0.1	$ 701.8	(1.2)	$ (39.7)	$ (5.0)	$ 331.7	$ 988.9
Balance at March 31, 2019	52.6	$ 0.1	$ 690.1	(1.2)	$ (39.6)	$ (4.5)	$ 341.2	$ 987.3
Employee equity plans activity	0.1	—	11.7	—	(0.1)	—		11.6
Net loss	—	—	—	—	—	—	(9.5)	(9.5)
Other comprehensive loss	—	—	—	—	—	(0.5)	—	(0.5)
Balance at June 30, 2019	52.7	$ 0.1	$ 701.8	(1.2)	$ (39.7)	$ (5.0)	$ 331.7	$ 988.9
Balance at December 31, 2017	50.6	$ 0.1	$ 618.4	(1.2)	$ (39.5)	$ (3.8)	$ 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**	**618.4**	**(1.2)**	**(39.5)**	**(3.8)**	**304.6**	**879.8**
Employee equity plans activity	0.6	—	14.1	—	(0.1)	—	—	14.0
Net income	—	—	—	—	—	—	45.2	45.2
Other comprehensive loss	—	—	—	—	—	(0.7)	—	(0.7)
Balance at June 30, 2018	51.2	$ 0.1	$ 632.5	(1.2)	$ (39.6)	$ (4.5)	$ 349.8	$ 938.3
Balance at March 31, 2018	51.0	$ 0.1	$ 624.4	(1.2)	$ (39.6)	$ (3.3)	$ 299.7	$ 881.3
Employee equity plans activity	0.2	—	8.1	—	—	—	—	8.1
Net income	—	—	—	—	—	—	50.1	50.1
Other comprehensive loss	—	—	—	—	—	(1.2)	—	(1.2)
Balance at June 30, 2018	51.2	$ 0.1	$ 632.5	(1.2)	$ (39.6)	$ (4.5)	$ 349.8	$ 938.3

See accompanying notes.

1. Business

Emergent 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 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 June 30, 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 six months ended June 30, 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 interest rate swaps and contingent consideration liabilities that are measured at fair value on a recurring basis (Note 8 and Note 9). The Company also records the assets and liabilities of acquisitions at fair value (Note 3). As of June 30, 2019 and December 31, 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, *Leases*, **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 of January 1, 2019 total right of use assets increased $13.4 million, while total operating lease liabilities increased $14.0 million. 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 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 (see Note 6).**

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 beginning in its March 31, 2019 Form 10-Q 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 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. The Company adopted the new standard effective January 1, 2019. 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, *Financial Instruments - Credit Losses*. 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 likely to result in the earlier recognition of allowances for losses. The guidance was further amended in January 2019 to clarify or address stakeholders' specific issues about certain aspects of the amendments in the update and in May 2019 to provide an option to irrevocably elect the fair value option for certain financial assets previously measured on an amortized cost basis. 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 its 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 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, *Compensation - Retirement Benefits - Defined Benefit Plans - General*. 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 six months ended June 30, 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 June 30, 2019, certain fair value estimates relating to intangible assets acquired and income taxes could be subject to further adjustment.

The total purchase price, revised for current period 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 June 30, 2019 and for the payment of additional consideration based on the collectability 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 inputs (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 June 30, 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 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 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 June 30, 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)	(0.4)	(34.0)
Total estimated fair value of tangible assets acquired and liabilities assumed	69.5	(0.4)	69.1
Acquired in-process research and development	9.0	(9.0)	—
Acquired intangible assets	133.0	—	133.0
Goodwill	61.6	9.4	71.0
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 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 assets

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

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 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 values an asset based on the market price of assets with comparable features such as design, location, size, construction, materials, use, capacity, specification, operational characteristics and other features or descriptions.

The Company recorded approximately $71.0 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.

	Three months ended June 30, 2019	Six months ended June 30, 2019
Revenue	$ 88.2	$ 163.1
Operating income	8.2	4.4

4. Inventories

The components of inventory are as follows:

	June 30, 2019	December 31, 2018
Raw materials and supplies	$ 66.3	$ 51.8
Work-in-process	119.1	103.2
Finished goods	46.6	50.8
Total inventories	$ 232.0	$ 205.8

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

5. Property, Plant and Equipment

Property, plant and equipment consisted of the following:

	June 30, 2019	December 31, 2018
Land and improvements	$ 46.7	$ 44.6
Buildings, building improvements and leasehold improvements	228.0	216.2
Furniture and equipment	318.8	293.9
Software	56.3	55.2
Construction-in-progress	59.9	71.8
Property, plant and equipment, gross	709.7	681.7
Accumulated depreciation and amortization	(189.2)	(171.5)
Total property, plant and equipment, net	$ 520.5	$ 510.2

6. Leases

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

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

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

The components of lease expense were as follows:

	Three months ended June 30, 2019	Six months ended June 30, 2019
Operating lease cost:		
Amortization of right-of-use assets	$ 0.7	$ 1.3
Interest on lease liabilities	0.2	0.3
Total operating lease cost	$ 0.9	$ 1.6

Supplemental balance sheet information related to leases was as follows:

(In millions, except lease term and discount rate)	Balance Sheet Location	June 30, 2019
Operating lease right-of-use assets	Other assets	$ 15.7
Operating lease liabilities, current portion	Other current liabilities	1.9
Operating lease liabilities	Other liabilities	14.6
Total operating lease liabilities		$ 16.5
Operating leases:		
Weighted Average Remaining Lease Term (years)		10.3
Weighted Average Discount Rate		4.62%

7. Intangible Assets

The Company's intangible assets consist of 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:

	June 30, 2019						
	Estimated Life (years)	Cost	Measurement Period Adjustment	Additions	Gross Total	Accumulated Amortization	Net
Intangible assets, net	5-22	$ 818.4	$ —	$ 10.0	$ 828.4	$ (86.0)	$ 742.4
IPR&D	indefinite	50.0	(9.0)	—	41.0	—	41.0
Goodwill	indefinite	259.7	8.6	—	268.3	—	268.3

	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 six months ended June 30, 2019 and 2018, the Company recorded amortization expense for intangible assets of $29.2 million and $7.8 million, respectively. During the three months ended June 30, 2019 and 2018, the Company recorded amortization expense for intangible assets of $14.7 million and 3.9 million, respectively. As of June 30, 2019, the weighted average amortization period remaining for intangible assets was 14.0 **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 and owners if future events occur or conditions are met. These liabilities associated with business combinations are measured at fair value at inception and at each subsequent reporting date with the exception of the milestone achievement. The changes in the fair value are primarily due to the expected amount and timing of future net sales, which are inputs that have no observable market (Level 3).

The Company also has contingent consideration associated with its asset acquisitions. These liabilities are not recorded as level 3 fair value measurements, but rather are accrued when the milestone has been achieved and is payable.

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

The following table is a reconciliation of the beginning and ending balance of contingent considerations and is based on level 3 significant unobservable inputs, other than the raxibacumb milestone accrual, which is based on achievement of contractual milestones.

Balance at December 31, 2018	$ 60.0
Milestone achievement - asset acquisition	10.0
Measurement period adjustment	1.5
Change in fair value	5.5
Settlements	(12.0)
Balance at June 30, 2019	$ 65.0

During the six months ended June 30, 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. Derivative Instruments and Hedging Activities

Risk Management Objective of Using Derivatives

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

Accounting Policy for Derivative Instruments and Hedging Activities

The Company's interest rate swaps qualify for hedge accounting as cash flow hedges. All derivatives are recorded on the balance sheet at fair value. Hedge accounting provides for the matching of the timing of gain or loss recognition on these interest rate swaps with the recognition of the changes in interest expense on the Company's variable rate debt. For derivatives designated as cash flow hedges of interest rate risk, the gain or loss on the derivative is recorded in accumulated other comprehensive income and subsequently reclassified into interest expense in the same period during which the hedged transaction affects earnings. Amounts reported in accumulated other comprehensive income related to derivatives will be reclassified to interest expense as interest payments are made on the Company's variable-rate debt. The cash flows from the designated interest rate swaps are classified as a component of operating cash flows, similar to interest expense. If current fair values of designated interest rate swaps remained static over the next twelve months, the Company would reclassify $0.4 million of net deferred gains from accumulated other comprehensive loss into income over the next twelve months. All outstanding cash flow hedges mature in October 2023.

As of June 30, 2019, the Company had the following outstanding interest rate derivatives that were designated as cash flow hedges of interest rate risk:

	Number of Instruments	Notional
Interest Rate Swaps	7	$ 350.0

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

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

	Asset Derivatives				Liability Derivatives			
	June 30, 2019		December 31, 2018		June 30, 2019		December 31, 2018	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Interest Rate Swaps	Other Assets	$ 0.4	Other Assets	—	Other Liabilities	$ 1.6	Other Liabilities	—

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

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

Hedging derivatives	Amount of Gain/(Loss) Recognized in OCI on Derivative		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain or (Loss) Reclassified from Accumulated OCI into Income	
	June 30, 2019	June 30, 2018		June 30, 2019	June 30, 2018
Interest Rate Swaps	$ 1.2	—	Interest expense	$ —	$ —

10. Debt

The components of debt are as follows:

	June 30, 2019	December 31, 2018
Senior secured credit agreement - Term loan due 2023	$ 441.6	$ 447.2
Senior secured credit agreement - Revolver loan due 2023	398.0	348.0
2.875% Convertible Senior Notes due 2021	10.6	10.6
Other	3.0	3.0
Total debt	853.2	808.8
Current portion of long-term debt, net of debt issuance costs	(10.1)	(10.1)
Unamortized debt issuance costs	(12.7)	(14.2)
Non-current portion of debt	$ 830.4	$ 784.5

Senior Secured Credit Agreement

On September 29, 2017, the Company entered into a senior secured credit agreement (the “2017 Credit Agreement”) with four lending financial institutions. On October 15, 2018, the Company entered into an Amended and Restated Credit Agreement (the "Amended Credit Agreement") with multiple lending institutions, which modified the 2017 Credit Agreement. The Amended Credit Agreement (i) increased the revolving credit facility (the "Revolving Credit Facility") from $200 million to $600 million, (ii) extended the maturity of the Revolving Credit Facility from September 29, 2022 to October 13, 2023, (iii) provided for a term loan in the original principal amount of $450 million (the "Term Loan Facility," and together with the Revolving Credit Facility, the "Senior Secured Credit Facilities"). The Company may request incremental term loan facilities or increases in the Revolving Credit Facility (each an "Incremental Loan") if requirements relating to net leverage ratio will be maintained on a pro forma basis.

Borrowings under the Revolving Credit Facility and the Term Loan Facility will bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.25% to 2.00% per annum, depending on the Company's consolidated net leverage ratio or (b) a base rate (which is the highest of the prime rate, the federal funds rate plus 0.50%, and a eurocurrency rate for an interest period of one month plus 1%) plus a margin ranging from 0.25% to 1.00%, depending on the Company's consolidated net leverage ratio. The Company is required to make quarterly payments under the Amended Credit Agreement for accrued and unpaid interest on the outstanding principal balance, based on the above interest rates. In addition, the Company is required to pay commitment fees ranging from 0.15% to 0.30% per annum, depending on the Company's consolidated net leverage ratio, in respect of the average daily unused commitments under the Revolving Credit Facility. The Company is to repay the outstanding principal amount of the Term Loan Facility in quarterly installments based on an annual percentage equal to 2.5% of the original principal amount of the Term Loan Facility during each of the first two years of the Term Loan Facility, 5% of the original principal amount of the Term Loan Facility during the third year of the Term Loan Facility and 7.5% of the original principal amount of the Term Loan Facility during each year of the remainder of the term of the Term Loan Facility until the maturity date of the Term Loan Facility, at which time the entire unpaid principal balance of the Term Loan Facility will be due and payable. The Company has the right to prepay the Term Loan Facility without premium or penalty. The Revolving Credit Facility and the Term Loan Facility mature (unless earlier terminated) on October 13, 2023.

The Amended Credit Agreement also requires mandatory prepayments of the Term Loan Facility in the event the Company or its Subsidiaries (a) incur indebtedness not otherwise permitted under the Amended Credit Agreement or (b) receive cash proceeds in excess of $100 million during the term of the Amended Credit Agreement from certain dispositions of property or from casualty events involving their property, subject to certain reinvestment rights.

The Amended Credit Agreement contains financial covenants, which were amended in June 2019. The financial covenants require the quarterly presentation of a minimum consolidated 12 month rolling debt service coverage ratio of 2.50 to 1.00, and an amended maximum consolidated net leverage ratio of 4.95 to 1.00 for the quarter ended June 30, 2019, 4.75 to 1.00 for the quarter ending September 30, 2019, 3.75 to 1.00 for the quarterly filing periods from October 1, 2019 through September 29, 2020 and 3.50 to 1.0 thereafter, which may be adjusted to 4.00 to 1.00 for a four quarter period in connection with a material permitted acquisition. The Amended Credit Agreement also contains affirmative and negative covenants, which were also amended in June 2019 to limit the amount of restricted payments as defined in the Amended Credit Agreement to $25 million until the filing of the Company's December 31, 2019 Form 10-K. Negative covenants in the Amended Credit Agreement, among other things, limit the ability of the Company to incur indebtedness and liens, dispose of assets, make investments and enter into certain merger or consolidation transactions. As of the date of these financial statements, the Company is in compliance with all affirmative and negative covenants.

2.875% Convertible Senior Notes due 2021

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

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

11. 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 June 30, 2019			Three Months Ended June 30, 2018		
	U.S. Government	Non-U.S. Government	Total	U.S. Government	Non-U.S. Government	Total
Product sales	$ 94.6	$ 88.9	$ 183.5	$ 169.9	$ 10.2	$ 180.1
Contract manufacturing	—	18.7	18.7	—	23.6	23.6
Contracts and grants	38.3	2.7	41.0	15.3	1.2	16.5
Total revenues	$ 132.9	$ 110.3	$ 243.2	$ 185.2	$ 35.0	$ 220.2

	Six months ended June 30, 2019			Six Months Ended June 30, 2018		
	U.S. Government	Non-U.S. Government	Total	U.S. Government	Non-U.S. Government	Total
Product sales	$ 167.9	$ 168.6	$ 336.5	$ 235.9	$ 19.9	$ 255.8
Contract manufacturing	—	34.6	34.6	—	49.8	49.8
Contracts and grants	58.7	4.1	62.8	30.1	2.3	32.4
Total revenues	$ 226.6	$ 207.3	$ 433.9	$ 266.0	$ 72.0	$ 338.0

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	23.8
Revenue recognized	(7.4)
June 30, 2019	**$ 89.5**

Transaction price allocated to remaining performance obligations

As of June 30, 2019, the Company had expected future revenues associated with performance obligations that have not been satisfied of approximately $533.2 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 USG under development contracts. In addition, the amount of future revenues associated with unsatisfied performance obligations excludes the value associated with unexercised option periods in the Company's contracts.

Contract assets

The Company considers unbilled accounts receivables and deferred costs associated with revenue generating contracts, which are not included in inventory or property, plant and equipment, as contract assets. As of June 30, 2019 and December 31, 2018, the Company had contract assets associated with deferred costs of $26.5 million and $1.2 million, respectively, which is reflected as a component of prepaid expenses and other current assets on the Company's consolidated balance sheets.

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

Accounts receivable

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

	June 30, 2019	December 31, 2018
Billed, net	$ 179.5	$ 234.0
Unbilled	38.6	28.5
Total, net	$ 218.1	$ 262.5

As of June 30, 2019 and December 31, 2018, allowances for doubtful accounts were de minimis.

12. Income taxes

The estimated effective annual tax rate for the Company, which excludes discrete adjustments, was 27% and 25% for the six months ended June 30, 2019 and 2018, respectively. The increase in the estimated effective annual tax rate is primarily due to the impact of foreign and state taxes. For each of the six month periods ended June 30, 2019 and 2018, the Company recorded a discrete tax benefit of $3.2 million, primarily due to activity associated with equity awards. For the three months ended June 30, 2019 and 2018, the Company recorded a discrete tax benefit of $1.4 million and $0.9 million, respectively, also primarily due to activity associated with equity awards.

13. (Loss) earnings per share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Numerator:				
Net (loss) earnings	$ (9.5)	$ 50.1	$ (35.6)	$ 45.2
Denominator:				
Weighted-average number of shares—basic	51.5	49.9	51.3	49.7
Dilutive securities—equity awards	—	1.3	—	1.3
Weighted-average number of shares—diluted	51.5	51.2	51.3	51.0
Net (loss) earnings per share - basic	$ (0.18)	$ 1.00	$ (0.69)	$ 0.91
Net (loss) earnings per share - diluted	$ (0.18)	$ 0.98	$ (0.69)	$ 0.89

For the three and six months ended June 30, 2019 and 2018, basic earnings per share is computed by dividing net gain/(loss) by the weighted average number of shares of common stock outstanding during the period.

For the three and six months ended June 30, 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 and six months ended June 30, 2019 due to the Company's net loss. The share-based awards that were excluded from the calculation of diluted loss per share, because they were anti-dilutive, were 3.0 million for the three and six months ended June 30, 2019.

14. Share-based compensation

During the six months ended June 30, 2019, the Company granted stock options to purchase 0.3 million shares of common stock and 0.5 million restricted stock units under the Emergent BioSolutions Inc. Stock Incentive Plan. The grants vest over three equal annual installments beginning on the day prior to the anniversary of the grant date.

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

15. 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 recognizes pension expense as a component of selling, general and administrative expense.

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 June 30, 2019	Six months ended June 30, 2019
Net service cost	$ 0.3	$ 0.6
Expected return on plan assets, net of expenses	(0.1)	(0.1)
Total pension expense	$ 0.2	$ 0.5

16. 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

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

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. At the time of the approval of the settlement 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.

17. Supplemental Information

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

	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 177.4	$ 112.2
Restricted cash	0.2	0.2
Total cash, cash equivalents and restricted cash	$ 177.6	$ 112.4

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and accompanying notes and other financial information included elsewhere in this quarterly report on Form 10-Q and our audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2018. 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 June 3, 2019, we announced a contract award by the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS) valued at approximately $535 million over 10 years for the continued supply of Vaccinia Immune Globulin Intravenous (VIGIV) into the U.S. Strategic National Stockpile (SNS) in support of smallpox preparedness.
- On May 15, 2019, we announced that BARDA informed the company that it will begin procuring AV7909 (anthrax vaccine adsorbed with CPG 7909 adjuvant) for delivery into the Strategic National Stockpile (SNS). Subject to the fulfillment of certain contractual obligations, the company plans to initiate deliveries of AV7909 in the second half of 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, following 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 six months ended June 30, 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 and Note 6 to the accompanying condensed consolidated financial statements).

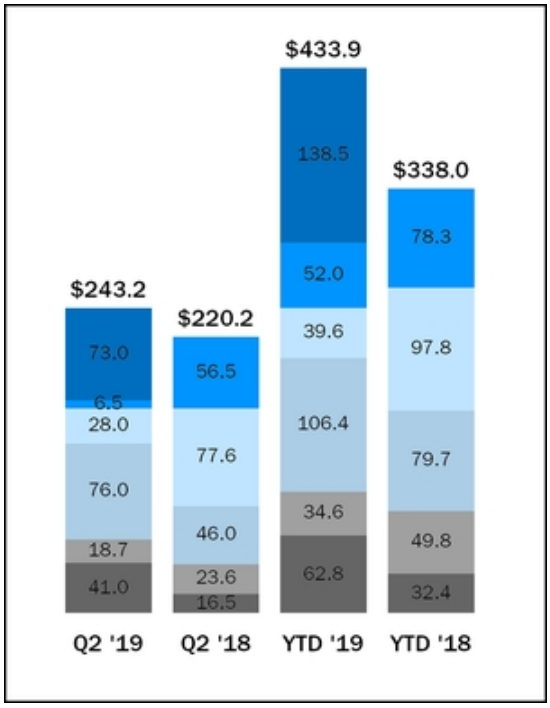
(unaudited, amounts in millions, except share and per share amounts)

Results of Operations

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Change	% Change	2019	2018	Change	% Change
Product sales net:								
NARCAN Nasal Spray	$ 73.0	$ —	$ 73.0	NM	$ 138.5	$ —	$ 138.5	NM
ACAM2000	6.5	56.5	(50.0)	(88%)	52.0	78.3	(26.3)	(34%)
BioThrax	28.0	77.6	(49.6)	(64%)	39.6	97.8	(58.2)	(60%)
Other	76.0	46.0	30.0	65 %	106.4	79.7	26.7	33%
Total product sales, net	183.5	180.1	3.4	2 %	336.5	255.8	80.7	32%
Contract manufacturing	18.7	23.6	(4.9)	(21)%	34.6	49.8	(15.2)	(31%)
Contracts and grants	41.0	16.5	24.5	NM	62.8	32.4	30.4	94%
Total revenues	243.2	220.2	23.0	10 %	433.9	338.0	95.9	28%
Operating expenses:								
Cost of product sales and contract manufacturing	100.8	85.3	15.5	18%	192.7	139.4	53.3	38%
Research and development	63.9	24.7	39.2	NM	110.0	53.8	56.2	NM
Selling, general and administrative	70.8	39.5	31.3	79%	136.4	79.7	56.7	71%
Amortization of intangible assets	14.7	3.9	10.8	NM	29.2	7.8	21.4	NM
Total operating expenses	250.2	153.4	96.8	63%	468.3	280.7	187.6	67%
(Loss) income from operations	(7.0)	66.8	(73.8)	NM	(34.4)	57.3	(91.7)	NM
Other income (expense):								
Interest expense	(9.5)	(1.0)	(8.5)	NM	(19.0)	(1.2)	(17.8)	NM
Other income, net	1.4	—	1.4	NM	0.4	0.3	0.1	33%
Total other expense, net	(8.1)	(1.0)	(7.1)	NM	(18.6)	(0.9)	(17.7)	NM
(Loss) income before income taxes	(15.1)	65.8	(80.9)	NM	(53.0)	56.4	(109.4)	NM
Income tax (benefit) expense	(5.6)	15.7	(21.3)	NM	(17.4)	11.2	(28.6)	NM
Net (loss) income	$ (9.5)	$ 50.1	$ (59.6)	NM	$ (35.6)	$ 45.2	$ (80.8)	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 quarter and year-to-date periods.

ACAM2000

The decrease in ACAM2000 sales for the three and six months ended June 30, 2019 was primarily due to the volume of ACAM2000 delivered to the SNS during the three and six months ended June 30, 2019 as compared to the three and six months ended June 30, 2018. Substantially all of the ACAM2000 product sales revenues during the six months ended June 30, 2019 and 2018 were made to the USG under a long-term procurement contract at a consistent value per dose. Delivery obligations under this long-term procurement contract were fully satisfied during the quarter ended March 31, 2019.

BioThrax

The decrease in BioThrax sales for the three and six months ended June 30, 2019 was primarily due to the number of BioThrax deliveries to the SNS during the period as compared to the three and six months ended June 30, 2018. The USG purchased fewer units of BioThrax during the three and six months ended June 30, 2019 partially in anticipation of the transition to the Company's next generation anthrax vaccine, AV7909, which we expect to begin delivering to the SNS in the second half of 2019. The decrease in units delivered was slightly offset by contractual per unit pricing increases. 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.

Other Product Sales

The increase in the Company's other product sales during the three and six months ended June 30, 2019 was primarily due to the contribution of products associated with the PaxVax acquisition as well as increased sales of raxibacumab, which was partially offset by a decrease in Trobigard sales compared to the three and six months ended June 30, 2018.

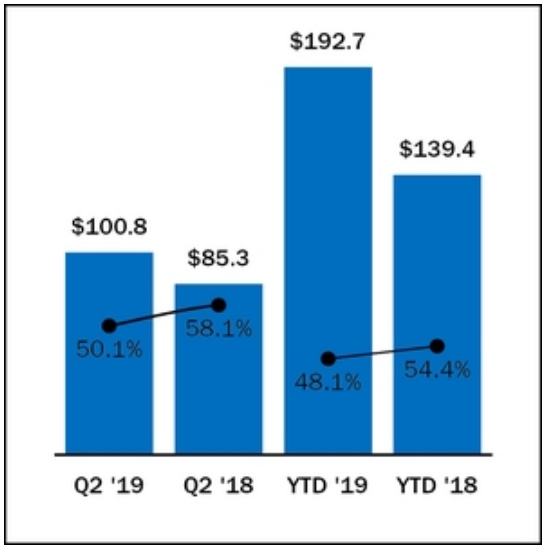
Contract Manufacturing

The decrease in contract manufacturing revenue for the three and six months ended June 30, 2019 compared to comparative periods in 2018 is due to Canton contract manufacturing activities in 2018 that did not recur in 2019. The six months ended June 30, 2019 was further impacted by 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 six months ended June 30, 2019.

Contracts and Grants

The increase in contracts and grants revenue for the three and six months ended June 30, 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 and six months ended June 30, 2018 for which no similar services were provided in current period.

Cost of Product Sales and Contract Manufacturing

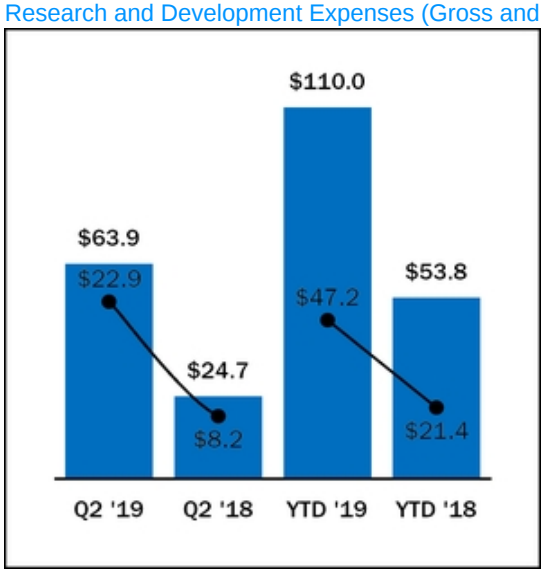


Cost of Product Sales and Contract Manufacturing

l Gross profit margin for product sales and contract manufacturing

Cost of product sales and contract manufacturing increased for the three and six months ended June 30, 2019 primarily due to the acquisitions of Adapt and PaxVax, both acquired in October 2018, as well as an increase in facilities related expenses during the three and six months ended June 30, 2019.

Research and Development Expenses (Gross and Net)

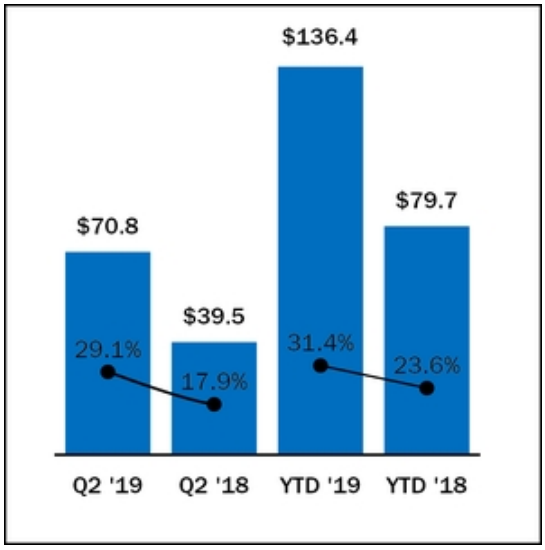


Research and Development expense

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

Research and development expenses increased the three and six months ended June 30, 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.

Selling, General and Administrative Expenses



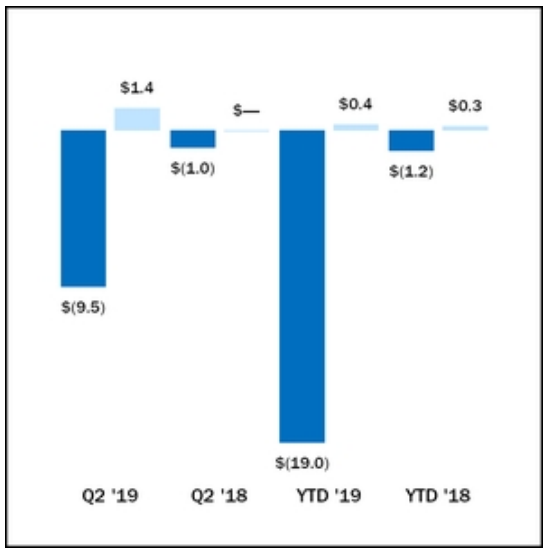
Selling, General and Administrative
SG&A as a percentage of total revenue

Selling, general and administrative expenses increased for the three and six months ended June 30, 2019 primarily due to $21.5 million and $42.0 million in expenses related to the operations and integration of newly acquired entities during the three and six months ended June 30, 2019, respectively. The newly acquired entities were 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 increase in amortization of intangible assets for the three and six months ended June 30, 2019 compared to 2018 was primarily due to the acquisitions of Adapt and PaxVax.

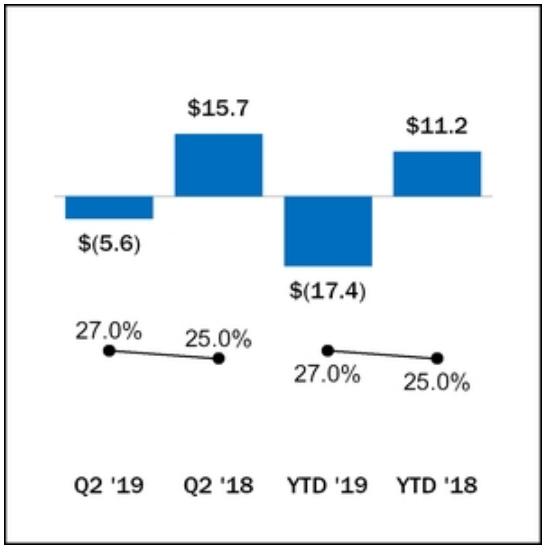
Total Other Income (Expense), Net



Interest expense
Other income (expense)

Total other expense, net increased by $7.1 million and $17.7 million for the three and six months ended June 30, 2019 due to an increase in **borrowings on our senior secured credit facilities established in October 2018 to fund our acquisitions of Adapt and PaxVax.**

Income Tax (Benefit) Expense



Income tax (benefit) expense

l Effective tax rate

The income tax benefit is the result of losses incurred during the three and six months ended June 30, 2019, whereas the three and six months ended June 30, 2018 had taxable income. These losses were impacted by corresponding increases in the effective foreign and state income tax rates.

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

Liquidity and Capital Resources

Sources of Liquidity

We have historically financed our operating and capital expenditures through cash on hand, cash from operations, debt financing and development funding. We also obtain financing from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the last five years for the period ended December 31, 2018. As of June 30, 2019, we had unrestricted cash and cash equivalents of $177.4 million. As of June 30, 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 six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,	
	2019	2018
Net cash provided by (used in):		
Operating activities	$ 69.0	$ 33.6
Investing activities	(45.5)	(22.6)
Financing activities	41.7	1.1
Effect of exchange rate changes on cash, cash equivalents and restricted cash	—	(0.1)
Net increase in cash, cash equivalents and restricted cash	$ 65.2	$ 12.0

Operating Activities

Net cash provided by operating activities of $69.0 million for the six months ended June 30, 2019 was primarily due to changes in working capital for accounts receivable and accounts payable. Net operating losses were offset by non cash charges.

Net cash provided by operating activities of $33.6 million for the six months ended June 30, 2018 was primarily due to net income offset by increases in accounts receivable.

Investing Activities

Net cash used in investing activities of $45.5 million for the six months ended June 30, 2019 reflects software, infrastructure and equipment investments.

Net cash used in investing activities of $22.6 million for the six months ended June 30, 2018 reflects infrastructure and equipment investments.

Financing Activities

Net cash provided by financing activities of $41.7 million for the six months ended June 30, 2019 was primarily due to the net $44.4 million of credit on our debt facility, offset by contingent consideration payments.

Net cash provided by financing activities of $1.1 million for the six months ended June 30, 2018 was primarily employee equity activity.

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 up to an aggregate of $50 million of our common stock under a board-approved share repurchase program through December 31, 2019. Any repurchased shares will be available for use in connection with our stock plans and for other corporate purposes. As of June 30, 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 Risk

We have interest rate and foreign currency market risk. We manage our interest rate risk in part by entering into interest rate swaps to swap a portion of our indebtedness that is based on variable interest rates to a fixed rate. We currently do not hedge our foreign currency exchange exposure, and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations. We have not used derivative financial instruments for speculative 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 variable and fixed rates of interest. Floating rate debt carries interest based 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 with consideration to outstanding debt and interest rate swap commitments as of June 30, 2019, would increase our interest expense by $4.9 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 June 30, 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 June 30, 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 June 30, 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 six months ended June 30, 2019, and which constituted $1.1 billion and $881.5 million of total assets and net assets, respectively as of June 30, 2019 and $163.1 million and $4.4 million of revenues and operating income, respectively, for the six months ended June 30, 2019.

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 Centers for Disease Control and Prevention (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 CDC 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, BARDA may never initiate the transition to stockpiling AV7909, 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.

RELIANCE ON THIRD PARTIES

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

We purchase certain supplies used in our manufacturing processes from non-exclusive, or single sources due to quality considerations, costs or constraints resulting from regulatory requirements, including key components for NARCAN® Nasal Spray (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.

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.

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.

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, purity and potency in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase 3 trials conducted in patients with the disease or condition being targeted.

However, 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.

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

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We and our collaborators must therefore comply with requirements concerning advertising and

promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved.

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

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

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

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

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

The FDA and other agencies, including the Department of Justice (DOJ), closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;

- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

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

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the ACA). Among the provisions of the ACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board (IPAB), which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within the Centers for Medicare & Medicaid Services (CMS) to test innovative payment and service delivery models.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to

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

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective on January 1, 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session. It is possible that such initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While the timing and scope of any potential future legislation to amend the ACA is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with an ACA coverage expansion provision. We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

The Trump Administration has also taken executive actions to challenge or delay implementation of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the Trump Administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

In addition, the CMS has proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the proposed rule changes would allow Medicare Advantage plans to use pre authorization (PA) and step therapy (ST) for six protected classes of drugs, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs; and change the definition of "negotiated prices," while providing a definition of "price concession" in the regulations. It is unclear whether these proposed changes will be accepted, and if so, what effect such changes will have on our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. The Trump Administration

has recently represented to the Court of Appeals considering this judgment that it does not oppose the lower court's ruling. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States, and members of Congress and the Trump Administration have stated that they will address such costs through new legislative and administrative measures. To date, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Specifically, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on May 11, 2018, the Administration issued a plan to lower drug prices. Under this blueprint for action, the Administration indicated that HHS will: take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' ads to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases. More recently, on January 31, 2019, the HHS Office of Inspector General proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations.

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

If *we fail to comply with foreign, federal, state and local 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;**

- **the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $10,781 to $21,563 per false claim;**

- **the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any 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.

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, integrity obligations, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs.

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.

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.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom had a period of a maximum of two years from the date of its formal notification to negotiate the terms of its withdrawal from, and future relationship with, the European Union. If no formal withdrawal agreement can be reached between the United Kingdom and the European Union, then it is expected that the United Kingdom's membership of the European Union would automatically terminate on the deadline, which was initially March 29, 2019. That deadline has been extended to October 31, 2019 to allow the parties to negotiate a withdrawal agreement, which has proven to be extremely difficult to date. Discussions between the United Kingdom and the European Union will continue to focus on withdrawal issues and transition agreements. However, limited progress to date in these negotiations and ongoing uncertainty within the government of the United Kingdom sustains the possibility of the United Kingdom leaving the European Union without a withdrawal agreement and associated

transition period in place, which is likely to cause significant market and economic disruption.

Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of our products or any future product candidate in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

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

As we continue to expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

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

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

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

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

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

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

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 raxibacumab and certain other products, which may not be obtained on a timely basis or at all.

FDA approval is required for the release of each lot of raxibacumab. We are not able to sell any lots that fail to satisfy the FDA 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 raxibacumab is performed against qualified control lots that we maintain. We continually monitor the status of our reference lots for FDA compliance 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 raxibacumab, our ability to sell raxibacumab would be impaired until such time as we become able to meet the FDA's requirements, which could materially harm our future business, financial condition, operating results and cash flows.

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

Our operations involve the use of hazardous materials, including chemicals, bacteria and viruses, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf, are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. Under the Federal Select Agent Program, pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act, we are required to register with and be inspected by the CDC and the Animal and Plant Health Inspection Service if we have in our possession, or if we use or transfer, select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires stringent safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel and establishes a comprehensive national database of registered entities. We are also subject to a variety of environmental and occupational health and safety laws. Compliance with current or future laws and regulations 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, nasal sprays or improvised nasal spray kits. In addition, other entrants may seek approval to market generic versions of NARCAN® Nasal Spray before the underlying patents expire. For example, in 2016 Teva filed, and in 2018 Perrigo filed, 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. Teva may decide to launch its approved generic product although the launch would be at risk since the litigation we instituted against Teva is still ongoing.

Additionally, in January 2019, the FDA released new proposed template Drug Facts Labels to assist sponsors of investigational naloxone nasal sprays and auto-injectors seeking approval from the FDA for over-the-counter naloxone products. Any reduction in demand for NARCAN® Nasal Spray in favor of a competing product, or unsuccessful efforts to defend underlying patents from infringement by generic entrants, could lead to a loss of market share and cause reduced revenues, margins and levels of profitability for us, which could adversely affect our business, financial condition, operating results and cash flows.

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

Products developed to counter the potential impact of PHTs, 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 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 in which we have an interest and, although we may have the right to assume the maintenance and defense of such intellectual property rights if these third parties do not do so, our ability to maintain and defend such intellectual property rights may be compromised by the acts or omissions of these third parties. For example, we license from:

- **Opiant Pharmaceuticals, Inc. formulations of naloxone, 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.

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

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

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

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

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

Further, the 2010 Patient Protection and Affordable Care Act, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA). That Act established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. As of January 1, 2018, the FDA has approved nine biosimilar products for use in the United States. No interchangeable biosimilars, have been approved. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidances are expected to be finalized by FDA in the near term.

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

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

FINANCIAL RISKS

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

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

- requiring us to dedicate a substantial portion of any cash flow from operations to payment on our debt, which would reduce the amounts available to fund other corporate initiatives;
- increasing the amount of interest that we have to pay on debt with variable interest rates, if market rates of interest increase;
- subjecting us, as under our senior secured credit facilities, to restrictive covenants that may reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing;
- requiring us to pledge our assets as collateral, which could limit our ability to obtain additional debt financing;
- limiting our flexibility in planning for, or reacting to, general adverse economic and industry conditions; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

We may not have sufficient funds or be able to obtain additional financing to pay the amounts due under our indebtedness. In addition, failure to comply with the covenants under our senior secured credit facilities and other debt agreements could result in an event of default under those agreements. An event of default could result in the acceleration of amounts due under a particular debt agreement and a cross default and acceleration under other debt agreements, and we may not have sufficient funds to pay or be able to obtain additional financing to make any accelerated payments. Under these circumstances, our lenders could seek to enforce security interests in our assets securing our indebtedness.

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

In connection with the acquisition of Adapt, we entered into an amendment and restatement of our 2017 credit agreement to provide for new five-year syndicated senior secured credit facilities that replaced our existing facility. The senior secured credit facilities include a $450 million Term Loan and the ability to borrow up to a $600 million revolver, of which we had outstanding borrowings of $442 million and $398 million, respectively, as of June 30, 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 agreements could result in an event of default under those instruments. An event of default could result in the acceleration of amounts due under a particular debt agreement and a cross default and acceleration under other debt agreements, and we may not have sufficient funds or be able to obtain additional financing to make any accelerated payments. Under these circumstances, our lenders could seek to enforce security interests in our assets securing our indebtedness.

Our hedging program is subject to counterparty default risk

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

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

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements. In August 2018, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a “well-known seasoned issuer” under SEC rules (which include, among other things, the timely filing of our reports under the Exchange Act and maintenance of at least $700 million of public float or issuing an aggregate amount of $1 billion of non-convertible securities, other than common stock, in registered offerings for cash during the past three years), this shelf registration statement, effective until August 8, 2021, allows us to issue an unrestricted amount of equity, debt and certain other types of securities through one or more future primary or secondary offerings. If we do not file a new shelf registration statement prior to August 8, 2021, the existing shelf registration statement will expire, and we will not be able to publicly raise capital or issue debt until a new registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatically effective shelf registration statement at a future date when we may need to raise funds publicly.

If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our senior secured credit facilities, limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities or declaring dividends. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us. We are not restricted under the terms of the indenture governing our 2.875% Convertible Senior Notes due 2021 (Senior Convertible Notes) from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that could have the effect of diminishing our ability to make payments on our indebtedness. However, our senior secured credit facilities restrict our ability to incur additional indebtedness, including secured indebtedness.

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

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

Although we have been profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. Our profitability has been substantially dependent on product sales, which historically have fluctuated significantly from quarter to quarter, and we expect that they will continue to fluctuate significantly based primarily on the timing of our fulfillment of orders from the USG. We may not be able to achieve consistent profitability on a quarterly

basis or sustain or increase profitability on an annual basis.

SPIN-OFF OF OUR BIOSCIENCES BUSINESS RISKS

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 July 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 July 26, 2019, our common stock has traded as high as $73.89 per share and as low as $4.20 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 June 30, 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

On June 27, 2019, certain amendments were made to the Amended Credit Agreement which extended the covenant relief period (collectively, the Amendment). The Amendment included, among other things, a change to the maximum consolidated net leverage ratio of 4.95 to 1.00 for the quarter ended June 30, 2019 and 4.75 to 1.00 for the quarter ended September 30, 2019. Covenants in the Amended Credit Agreement were also amended to limit the amount of restricted payments as defined in the Amended Credit Agreement to $25 million until the filing of the Company's December 31, 2019 Form 10-K. This description of the Amendment does not purport to be complete and is qualified in its entirety by the full text of the Amendment, which is filed hereto as Exhibit 10.2.

ITEM 6. EXHIBITS

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

EXHIBIT INDEX

Exhibit Number	Description
10.1#†	Modification No. 17, effective June 13, 2019, to the Solicitation/Contract/Order for Commercial Items, effective December 8, 2016, from the Centers for Disease Control and Prevention to Emergent Biodefense Operations Lansing LLC.
10.2#	First Amendment, dated June 27, 2019, to Amended and Restated Credit Agreement, dated October 15, 2018, by and among Emergent BioSolutions Inc., the lenders party thereto from time to time, and Wells Fargo Bank, National Association, as the Administrative Agent.
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 the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Calculation Linksbase Document.
101.DEF	Inline XBRL Taxonomy Definition Linksbase Document.
101.LAB	Inline XBRL Taxonomy Label Linksbase Document.
101.PRE	Inline 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 and six months ended June 30, 2019 and 2018;
(ii) Condensed Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2019 and 2018;
(iii) Condensed Consolidated Balance Sheets at June 30, 2019 and December 31, 2018;
(iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2019 and 2018; and
(v) Condensed Consolidated Statement of Changes in Stockholders' Equity for the six months ended June 30, 2019 and 2018; and
(vi) Notes to Condensed Consolidated Financial Statements.

Filed herewith.

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

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

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

Date: August 1, 2019

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

Date: August 1, 2019

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES 1 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ NO.	5. PROJECT NO. *(If applicable)*
P00017	06/13/2019	OS242076	

6. ISSUED BY CODE	ASPR-BARDA	7. ADMINISTERED BY *(If other than Item 6)* CODE	ASPR-BARDA02
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*			
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 330303 Attn: DIANA EMERGENT BIODEFENSE OPERATIONS LANS 3500 N MARTIN LUTHER KING JR BLVD LANSING MI 489062933		(x)	9A. AMENDMENT OF SOLICITATION NO.
			9B. DATED *(SEE ITEM 11)*
		x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSD200201792634C
			10B. DATED *(SEE ITEM 13)* 12/08/2016
CODE 330303	FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)* Net Increase: $27,927,000.00
See Schedule

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.217-7 Option for Increased Quantity – Separately Priced Line Item
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor is not, is required to sign this document and return ____1____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
Tax ID Number: [**]
DUNS Number: [**]
The purpose of this modification is to:

1. Order an increased quantity of [**] doses of BioThrax [**] year product at a unit price of $[**] per dose for a total cost of $27,927,000.00.

2. Accordingly, total contract value is hereby increased from $492,321,363.90 by $27,927,000.00 to read $520,248,368.90.

3. This modification supersedes the Authorization to Proceed dated June 13, 2019. Continued…

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)	
Michael Mann, Sr. Manager Comm. Ops.		Natasha Y. Rowland	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ J. Michael Mann II *(Signature of person authorized to sign)*	9 Jul 19	By /s/ Natasha Y. Rowland *(Signature of Contracting Officer)*	7/9/2019

NAME OF OFFEROR OR CONTRACTOR

EMERGENT BIODEFENSE OPERATIONS LANSING LLC 330303

ITEM No. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	4. No further changes. Delivery Location Code: HHS HHS 200 Independence Avenue, SW Washington DC 20201 US FOB: Origin Period of Performance: [**] to [**] Change Item 3 to read as follows (amount shown is the obligated amount):				
3	Optional Line Item 0003 BioThrax [**] product Expiry dating upon date of delivery: No less than [**] Months and no more than [**] months for [**]-year product at a unit price of [**] Quantity: [**] Unit Price: [**] Total Value: $27,927,000.00 Total dollar value ordered under Item 3 is increased by $27,927,000.00 from $[**] to $[**]. Delivery Address: Contractor's Facility Delivery is estimated to occur by NLT [**] Amount: $[**] Accounting Info: [**] Appr. Yr.: 2019 CAN: [**] Object Class: 26402 Funded: $0.00 Amount: $[**] Accounting Info: [**] Appr. Yr.: 2019 CAN: [**] Object Class: 26402 Funded: $0.00 Amount: $27,927,000.00 Accounting Info: [**] Appr. Yr.: 2019 CAN: 199SNS1 Object Class: 26402 Funded: $27,927,000.00				$27,927,000.00

FIRST AMENDMENT TO AMENDED AND RESTATED CREDIT AGREEMENT

FIRST AMENDMENT TO AMENDED AND RESTATED CREDIT AGREEMENT (this "Amendment"), dated as of June 27, 2019, among EMERGENT BIOSOLUTIONS INC., a Delaware corporation (the "Borrower"), the Guarantors (as defined in the Credit Agreement referred to below) party hereto, the Lenders party hereto (the "Consenting Lenders"), and WELLS FARGO BANK, NATIONAL ASSOCIATION, as administrative agent (the "Administrative Agent"). Unless otherwise indicated, all capitalized terms used herein and not otherwise defined herein shall have the respective meanings provided such terms in the Credit Agreement referred to below.

W I T N E S S E T H:

WHEREAS, the Borrower, the lenders party thereto from time to time (the "Lenders") and the Administrative Agent have entered into that certain Amended and Restated Credit Agreement, dated as of October 15, 2018 (as amended, supplemented or otherwise modified prior to the date hereof, the "Existing Credit Agreement"; the Existing Credit Agreement, as amended by this Amendment, the "Credit Agreement");

WHEREAS, the Borrower has requested, and subject to the terms and conditions set forth herein, the Administrative Agent and the Consenting Lenders have agreed, to certain amendments to the Existing Credit Agreement as more specifically set forth herein;

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is agreed as follows:

SECTION 1. Amendments to Existing Credit Agreement. Effective as of the Amendment Effective Date (as defined in Section 2 below) and subject to the terms and conditions set forth herein and in reliance upon the representations and warranties set forth herein, the Existing Credit Agreement is hereby amended as follows:

(a) Article I of the Existing Credit Agreement is hereby amended by adding the following defined terms in appropriate alphabetical order:

"Covenant Relief Period" means the period commencing with the First Amendment Effective Date and ending on the date that the Borrower provides the financial statements referred to in Section 8.1(a) for the fiscal year ended December 31, 2019, together with a duly completed Compliance Certificate for such period pursuant to Section 8.2(a) demonstrating compliance with the financial covenants set forth in Section 9.11.

"First Amendment Effective Date" means June 27, 2019.

"PTE" means a prohibited transaction class exemption issued by the U.S. Department of Labor, as any such exemption may be amended from time to time.

(b) Article I of the Existing Credit Agreement is hereby amended by adding the following new Section 1.16 thereto and in connection therewith the table of contents shall be amended to include a reference to "SECTION 1.16 Divisions":

"SECTION 1.16 Divisions. For all purposes under the Loan Documents, in connection with any division or plan of division under Delaware law (or any comparable event under a different jurisdiction's laws): (a) if any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then it shall be deemed to have been transferred from the original Person to the subsequent Person, and (b) if any new Person comes into existence, such new Person shall be deemed to have been organized on the first date of its existence by the holders of its Equity Interests at such time."

(c) Section 5.13(a) of the Existing Credit Agreement is hereby amended by adding the parenthetical "(without giving effect to the increased maximum Consolidated Net Leverage Ratio levels permitted during the Covenant Relief Period set forth in Section 9.11(b))" immediately following the reference to "Section 9.11" in proviso (B) of such Section.

(d) Section 9.2 of the Existing Credit Agreement is hereby amended by adding the parenthetical "(without giving effect to the increased maximum Consolidated Net Leverage Ratio levels permitted during the Covenant Relief Period set forth in Section 9.11(b))" immediately following the reference to "Section 9.11" in clause (g)(iv)(A) of such Section.

(e) Section 9.3 of the Existing Credit Agreement is hereby amended by adding the parenthetical "(without giving effect to the increased maximum Consolidated Net Leverage Ratio levels permitted during the Covenant Relief Period set forth in Section 9.11(b))" immediately following the reference to "Section 9.11(b)" in clause (h)(ii)(A) of such Section.

(f) Section 9.6 of the Existing Credit Agreement is hereby amended by replacing the proviso at the end of clause (d) of such Section with "; provided that the aggregate amount of Restricted Payments made pursuant to this Section 9.6(d) shall not exceed (x) $100,000,000 per calendar year and (y) $25,000,000 during the Covenant Relief Period;".

(g) Section 9.11 of the Existing Credit Agreement is hereby amended by (i) replacing the word "Permit" in the first sentence of such Section with "Subject to the sentence below during the Covenant Relief Period, permit" and (ii) adding the following paragraph to the end of clause (b) of such Section as follows:

"Notwithstanding any of the foregoing, the maximum Consolidated Net Leverage Ratio permitted pursuant to Section 9.11(b) during the Covenant Relief Period as of the last day of the applicable Measurement Period of the Borrower shall be (x) 4.95 to 1.00 for the

fiscal quarter ended June 30, 2019 and (y) 4.75 to 1.00 for the fiscal quarter ended September 30, 2019, after which the maximum Consolidated Net Leverage Ratio permitted pursuant to this Section 9.11(b) shall be subject to the levels set forth in the table above."

(h) Article XII of the Existing Credit Agreement is hereby amended by adding the following new Section 12.26 thereto and in connection therewith the table of contents shall be amended to include a reference to "SECTION 12.26 Acknowledgement Regarding Any Supported QFCs":

"SECTION 12.26 Acknowledgement Regarding Any Supported QFCs. To the extent that the Loan Documents provide support, through a guarantee or otherwise, for Hedge Agreements or any other agreement or instrument that is a QFC (such support, "QFC Credit Support" and, each such QFC, a "Supported QFC"), the parties acknowledge and agree as follows with respect to the resolution power of the FDIC under the Federal Deposit Insurance Act and Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act (together with the regulations promulgated thereunder, the "U.S. Special Resolution Regimes") in respect of such Supported QFC and QFC Credit Support (with the provisions below applicable notwithstanding that the Loan Documents and any Supported QFC may in fact be stated to be governed by the laws of the State of New York and/or of the United States or any other state of the United States):

(a) In the event a Covered Entity that is party to a Supported QFC (each, a "Covered Party") becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer of such Supported QFC and the benefit of such QFC Credit Support (and any interest and obligation in or under such Supported QFC and such QFC Credit Support, and any rights in property securing such Supported QFC) from such Covered Party will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if the Supported QFC and such QFC Credit Support (and any such interest, obligation and rights in property) were governed by the laws of the United States or a state of the United States. In the event a Covered Party or a BHC Act Affiliate of a Covered Party becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under the Loan Documents that might otherwise apply to such Supported QFC or any QFC Credit Support that may be exercised against such Covered Party are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if the Supported QFC and the Loan Documents were governed by the laws of the United States or a state of the United States. Without limitation of the foregoing, it is understood and agreed that rights and remedies of the parties with respect to a Defaulting Lender shall in no event affect the rights of any Covered Party with respect to a Supported QFC or any QFC Credit Support.

(b) As used in this Section 12.26, the following terms have the following meanings:

"BHC Act Affiliate" of a party means an "affiliate" (as such term is defined under, and interpreted in accordance with, 12 U.S.C. 1841(k)) of such party.

"Covered Entity" means any of the following:

(i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b);

(ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or

(iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b).

"Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable.

"QFC" has the meaning assigned to the term "qualified financial contract" in, and shall be interpreted in accordance with, 12 U.S.C. 5390(c)(8)(D)."

SECTION 2. Conditions of Effectiveness of Amendment. This Amendment, and the amendments set forth in Section 1 above, shall become effective on the date (such date, the "Amendment Effective Date") when the Administrative Agent shall have received this Amendment, duly executed by a Responsible Officer of the Borrower, the Guarantors existing as of the Amendment Effective Date, the Administrative Agent and the Required Lenders.

SECTION 3. Representations and Warranties. To induce the Administrative Agent and the Lenders to enter into this Amendment, each Credit Party represents and warrants to the Administrative Agent and the Lenders on and as of the Amendment Effective Date that, in each case:

(a) the representations and warranties of each Credit Party set forth in the Credit Agreement and in each other Loan Document to which it is a party are true and correct in all material respects on and as of the Amendment Effective Date with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date, in which case they shall be true and correct in all material respects as of such earlier date; provided that any representation and warranty that is qualified as to "materiality," "Material Adverse Effect" or similar language shall be true and correct (after giving effect to any qualification therein) in all respects on such respective dates;

(b) no Default or Event of Default has occurred and is continuing;

(c) it has all requisite power and authority and has taken all necessary corporate and other action to authorize the execution, delivery and performance of this Amendment and each other document executed in connection herewith to which it is a party in accordance with their respective terms and the transactions contemplated hereby; and

(d) this Amendment and each other document executed in connection herewith has been duly executed and delivered by the duly authorized officers of each Credit Party, and each such document constitutes the legal, valid and binding obligation of each such Credit Party, enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other laws affecting creditors' rights generally and subject to general principals of equity.

SECTION 4. Reference to and Effect on the Credit Agreement and the Loan Documents. Except as expressly provided herein, the Existing Credit Agreement and the other Loan Documents shall remain unmodified and in full force and effect. This Amendment shall not be deemed (a) to be a waiver of, or consent to, or a modification or amendment of, any other term or condition of the Existing Credit Agreement or any other Loan Document other than as expressly set forth herein, (b) to prejudice any right or rights which the Administrative Agent or the Lenders may now have or may have in the future under or in connection with the Existing Credit Agreement or the other Loan Documents or any of the instruments or agreements referred to therein, as the same may be amended, restated, supplemented or modified from time to time, or (c) to be a commitment or any other undertaking or expression of any willingness to engage in any further discussion with the Borrower, any of its Subsidiaries or any other Person with respect to any other waiver, amendment, modification or any other change to the Existing Credit Agreement or the Loan Documents or any rights or remedies arising in favor of the Lenders or the Administrative Agent, or any of them, under or with respect to any such documents. References in the Credit Agreement to "this Agreement" (and indirect references such as "hereunder", "hereby", "herein", "hereof" or other words of like import) and in any Loan Document to the "Credit Agreement" shall be deemed to be references to the Existing Credit Agreement as modified hereby.

SECTION 5. Further Assurances. Each Credit Party agrees to, to the extent required by the Loan Documents, make, execute and deliver all such additional and further acts, things, deeds, instruments and documents as the Administrative Agent may reasonably require for the purposes of implementing or effectuating the provisions of this Amendment and the other Loan Documents.

SECTION 6. Acknowledgement and Reaffirmation. Each Credit Party (a) consents to this Amendment and agrees that the transactions contemplated by this Amendment shall not limit or diminish the obligations of such Person under, or release such Person from any obligations under, any of the Loan Documents to which it is a party (as amended pursuant to this Amendment), (b) confirms and reaffirms its obligations under each of the Loan Documents to which it is a party (as amended pursuant to this Amendment) and (c) agrees that each of the Loan Documents to which it is a party (as amended pursuant to this Amendment) remains in full force and effect and is hereby ratified and confirmed.

SECTION 7. Costs and Expenses. The Borrower hereby reconfirms its obligations pursuant to Section 12.3(a) of the Credit Agreement to pay and reimburse the Administrative Agent in accordance with the terms thereof.

SECTION 8. Governing Law. THIS AMENDMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

SECTION 9. Counterparts. This Amendment may be executed in any number of counterparts and by the different parties hereto on separate counterparts, each of which counterparts when executed and delivered shall be an original, but all of which shall together constitute one and the same instrument. Delivery by facsimile or electronic transmission of an executed counterpart of a signature page to this Amendment shall be effective as delivery of an original executed counterpart of this Amendment.

SECTION 10. Entire Agreement. This Amendment is the entire agreement, and supersedes any prior agreements and contemporaneous oral agreements, of the parties concerning its subject matter. This Amendment is a Loan Document and is subject to the terms and conditions of the Credit Agreement.

SECTION 11. Successors and Assigns. This Amendment shall be binding on and inure to the benefit of the parties hereto and their successors and permitted assigns.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized officers to execute and deliver this Amendment as of the date first above written.

EMERGENT BIOSOLUTIONS INC., as Borrower

By: /s/ Richard S. Lindahl

Name: Richard S. Lindahl
Title: EVP, Chief Financial Officer and Treasurer

CANGENE BIOPHARMA LLC, as Guarantor

By: /s/ Richard S. Lindahl

Name: Richard S. Lindahl
Title: Treasurer

EMERGENT BIODEFENSE OPERATIONS LANSING LLC, as Guarantor

By: /s/ Richard S. Lindahl

Name: Richard S. Lindahl
Title: Treasurer

EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC, as Guarantor

By: /s/ Richard S. Lindahl

Name: Richard S. Lindahl
Title: Executive Manager

EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC., as Guarantor

By: /s/ Richard S. Lindahl

Name: Richard S. Lindahl
Title: Treasurer

EMERGENT INTERNATIONAL INC., as Guarantor

By: /s/ Richard S. Lindahl

Name: Richard S. Lindahl
Title: Treasurer

EMERGENT TRAVEL HEALTH INC. (FORMERLY KNOWN AS PAXVAX, INC.), as Guarantor

By: /s/ Richard S. Lindahl

Name: Richard S. Lindahl
Title: CFO and Treasurer

ADAPT PHARMA INC., as Guarantor

By: /s/ Richard S. Lindahl

Name: Richard S. Lindahl
Title: Treasurer

WELLS FARGO BANK, NATIONAL ASSOCIATION, as Administrative Agent, Swingline Lender, Issuing Lender and Lender

By: /s/ Kent S. Davis
Name: Kent S. Davis
Title: Managing Director

JPMORGAN CHASE BANK, N.A., as Lender

By: /s/ Anthony Galea

Name: Anthony Galea
Title: Executive Director

PNC BANK, NATIONAL ASSOCIATION, as Lender

By: /s/ Eric H. Williams
Name: Eric H. Williams
Title: Senior Vice President

ROYAL BANK OF CANADA, as Lender

By: /s/ Steven T. Bachman
Name: Steven T. Bachman
Title: Authorized Signatory

BMO HARRIS BANK, N.A., as Lender

By: /s/ Eric Oppenheimer
Name: Eric Oppenheimer
Title: Managing Director

CAPITAL ONE, N.A., as Lender

By: /s/ Jeffrey Schaal
Name: Jeffrey Schaal
Title: Duly Authorized Signatory

CITIZENS BANK, N.A., as Lender

By: /s/ Jack J. Euston
Name: Jack J. Euston
Title: Vice President

MUFG UNION BANK, N.A., as Lender

By: /s/ Teuta Ghilaga
Name: Teuta Ghilaga
Title: Director

REGIONS BANK, as Lender

By: /s/ Ned Spitzer
Name: Ned Spitzer
Title: Managing Director

SUNTRUST BANK, as Lender

By: /s/ Katherine Bass
Name: Katherine Bass
Title: Director

THE HUNTINGTON NATIONAL BANK, as Lender

By: /s/ Joseph A. Miller
Name: Joseph A. Miller
Title: Managing Director

BANK OF AMERICA, N.A., as Lender

By: /s/ H. Hope Walker
Name: H. Hope Walker

Title: Senior Vice President

BANK OF THE WEST, as a Lender

By: /s/ Harry Yergey
Name: Harry Yergey
Title: Managing Director

By: /s/ Michael Weinert
Name: Michael Weinert
Title: Director

DNB CAPITAL LLC, as a Lender

By: /s/ Kristi Birkeland Sorensen
Name: Kristi Birkeland Sorensen
Title: Senior Vice President
Head of Corporate Banking

By: /s/ Devan Patel
Name: Devan Patel
Title: Vice President

FIRST NATIONAL BANK, as a Lender

By: /s/ Douglas T. Brown
Name: Douglas T. Brown
Title: Senior Vice President

FIFTH THIRD BANK, as a Lender

By: /s/ Vera B. McEvoy
Name: Vera B. McEvoy
Title: Director II

HSBC BANK USA, N.A., as a Lender

By: /s/ Reed R. Menefee
Name: Reed R. Menefee
Title: Managing Director

MORGAN STANLEY BANK, as a Lender

By: /s/ Jackson Eng
Name: Jackson Eng
Title: Authorized Signatory

TD BANK, N.A., as a Lender

By: /s/ Shivani Agarwal
Name: Shivani Agarwal
Title: Senior Vice President

U.S. BANK NATIONAL ASSOCIATION, as a Lender

By: /s/ Tom Priedeman

Name: Tom Priedeman

Title: Vice President

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: August 1, 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: August 1, 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 June 30, 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: August 1, 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 June 30, 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: August 1, 2019

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