Emergent BioSolutions Inc.
Form 10-Q
May 04, 2018
UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q
(Mark
One)

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

For the quarterly period ended March 31, 2018

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)

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 and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted 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 and post 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

(Do not check if a smaller reporting company)

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

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

As of April 27, 2018, the registrant had 49,823,291 shares of common stock outstanding.

Emergent BioSolutions Inc.
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Part I. Financial Information

Part II. Other 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;
- our ability to perform under our contracts with the U.S. government related to BioThrax, our NuThrax product candidate, and our other public health threat products, including the timing of and specifications relating to deliveries;
- our ability to obtain Emergency Use Authorization pre-approval for NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant) from the U.S. Food and Drug Administration, or FDA;
- the availability of funding for our U.S. government grants and contracts;
- our ability to secure follow-on procurement contracts for our public health threat products that are under procurement contracts that have expired or will be expiring;
- our ability to successfully integrate and develop the products or product candidates, programs, operations and personnel of any entities, businesses or products that we acquire, including our recently completed acquisitions of the ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) and Raxibacumab and the timing and receipt of required FDA approvals for actions contemplated in connection with our integration of these products;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- our ability to successfully identify and respond to new development contracts with the U.S. government, as well as successfully maintain, through achievement of development milestones, current development contracts with the U.S. government;
- 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 facility;
- the outcome of the purported class action lawsuit;
- our ability to obtain and maintain regulatory approvals for our product candidates and the timing of any such approvals;
- the procurement of products by U.S. government 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 when evaluating our forward-looking statements.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$163,606	$178,292
Restricted cash	1,043	1,043
Accounts receivable	122,090	143,653
Inventories	155,196	142,812
Income tax receivable, net	7,044	2,432
Prepaid expenses and other current assets	27,670	17,157
Total current assets	476,649	485,389
Property, plant and equipment, net	411,269	407,210
Intangible assets, net	115,685	119,597
Goodwill	49,130	49,130
Deferred tax assets, net	12,656	2,834
Other assets	3,078	6,046
Total assets	$1,068,467	$1,070,206
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$46,216	$41,751
Accrued expenses and other current liabilities	6,840	4,831
Accrued compensation	24,513	37,882
Contingent consideration, current portion	2,337	2,372
Deferred revenue, current portion	6,964	13,232
Total current liabilities	86,870	100,068
Contingent consideration, net of current portion	10,133	9,902
Long-term indebtedness	13,469	13,457
Income taxes payable, net of current	12,500	12,500
Deferred revenue, net of current portion	59,365	17,259
Other liabilities	4,850	4,675
Total liabilities	187,187	157,861
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at both March 31, 2018 and December 31, 2017	-	-
Common stock, $0.001 par value; 200,000,000 shares authorized, 51,025,978 shares issued and 49,808,692 shares outstanding at March 31, 2018; 50,619,808 shares issued and	50	50

49,405,365 shares outstanding at December 31, 2017		
Treasury stock, at cost, 1,217,286 and 1,214,443 common shares at March 31, 2018 and December 31, 2017, respectively	(39,642)	(39,497)
Additional paid-in capital	624,484	618,416
Accumulated other comprehensive loss	(3,251)	(3,698)
Retained earnings	299,639	337,074
Total stockholders' equity	881,280	912,345
Total liabilities and stockholders' equity	$1,068,467	$1,070,206

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

Emergent BioSolutions Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2018	2017
	(Unaudited)	
Revenues:		
Product sales	$75,771	$81,969
Contract manufacturing	26,178	17,628
Contracts and grants	15,865	17,261
Total revenues	117,814	116,858
Operating expenses:		
Cost of product sales and contract manufacturing	58,044	46,322
Research and development	29,051	20,476
Selling, general and administrative	40,204	35,150
Income (loss) from operations	(9,485)	14,910
Other income (expense):		
Interest income	222	373
Interest expense	(234)	(1,938)
Other income, net	74	300
Total other income (expense), net	62	(1,265)
Income (loss) before provision for (benefit from) income taxes	(9,423)	13,645
Provision for (benefit from) income taxes	(4,515)	3,160
Net income (loss)	$(4,908)	$10,485
Net income (loss) per share - basic	$(0.10)	$0.26
Net income (loss) per share - diluted (1)	$(0.10)	$0.23
Weighted-average number of shares - basic	49,580,089	40,727,755
Weighted-average number of shares - diluted	49,580,089	49,718,426

(1) See "Earnings per share" footnote for details on calculation.

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

Emergent BioSolutions Inc. and Subsidiaries
Condensed Consolidated Statements of Comprehensive Income (Loss)
(in thousands)

	Three Months Ended March 31,	
	2018	2017
	(Unaudited)	
Net income (loss)	$(4,908)	$10,485
Foreign currency translations, net of tax	447	584
Comprehensive income (loss)	$(4,461)	$11,069

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

Emergent BioSolutions Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(in thousands)

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:	(Unaudited)	
Net income (loss)	$ (4,908)	$ 10,485
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	7,255	4,284
Depreciation and amortization	12,373	10,166
Income taxes	(4,468)	4,299
Change in fair value of contingent consideration	989	200
Impairment of long-lived assets	34	-
Other	102	87
Changes in operating assets and liabilities:		
Accounts receivable	21,825	10,561
Inventories	(12,384)	3,270
Income taxes	(113)	-
Prepaid expenses and other assets	(7,605)	2,338
Accounts payable	3,576	81
Accrued expenses and other liabilities	2,240	(1,962)
Accrued compensation	(13,365)	(11,203)
Deferred revenue	(6,542)	9,065
Net cash (used in) provided by operating activities	(991)	41,671
Cash flows from investing activities:		
Purchases of property, plant and equipment and other	(11,615)	(20,304)
Net cash used in investing activities	(11,615)	(20,304)
Cash flows from financing activities:		
	4,693	2,957

Issuance of common stock upon exercise of stock options						
Taxes paid on behalf of employees for equity activity		(5,880	)		(4,015	)
Payments of notes payable to Aptevo		-			(20,000	)
Contingent consideration payments		(793	)		(1,568	)
Purchase of treasury stock		(145	)		(81	)
Net cash used in financing activities		(2,125	)		(22,707	)
Effect of exchange rate changes on cash, cash equivalents and restricted cash		45			(3	)
Net decrease in cash, cash equivalents and restricted cash		(14,686	)		(1,343	)
Cash, cash equivalents and restricted cash at beginning of period (1)		179,335			271,513	
Cash, cash equivalents and restricted cash at end of period (1)	$	164,649		$	270,170	

(1) As of December 31, 2017 and March 31, 2018, the balance includes $1,043 of restricted cash.

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

Emergent BioSolutions Inc. and Subsidiaries
Condensed Consolidated Statement of Changes in Stockholders' Equity
(in thousands, except share and per share data)

	$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, 2017	50,619,808	$ 50	$618,416	(1,214,443)	$(39,497)	$ (3,698)	$337,074	$ 912,345
Adoption of new accounting standard (ASC 606), net of tax	-	-	-	-	-	-	(32,527)	(32,527)
Balance at January 1, 2018	50,619,808	50	618,416	(1,214,443)	(39,497,000)	(3,698)	304,547	879,818
Employee equity plans activity	406,170	-	6,068	-	-	-	-	6,068
Treasury stock	-	-	-	(2,843)	(145)	-	-	(145)
Net loss	-	-	-	-	-	-	(4,908)	(4,908)
Foreign currency translation, net of tax	-	-	-	-	-	447	-	447
Balance at March 31, 2018	51,025,978	$ 50	$624,484	(1,217,286)	$(39,642)	$ (3,251)	$299,639	$ 881,280

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

EMERGENT BIOSOLUTIONS INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Summary of significant accounting policies

Basis of presentation and consolidation

The accompanying unaudited condensed consolidated financial statements include the accounts of Emergent BioSolutions Inc. ("Emergent" or the "Company") and its wholly owned and majority 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 for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X issued by the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles 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, 2017, as filed with the SEC.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited condensed consolidated financial statements are of a normal recurring nature and are necessary to present fairly the financial position of the Company as of March 31, 2018. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Significant accounting policies

During the three months ended March 31, 2018, 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, 2017, as filed with the SEC, except for the new revenue recognition standard the Company adopted effective January 1, 2018. See Note 2. "Revenue recognition" for further details.

Recently issued accounting standards

ASU 2016-02, Leases (Topic 842)

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2016-02, Leases (Topic 842) ("ASU No. 2016-02"). ASU No. 2016-02 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 standard will be effective January 1, 2019 for the Company, with early adoption permitted. The standard will be applied using a modified retrospective approach to the beginning of the earliest period presented in the financial statements. The Company is currently evaluating the expected impact to its condensed consolidated financial statements and related disclosures.

ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments ("ASU No. 2016-15"). ASU No. 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayments or extinguishment costs, the maturing of a zero-coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds

from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU No. 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components of these cash receipts and payments among operating, investing and financing activities. The Company adopted the new standard effective January 1, 2018, and has determined the impact of ASU No. 2016-15 on its condensed consolidated financial statements will be related to the settlement of contingent liabilities arising from a business combination.

ASU 2016-18, Restricted Cash (Topic 230): Statement of Cash Flows

In November 2016, the FASB issued ASU No. 2016-18, Restricted Cash (Topic 230): Statement of Cash Flows ("ASU No. 2016-18"). ASU No. 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Restricted cash and restricted cash equivalents will be included with cash and cash equivalents when reconciling the beginning of period and end of period balances on the statement of cash flows upon adoption of this standard. The Company adopted the new standard effective January 1, 2018. Restricted cash primarily consist of collateralized cash for a standby letter of credit and guarantee arrangement with a bank.

ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting

In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU No. 2017-09"). ASU No. 2017-09 clarifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The Company adopted the new standard effective January 1, 2018, which did not have a material impact on its condensed 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.

2. Revenue recognition

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU No. 2014-09"). ASU No. 2014-09 (known as ASC606) supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, as well as most industry-specific guidance, and significantly enhances comparability of revenue recognition practices across entities and industries by providing a principles-based, comprehensive framework for addressing revenue recognition issues. In order for a provider of promised goods or services to recognize as revenue the consideration that it expects to receive in exchange for the promised goods or services, the provider should apply the following five steps: (1) identify the contract with a customer(s); (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. ASU No. 2014-09 also specifies the accounting for some costs to obtain or fulfill a contract with a customer and provides enhanced disclosure requirements. The Company adopted the requirements of the new standard during the first quarter of 2018 using the modified retrospective method. The modified retrospective method requires companies to recognize the cumulative effect of initially applying the new standard as an adjustment to opening retained earnings.

A performance obligation is a promise in a contract to transfer a distinct product or service to a customer and is the unit of account under ASC 606. For contracts with multiple performance obligations, the Company allocates the contract's transaction price to each performance obligation on a relative standalone selling price basis using the Company's best estimate of the standalone selling price of each distinct product or service in the contract. The primary method used to estimate standalone selling price is the price observed in standalone sales to customers, however when prices in standalone sales are not available the Company may use third-party pricing for similar products or services

or estimate the standalone selling price. Allocation of the transaction price is determined at the contracts' inception.

Once the performance obligations in the contract have been identified, the Company estimates the transaction price of the contract. The estimate includes amounts that are fixed as well as those that can vary based on expected outcomes of the activities or contractual terms. The Company's variable consideration primarily includes consideration transferred under its development contracts with the U.S. government as consideration received can vary based on developmental progression of the product candidate(s). When a contract's transaction price includes variable consideration, the Company evaluates the estimate of the variable consideration to determine whether the estimate needs to be constrained; therefore, the Company includes the variable consideration in the transaction price only to the extent that it is probable that a significant reversal of the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration estimates are updated at each reporting date. There were no constraints or material changes to the Company's variable consideration estimates as of or during the three months ended March 31, 2018.

To indicate the transfer of control for the Company's product sales and contract manufacturing services, it must have a present right to payment, legal title must have passed to the customer, and the customer must have the significant risks and rewards of ownership. Revenue for long-term development contracts is generally recognized based upon the cost-to-cost measure of progress, provided that the Company meets the criteria associated with transferring control of the good or service over time.

The Company derives revenues primarily from the sale of its marketed medical countermeasures ("MCMs") products and contract revenues associated with development of its MCMs. The primary customer for the Company's MCM products and the development of the Company's MCM product candidate portfolio is the U.S. government. The Company's contracts for the sale of its MCM products generally have single performance obligation. Certain product sales contracts with the U.S. government include multiple performance obligations, which generally include the marketed product, stability testing associated with that product, expiry extensions and plasma collection. The Company's development contracts for its MCM product candidates generally are cost plus fixed fee arrangements which the Company treats a single performance obligation with variable consideration. The U.S. government contracts for the sale and development of the Company's MCM products and product candidates are normally multi-year contracts.

In addition, the Company performs contract manufacturing services for third parties which includes 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. These contracts generally include a single performance obligation with a duration that is less than one-year.

The Company has finalized the review of its portfolio of revenue contracts that were not complete as of the adoption date and made its determination of its revenue streams as well as completed extensive contract specific reviews to determine the impact of the new standard on its historical and prospective revenue recognition. Because many of the Company's contracts with customers have unique contract terms, the Company reviewed all of its non-standard agreements in order to determine the effect of adoption.

The Company has determined its Centers for Innovation in Advanced Development and Manufacturing ("CIADM") contract with the Biomedical Advanced Research and Development Authority ("BARDA") will have a material change in revenue recognition under the new guidance. Under ASC 606, the Company determined that there is one performance obligation which is a stand-ready obligation and will recognize the consideration received in the base period on a straight-line basis over a 24-year period as the capability being created during the base period of the contract is being provided to the customer over both the base period contract term as well as 17 additional option periods. In addition, the Company determined the CIADM contract includes a significant financing component which is included in the transaction price. The Company calculated the financing component using an interest rate the

Company had on its other debt obligations at inception of the contract. Prior to the adoption of ASC 606, the Company recognized revenue under the CIADM contract on a straight-line basis, based upon its estimate of the total payments to be received under the contract. The Company analyzed the estimated payments to be received on a quarterly basis to determine if an adjustment to revenue was required. As a result of the adoption of ASC 606 as of January 1, 2018, there was an increase in the deferred revenue liability of $42.4 million and an increase in deferred tax assets of $9.9 million with an offsetting reduction to retained earnings of $32.5 million.

The Company considers accounts receivables and deferred costs associated with revenue generating contracts, that are not included in inventory or property, plant and equipment, as contract assets. As of March 31, 2018 and December 31, 2017, the Company had $122.1 million and $143.7 million, respectively, in contract assets associated with accounts receivable which is included in accounts receivable on the company's condensed consolidated balance sheets. As of March 31, 2018 and December 31, 2017, the Company had contract assets associated with deferred costs of $3.3 million and $2.9 million, respectively, which is included in prepaid and other current assets on the Company's condensed consolidated balance sheets.

When performance obligations are not transferred to a customer at the end of a reporting period, the amount allocated to those performance obligations are deferred until control of these performance obligations is transferred to the customer. The following table presents the rollforward of the contract liabilities, which is included in the Company's current and long-term deferred revenue line items in the condensed consolidated balance sheets:

(in thousands)	
Balance at December 31, 2017	$30,491
Adoption of new accounting standard (ASC 606)	42,379
Balance at January 1, 2018	72,870
Deferral of revenue	5,761
Recognition of revenue included in beginning of year contract liability	(12,302)
Balance at March 31, 2018	$66,329

We operate in one business segment. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. For the three months ended March 31, 2018, there was a nominal difference between revenues recognized under ASC 606 and revenues recognized based on the prior revenue recognition guidance for the same period. For the three months ended March 31, 2018, the Company's revenues disaggregated by the major sources was as follows:

	Three Months Ended March 31, 2018		
(in thousands)	U.S. Government	Non-U.S. Government	Total
Product sales	$66,025	$ 9,746	$75,771
Contract manufacturing	-	26,178	26,178
Contracts and grants	14,806	1,059	15,865
Total revenues	$80,831	$ 36,983	$117,814

As of March 31, 2018, for contracts with a remaining term of greater than one year, the Company had expected future revenues associated with performance obligations that have not been satisfied of approximately $615 million. The Company expects to recognize a majority of its revenues within the next 24 months with the remainder recognized thereafter. However, the amount and timing of recognition of revenue for unsatisfied performance obligations can materially change due to timing of funding appropriations from the U.S. government and the overall success of the Company's development activities associated with its MCM product candidates. In addition, the amount of future revenues associated with unsatisfied performance obligations excludes the value associated with unexercised option periods in the Company's contracts (which are not performance obligations as of March 31, 2018).

3. Acquisitions

Acquisition of ACAM2000 business

On October 6, 2017, the Company completed the acquisition of the ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) business of Sanofi Pasteur Biologics, LLC ("Sanofi"). This acquisition included ACAM2000, the only smallpox vaccine licensed by the FDA, a current good manufacturing practices ("cGMP") live viral manufacturing facility and office and warehouse space, both in Canton, Massachusetts, and a cGMP viral fill/finish facility in Rockville, Maryland. With this acquisition, the Company also acquired an existing 10-year contract with the Centers for Disease Control and Prevention ("CDC"), which under the terms expired in March 2018. This contract had a stated value up to $425 million, with a remaining contract value of up to approximately $160 million as of the acquisition date, for the delivery of ACAM2000 to the SNS and the establishment of U.S.-based manufacturing of ACAM2000. This acquisition added to the Company's product portfolio and expanded the Company's manufacturing capabilities.

At the closing, the Company paid $97.5 million in an upfront payment and $20 million in milestone payments earned as of the closing date tied to the achievement of certain regulatory and manufacturing-related milestones, for a total payment in cash of $117.5 million. The agreement includes an additional milestone payment of up to $7.5 million upon achievement of a regulatory milestone, which was achieved in November 2017. The $7.5 million milestone payment was made during the fourth quarter of 2017. This transaction was accounted for by the Company under the acquisition method of accounting, with the Company as the acquirer. Under the acquisition method of accounting, the assets and liabilities of the ACAM2000 business were preliminarily recorded as of October 6, 2017, the acquisition date, at their respective fair values, and combined with those of the Company.

The contingent purchase consideration obligation is based on a regulatory milestone. At October 6, 2017, the contingent purchase consideration obligation related to the regulatory milestone was recorded at a fair value of $2.2 million. The fair value of this obligation is based on a present value model of management's assessment of the probability of achievement of the regulatory milestone as of the acquisition date. This assessment is based on inputs that have no observable market (Level 3).

The total purchase price is summarized below:

(in thousands)	
Amount of cash paid to Sanofi	$117,500
Fair value of contingent purchase consideration	2,200
Total purchase price	$119,700

The table below summarizes the preliminary allocation of the purchase price based upon estimated fair values of assets acquired and liabilities assumed at October 6, 2017. The allocation is preliminary based upon the finalization of valuation reports and as management gathers additional information on the acquired assets.

(in thousands)	
Fair value of tangible assets acquired and liabilities assumed:	
Inventory	$74,876
Property, plant and equipment	19,995
Total fair value of tangible assets acquired and liabilities assumed	94,871
Acquired intangible asset	16,700
Goodwill	8,129
Total purchase price	$119,700

The Company determined the fair value of the intangible asset 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 Company's products. The Company determined the fair value of the ACAM2000 intangible asset using the income approach with a present value discount rate of 15.5%; this discount rate is derived from the estimated weighted-average cost of capital for substantially similar companies and assets. 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 ACAM2000 intangible asset were based on key assumptions, including: estimates of revenues and operating profits, the life of the potential commercialized product and associated risks, and risks related to the viability of and potential alternative treatments in any future target markets. The Company has determined the ACAM2000 intangible asset will be amortized over 10 years.

The Company determined the fair value of the inventory using the probability adjusted 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 either the cost approach or the sales comparison approach. The cost approach is derived by determining 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 is derived by the determination that an asset is equal to the market price of an asset of comparable features such as design, location, size, construction, materials, use, capacity, specification, operational characteristics and other features or descriptions.

The Company recorded approximately $8.1 million in goodwill related to the ACAM2000 acquisition, representing the purchase price paid in the acquisition that was in excess of the fair value of the tangible and intangible assets acquired. There is no goodwill for tax purposes.

4. Fair value measurements

Contingent consideration consists of liabilities measured at fair value on a recurring basis. For the three months ended March 31, 2018, the contingent consideration obligation associated with the EV-035 series of molecules increased by a nominal amount. For the three months ended March 31, 2017, the contingent consideration obligation associated with the EV-035 series of molecules and the broad spectrum antiviral platform program decreased by $0.2 million. The changes are primarily due to the estimated timing and probability of success for certain development and regulatory milestones of the program, which are inputs that have no observable market (Level 3). These changes are classified in the Company's statement of operations as both selling, general and administrative expense and research and development expense.

During the three months ended March 31, 2018 and 2017, the contingent purchase consideration obligations associated with RSDL increased by $1.0 million and $0.4 million, respectively. The changes in the fair value of the RSDL contingent consideration obligations are primarily due to the expected amount and timing of future net sales, which are inputs that have no observable market (Level 3). These changes are classified in the Company's statement of operations as cost of product sales and contract manufacturing.

The following table is a reconciliation of the beginning and ending balance of the liabilities, consisting only of contingent consideration, measured at fair value, using significant unobservable inputs (Level 3) during the three months ended March 31, 2018.

(in thousands)	
Balance at December 31, 2017	$12,274
Expense included in earnings	989

Settlements	(793)
Balance at March 31, 2018	$12,470

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. As of March 31, 2018 and 2017 and for the quarters then ended, the Company had no significant assets or liabilities that were measured at fair value on a non-recurring basis.

5. Inventories

Inventories consisted of the following:

(in thousands)	March 31, 2018	December 31, 2017
Raw materials and supplies	$36,080	$36,069
Work-in-process	82,089	76,610
Finished goods	37,027	30,133
Total inventories	$155,196	$142,812

6. Property, plant and equipment

Property, plant and equipment consisted of the following:

(in thousands)	March 31, 2018	December 31, 2017
Land and improvements	$21,848	$21,843
Buildings, building improvements and leasehold improvements	159,267	160,005
Furniture and equipment	210,979	206,819
Software	51,562	50,829
Construction-in-progress	112,354	100,088
Property, plant and equipment, gross	556,010	539,584
Less: Accumulated depreciation and amortization	(144,741)	(132,374)
Total property, plant and equipment, net	$411,269	$407,210

In the table presented above, as of March 31, 2018 and December 31, 2017, construction-in-progress primarily includes costs related to the build out of the Company's Center for Innovation in Advanced Development and Manufacturing ("CIADM") facility.

7. Intangible assets

During the three months ended March 31, 2018 and 2017, the Company recorded amortization expense of $3.9 million and $1.6 million, respectively, for intangible assets, which has been recorded in operating expenses, specifically selling, general and administrative and cost of product sales and contract manufacturing. As of March 31, 2018, the weighted average amortization period remaining for intangible assets was 8.6 years.

8. Equity

During the three months ended March 31, 2018, the Company granted 0.3 million shares of stock options and 0.3 million shares of restricted stock units under the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan. The grant price was $49.64 as of March 31, 2018. The grants vest over three equal annual

installments beginning on the day prior to the anniversary of the grant date.

9. Income taxes

The estimated effective annual tax rate for the Company, which excludes discrete adjustments, was 24% and 31% for the three months ended March 31, 2018 and 2017, respectively. The decrease in the estimated effective annual tax rate is primarily due to the impact of the Tax Reform Act enacted on December 22, 2017 which reduced the U.S. federal corporate income tax rate from 35% to 21%, offset by state taxes, non-deductible expenses, international provisions from the U.S. tax reform and the impact of a change in the Company's jurisdictional mix of earnings. For the three months ended March 31, 2018 and 2017, the Company recorded a discrete tax benefit associated with equity awards activity of $2.3 million and $1.1 million, respectively.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Reform Act. For the three months ended March 31, 2018, the Company did not change the provisional estimates recognized in 2017. Additional work is necessary for a more detailed analysis of the Company's deferred tax assets and liabilities and its historical foreign earnings as well as potential correlative adjustments. Any adjustment to these amounts will be recorded to current tax expense in the quarter of 2018 when the analysis is complete.

10. Purchase commitments

During the first quarter of 2018, the Company entered into a contract with Norwood Laboratories Inc. ("Norwood") to purchase approximately $12.0 million of raw materials related to the Company's RSDL product. As of March 31, 2018, the Company has not purchased any materials under this commitment.

11. Earnings per share

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

	Three Months Ended March 31,	
(in thousands, except share and per share data)	2018	2017
Numerator:		
Net income (loss)	$(4,908)	$10,485
Interest expense, net of tax	-	907
Amortization of debt issuance costs, net of tax	-	195
Net income (loss), adjusted	$(4,908)	$11,587
Denominator:		
Weighted-average number of shares—basic	49,580,089	40,727,755
Dilutive securities—equity awards	-	894,171
Dilutive securities—convertible debt	-	8,096,500
Weighted-average number of shares—diluted	49,580,089	49,718,426
Net income (loss) per share - basic	$(0.10)	$0.26
Net income (loss) per share - diluted	$(0.10)	$0.23

For the three months ended March 31, 2018 and 2017, basic earnings per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period.

For the three months ended March 31, 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. No adjustment to the dilutive number of shares for the potential dilutive effect of other securities was computed under the treasury method as the effect would have been anti-dilutive for the three months ended March 31, 2018 due to the Company's net loss. For the three months ended March 31, 2018, approximately 3.2 million of equity awards were excluded from the calculation of diluted earnings per share.

For the three months ended March 31, 2017, diluted earnings per share is computed using the "if-converted" method by dividing the net income adjusted for interest expense and amortization of debt issuance cost, both net of tax, associated with the 2.875% Convertible Senior Notes due 2021 (the "Notes") by the weighted average number of shares of common stock outstanding during the period. The weighted average number of shares is adjusted for the potential dilutive effect of the exercise of stock options and the vesting of restricted stock units along with the assumption of the conversion of the Notes, at the beginning of the period. The "if-converted" method was not utilized for the three months ended March 31, 2018 as the conversion rights associated with the Notes were terminated during the fourth quarter of 2017. For the three months ended March 31, 2017, approximately 0.8 million stock options were excluded from the calculation of diluted earnings per share due to the fact that the exercise prices were in excess of the average per share closing price during the period.

12. Litigation

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 Securities Exchange Act of 1934 against the Company and certain of its senior officers and directors, collectively, the Defendants. The complaint alleges, among other things, that the Company 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 is seeking 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 Robins Geller Rudman & Dowd LLP as Lead Counsel. On December 27, 2016, the Plaintiffs filed an amended complaint that cites the same class period, names the same defendants and makes similar allegations to the original complaint. The Company filed a Motion to Dismiss on February 27, 2017. The Plaintiffs filed an opposition brief on April 28, 2017. The Company's Motion to Dismiss was heard and denied on July 6, 2017. The Company filed its answer on July 28, 2017. The parties are currently in the process of exchanging discovery. The Plaintiffs filed an amended motion for class certification and appointment of Sponn and Geoffrey L. Flagstad as lead plaintiffs on December 20, 2017. A hearing on that motion was heard on May 2, 2018. The Defendants believe that the allegations in the complaint are without merit and intend to defend themselves vigorously against those claims. As of the date of this filing, the range of potential loss cannot be determined or estimated.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this quarterly report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, including information with respect to our plans and strategy for our business and financing, includes 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 specialty products for civilian and military populations that address accidental, intentional and naturally occurring public health threats, or PHTs. Within the category of our specialty products, we are focused on developing, manufacturing and commercializing medical countermeasures, or MCMs, that address PHTs. The PHTs that we address fall into two categories: Chemical, Biological, Radiological, Nuclear and Explosives or CBRNE; and emerging infectious diseases, or EID. We have a portfolio of eight products through which we generate our product sales revenue, which accounts for a majority our total revenue, a fully-integrated portfolio of contract manufacturing services, and a research and development pipeline of various investigational stage product candidates. The U.S. government is the primary purchaser of our products and provides us with substantial funding for the development of many of our product candidates. Our development pipeline consists of a diversified mix of both pre-clinical- and clinical-stage candidates.

Our MCM products are:

- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or 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 (acquired from Sanofi Pasteur Biologics, LLC in October 2017);
- Raxibacumab (Anthrax Monoclonal), the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax (acquired from GlaxoSmithKline LLC in October 2017);
- 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;
- VIGIV [Vaccinia Immune Globulin Intravenous (Human)], the only antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination;
- 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.

Our lead investigational stage MCM candidates, many of which are under an active development contract with significant funding from the U.S. government, are:

- NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), a next generation anthrax vaccine;
- FLU-IGIV (NP025), a human polyclonal antibody therapeutic being developed for the treatment of serious influenza A infection in hospitalized patients;
- ZIKV-IG (NP024), a human polyclonal antibody therapeutic being developed as a prophylaxis for Zika infections in at risk populations;
- FILOV (NP026), an equine polyclonal antibody therapeutic being developed to treat hemorrhagic fever caused by Filoviruses (Ebola, Marburg and Sudan);
- VLA1601, a highly purified inactivated vaccine against the Zika virus;
- UNI-FLU, a universal influenza vaccine;

- EBX-205, an oral therapeutic to treat acute bacterial skin and skin structure infection, including those caused by methicillin-resistant Staphylococcus aureus, or MRSA, as well as to treat other serious bacterial infections caused by biothreat pathogens;
- EBI-001, a pan respiratory antiviral from our iminosugar-based discovery program;
- GC-072, an oral and intravenous treatment for Burkholderia pseudomallei infection (GC-072 is the lead compound in the EV-035 series of broad-spectrum antibiotics);
- D4, a multi-drug delivery device being developed for nerve agent antidote delivery (atropine and pralidoxime chloride in combination); and
- SIAN (stabilized isoamyl nitrite), a stabilized form of isoamyl nitrite in an intra-nasal spray device being developed as a treatment for known or suspected acute cyanide poisoning.

Highlights and Business Accomplishments for 2018

On April 12, 2018, we announced the successful completion of the Mutual Recognition Procedure, or MRP, for market authorization of BioThrax® in five Concerned Member States, or CMS, within the European Union, or EU, consisting of Italy, the Netherlands, Poland, the U.K., and France (where it will be marketed as BaciThrax™). We filed the mutual recognition application based on the existing Marketing Authorization of BioThrax in Germany granted by the PaulEhrlich-Institut. Following the positive MRP outcome, national licenses are due to be issued shortly by the five CMS countries.

On February 28, 2018, we announced a contract award by the Centers for Disease Control and Prevention, or CDC, valued at $26 million over 12 months, for the continued supply of VIGIV into the U.S. Strategic National Stockpile, or SNS. VIGIV is the only therapeutic licensed by the FDA for the treatment of complications due to smallpox vaccination. Under the contract, we will conduct manufacturing runs, collect plasma for future manufacturing, and undertake additional activities in support of maintaining FDA licensure of VIGIV. VIGIV was developed on our hyperimmune platform, on which several marketed antibody therapeutics have been licensed, including Anthrasil®. This contract will continue the CDC's commitment to VIGIV, which was licensed in the U.S. by the FDA in 2005 and in Canada by Health Canada in 2007.

On February 26, 2018, we, together with Valneva SE, or Valneva, announced the initiation of a Phase 1 clinical trial in the U.S. to evaluate the safety and immunogenicity of VLA1601, Valneva's vaccine candidate against Zika virus. The Phase 1 clinical trial is a randomized, observer-blinded, placebo-controlled, single center study. This study, in approximately 65 healthy adults, will investigate two dose levels of VLA1601 when administered using two different vaccination schedules. Initial data from the trial are expected to be available in late 2018 or early 2019. Under the terms of the agreement signed in July 2017, the parties will share all costs until the availability of Phase 1 data in the U.S. Valneva will be responsible for the program's execution until completion of the Phase 1 trial through a joint governance structure. Upon availability of Phase 1 data, we will have the option to continue the development and commercialization of a Zika vaccine under its worldwide exclusive license agreement with Valneva for a milestone payment of €5 million. The agreement provides Valneva potential additional milestone payments of up to €44 million related to product development, approval, commercialization, and product sales, future royalties on annual net sales, and the right, prior to a Phase 3 clinical trial, to negotiate with our exclusive commercialization rights in Europe. We are expected to enter into a technology transfer agreement at a later time to enable transfer of Valneva's technology to our Bayview manufacturing facility in Baltimore, Maryland.

On January 4, 2018, we announced the initiation of a Phase 2 dose ranging study to evaluate the safety, pharmacokinetics, and clinical benefit of FLU-IGIV, our anti-influenza immune globulin being developed as an intravenous treatment for serious illness caused by influenza A infection in hospitalized patients. This Phase 2 clinical study will enroll approximately 75 adult patients hospitalized with serious illness caused by influenza A infection in up to 50 sites within the U.S. The study will evaluate FLU-IGIV in conjunction with standard of care, including a minimum five-day course of an anti-viral drug. FLU-IGIV is a purified immunoglobulin containing a standardized amount of antibody to influenza A virus. It is developed on our hyperimmune platform, on which several marketed

antibody therapeutics have been licensed, including Anthrasil® and VIGIV.

Financial Operations Overview

Revenues

We have derived a majority of our historical product sales revenues from BioThrax sales to the U.S. government. We are a party to a contract with the CDC, an operating division of the U.S. Department of Health and Human Services, or HHS, valued at up to $911 million, to supply approximately 29.4 million doses of BioThrax to the SNS through September 2021. For at least the next two to three years, we expect to continue to derive a substantial portion of our product sales revenues from sales of BioThrax to the U.S. government. We are focused on increasing the sales of our marketed MCMs to U.S. government customers, as well as expanding the market for our MCM product portfolio to other customers domestically and internationally.

For at least the next two to three years, we expect to continue to derive a substantial portion of our product sales revenues from sales of BioThrax to the U.S. government.

We have received contract and grant funding from the Biomedical Advanced Research and Development Authority, or BARDA, Department of Defense, or DoD, CDC, the Defense Threat Reduction Agency, or DTRA, and the National Institute of Allergy and Infectious Diseases, or NIAID, for the following development programs:

Development Programs	Funding Source	Award Date	Performance Period
Anthrasil	BARDA	09/2005	9/2005 — 4/2021
	BARDA	09/2013	9/2013 — 9/2018
Auto-injector platform	DoD	07/2017	7/2017 — 6/2022
BAT	BARDA	05/2006	5/2006 — 12/2027
CIADM	BARDA	06/2012	6/2012 — 6/2037
GC-072	DTRA	08/2014	8/2014 — 8/2019
NuThrax	NIAID	08/2014	8/2014 — 1/2020
	BARDA	03/2015	3/2015 — 10/2018
	BARDA	09/2016	9/2016 — 9/2021
SIAN	BARDA	09/2017	9/2017 — 9/2022
UV-4B	NIAID	09/2011	9/2011 — 9/2018
VIGIV	CDC	02/2018	2/2018 — 2/2019

Our revenue, operating results and profitability have varied, and we expect that they will continue to vary on a quarterly basis, primarily due to the timing of our fulfilling orders for BioThrax and work done under new and existing grants and development contracts.

Critical Accounting Policies and Estimates

During the three months ended March 31, 2018, 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, 2017, as filed with the Securities and Exchange Commission, except for the adoption of the new revenue recognition standard.

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606), or ASU No. 2014-09. ASU No. 2014-09 supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, as well as most industry-specific guidance, and significantly enhances comparability of revenue recognition practices across entities and industries by providing a principles-based, comprehensive framework for addressing revenue recognition issues. In order for a provider of promised goods or services to recognize as revenue the consideration that we expect to

receive in exchange for the promised goods or services, the provider should apply the following five steps: (1) identify the contract with a customer(s); (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. ASU No. 2014-09 also specifies the accounting for some costs to obtain or fulfill a contract with a customer and provides enhanced disclosure requirements.

We first identify whether a legally enforceable contract with a customer exists. A legally enforceable contract creates enforceable rights and obligations on both parties. We evaluate the following criteria in our evaluation and if all criteria are not met, a contract does not exist and any revenue that otherwise would be recorded because a good or service had been transferred to a customer is deferred until such time that a contract exists: (1) both we and the customer have approved the contract and are committed to perform, (2) we can identify each party's rights regarding the goods or services to be transferred, (3) we can identify the payment terms for the goods or services to be delivered, (4) the contract has commercial substance, and (5) it is probable that we will collect substantially all of the consideration to which we will be entitled in exchange for the goods or services that will be transferred to the customer.

Once the contract has been identified, we evaluate the promises in the contract to identify performance obligations. A performance obligation is a promise in a contract to transfer a distinct product or service to a customer and is the unit of account under ASC 606. Many of the contracts include more than one performance obligation – for example the sale of BAT to the U.S. government includes the performance of stability testing and storage of the product. Promises in contracts which do not result in the transfer of a good or service are not performance obligations, as well as those promises that are administrative in nature, or are immaterial in the context of the contract.

Once the performance obligations in the contract have been identified, we estimate the transaction price of the contract. The estimate includes amounts that are fixed as well as those that can vary based on expected outcomes of the activities or contractual terms. Our variable consideration primarily includes consideration transferred under our development contracts with the U.S. government as the development efforts can vary based on successful or unsuccessful progression of the product candidate. When a contract includes variable consideration, we evaluate the estimate of the variable consideration to determine whether the estimate needs to be constrained; therefore, we include the variable consideration in the transaction price only to the extent that it is probable that a significant reversal of the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration estimates are updated at each reporting date. There were no material changes to our variable consideration estimates during the three months ended March 31, 2018.

In determining the transaction price, we adjust the promised amount of consideration for the effects of the time value of money if the timing of payments agreed to by the parties to the contract (either explicitly or implicitly) provides we with a significant benefit of financing the transfer of goods or services to the customer, which is called a significant financing component. A significant financing component may exist regardless of whether the promise of financing is explicitly stated in the contract or implied by the payment terms agreed to by the parties to the contract. We do not adjust transaction price for the effects of a significant financing component when the period between the transfer of the promised good or service to the customer and payment for that good or service by the customer is expected to be one year or less.

For contracts with multiple performance obligations, we allocate the contract's transaction price to each performance obligation on a relative standalone selling price basis using our best estimate of the standalone selling price of each distinct product or service in the contract. The primary method used to estimate standalone selling price is the price observed in standalone sales to customers, however when prices in standalone sales are not available we may use third-party pricing for similar products or services or estimate the standalone selling price. Allocation of the transaction price is determined at the contracts' inception.

Finally, we record the amount allocated to each performance obligation as revenue when control of that good or service has transferred to the customer. We first evaluate whether a good or service is transferred "over time", and if it is not, then it is recorded at a "point in time". For our development contracts, we recognize revenue "over time" based upon the cost-to-cost measure of progress, provided that we meet the criteria associated with transferring control of the good or service "over time". For our product sales and contract manufacturing activities, we recognize revenue at a "point in time" We evaluates the following indicators to determine the "point in time" at which control transfers to the customer, and may apply judgment in this evaluation: (1) whether we has a present right to payment, (2) whether the customer has legal title, (3) whether the customer has physical possession, (4) whether the customer has significant risks and rewards of ownership, and (5) whether customer acceptance is a formality (i.e., whether customer acceptance of the tool is reasonably assured). In almost all other situations, there is little or no significant judgment applied by the Company in determining if control of a good or service has transferred to a customer. The timing of satisfaction of the performance obligation to payment is dependent upon the negotiated payment terms but generally occurs within 30 to 60 days.

Results of Operations

Three Months Ended March 31, 2018 Compared to Three Months Ended March 31, 2017

Revenues

	Three Months Ended March 31,			
(in millions)	2018	2017	Change	% Change
Product sales:				
BioThrax	$20.2	$43.8	$(23.6)	(54%)
Other	55.6	38.2	17.4	46%
Total Product sales	75.8	82.0	(6.2)	(8%)
Contract manufacturing	26.1	17.6	8.5	48%
Contracts and grants	15.9	17.3	(1.4)	(8%)
Total revenues	$117.8	$116.9	$0.9	1%

Product sales:

The decrease in BioThrax sales was primarily due to the timing of BioThrax deliveries to the SNS. BioThrax product sales revenues during the three months ended March 31, 2018 and 2017 primarily consisted of sales to the CDC of $18.8 million and $41.1 million, respectively.

The increase in Other product sales relates primarily to:

- sales of ACAM2000 to the CDC and Raxibacumab to BARDA; both products were acquired in October 2017;
- sales of Trobigard to the U.S. Department of State; and
- international sales of VIGIV.

These increases in Other product sales were partially offset by a decrease in the sales of BAT and RSDL primarily due to the timing of BAT deliveries to the SNS and RSDL shipments to the DoD.

Contract manufacturing:

The increase in Contract manufacturing revenue is primarily due to:

- the design, construction and validation of manufacturing capability for a third party at our Lansing, Michigan site; and
- manufacturing services for Aptevo Therapeutics Inc. ("Aptevo").

These increases in Contract manufacturing revenue were partially offset by a decrease in manufacturing services performed for third party development stage product candidates.

Contracts and grants:

The decrease in Contracts and grants revenue primarily reflects a reduction in revenue associated with the successful completion of multiple U.S. Government contracts as well as reduced R&D activities related to certain ongoing funded development programs, including:

- decreased development funding of $3.2 million related to our CIADM program, which includes a decrease of $0.9 million for CIADM task orders primarily related to Ebola and Zika which occurred in the first quarter of 2017 with no activity in 2018;
- decreased revenue for our BAT program related to the timing of stability testing; and
- decreased development funding for our UV-4B program due to the determination that the program is no longer viable.

These decreases in Contracts and grants revenue were partially offset by an increase in the following R&D development programs:

- development funding of $3.2 million for ACAM2000 (acquired October 2017) primarily related to stability testing; and
- increased development funding of $1.2 million for SIAN related to a non-clinical pharmacokinetics study and manufacturing development.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $11.7 million, or 25%, to $58.0 million for the three months ended March 31, 2018 from $46.3 million for the three months ended March 31, 2017. The increase was primarily attributable to the sales of the newly acquired ACAM2000 and Raxibacumab products (both acquired in October 2017). These increases were partially offset by a decrease in BAT and BioThrax sales to the SNS due to timing.

Research and Development Expenses

Research and development expenses increased by $8.6 million, or 42%, to $29.1 million for the three months ended March 31, 2018 from $20.5 million for the three months ended March 31, 2017. This increase primarily reflects higher contract service costs. Net of contracts and grants revenues, during the three months ended March 31, 2018 and 2017, we incurred net research and development expenses of $13.2 million and $3.2 million, respectively.

Our principal research and development expenses for the three months ended March 31, 2018 and 2017 are shown in the following table:

	Three Months

(in millions)	Ended March 31, 2018	2017	Change	% Change
NuThrax	$7.5	$6.0	$ 1.5	25 %
Raxibacumab	4.5	-	4.5	N/A
FLU-IGIV (NP025)	2.6	1.0	1.6	160 %
Auto-injector program	1.8	0.9	0.9	100 %
UNI-FLU	1.4	0.2	1.2	600 %
EV-035 series of molecules	1.2	0.8	0.4	50 %
ZIKV-IG	1.2	0.3	0.9	300 %
SIAN	1.1	-	1.1	N/A
BAT	0.6	0.9	(0.3)	33 %
BioThrax related programs	0.6	0.4	0.2	50 %
UV-4B	0.2	1.9	(1.7)	(89 %)
VIGIV	0.2	0.6	(0.4)	(67 %)
Anthrasil	0.1	0.2	(0.1)	50 %
Large-scale manufacturing for BioThrax	0.1	0.5	(0.4)	(80 %)
CIADM task orders	-	1.1	(1.1)	(100 %)
Other	6.0	5.7	0.3	5 %
Total	$29.1	$20.5	$ 8.6	42 %

The increase in research and development expense was primarily attributable to:

- manufacturing development activities associated with the preparation to produce process performance qualification (PPQ) lots for our NuThrax product candidate;
- technology transfer activities for Raxibacumab (acquired in October 2017), moving the manufacturing from GlaxoSmithKline's facility to our Bayview facility;
- the timing of the Phase 2 clinical study related to our FLU-IGIV (NP025) program;
- the timing of device and cartridge supply development work related to our Auto-injector program;
- proof of concept activities for our UNI-FLU program;
- preparation activities for the Phase 1 clinical study for our ZIKV-IG product candidate;
- manufacturing and pharmakinetic activities for our SIAN product candidate; and
- increased expenses related to our funded pre-clinical product candidates and manufacturing development activities within our other development activities.

These increases were partially offset by decreased research and development activity primarily attributable to the timing of:

- clinical trial activity to evaluate safety and tolerability related to our UV-4B product candidate; we anticipate a reduction in funding by the U.S. government for this product candidate and, as a result, we will cease further development work on UV-4B and expect the spending to be minimal in the future; and
- the successful completion of manufacturing development in 2017 for Ebola monoclonal antibodies and a virion inactivated Zika vaccine under current CIADM-related task order awards.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $5.0 million, or 14%, to $40.2 million for the three months ended March 31, 2018 from $35.2 million for the three months ended March 31, 2017. The increase was primarily attributable to an increase in professional services to support our strategic growth initiatives, along with an increase in

compensation related costs.

Total Other Income (Expense), Net

Total other income, net of $0.1 million for the three months ended March 31, 2018 represents an increase of $1.4 million from total other expense, net of $1.3 million for the three months ended March 31, 2017. The increase was primarily attributable to a decrease in interest expense primarily due to the conversion of 96% of the outstanding debt to equity during the fourth quarter of 2017.

Provision for (Benefit from) Income Taxes

Benefit from income taxes of $4.5 million for the three months ended March 31, 2018 decreased by $7.7 million from a provision of income taxes of $3.2 million for the three months ended March 31, 2017. The decrease was primarily due to a decrease in pre-tax income of $23.0 million. For three months ended March 31, 2018 and 2017, we recorded a discrete tax benefit associated with equity awards activity of $2.3 million and $1.1 million, respectively.

Liquidity and Capital Resources

Sources of Liquidity

From inception through March 31, 2018, we have funded our cash requirements principally with a combination of cash from our operations, debt financing, development funding, the net proceeds from our initial public offering and the sale of our common stock upon exercise of stock options. We have operated profitably for each of the last five years ended December 31, 2017. As of March 31, 2018, we had cash and cash equivalents of $163.6 million. As of March 31, 2018, we believe that we have sufficient liquidity to support operations over the next 12 months.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,	
(in millions)	2018	2017
Net cash provided by (used in):		
Operating activities(i)	$(1.0)	$41.7
Investing activities	(11.6)	(20.3)
Financing activities	(2.1)	(22.7)
Net decrease in cash and cash equivalents	$(14.7)	$(1.3)

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

Operating Activities:

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

materials, and a decrease in deferred revenue primarily related to our contract with PAR Pharmaceutical.

Net cash provided by operating activities of $41.7 million for the three months ended March 31, 2017 was primarily due to our net income excluding non-cash items of $29.5 million and changes in working capital which resulted in a net cash inflow of $12.2 million. Cash inflow includes the timing of collection of accounts receivables related to amounts billed (primarily to the CDC), an increase in deferred revenue, and a decrease in inventories primarily due to the timing of deliveries of BioThrax to the CDC, partially offset by a decrease in accrued compensation primarily related to the payment of 2016 annual bonuses.

Investing Activities:

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

Net cash used in investing activities of $20.3 million for the three months ended March 31, 2017 reflects infrastructure and equipment investments, including construction at our Baltimore CIADM manufacturing facility.

Financing Activities:

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

Net cash used in financing activities of $22.7 million for three months ended March 31, 2017 was primarily due to the payment of a $20.0 million note payable to Aptevo in conjunction with the spin-off, $4.0 million associated with the taxes paid on behalf of employees for equity activity and $1.6 million in contingent obligation payments, partially offset by $3.0 million in proceeds from the issuance of common stock pursuant to our employee equity awards plan.

Funding Requirements

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

- existing cash and cash equivalents;
- net proceeds from the sale of our products and contract manufacturing services;
- development contracts and grants funding; and
- our senior secured credit facility 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 our common stock under our 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. In May 2015, we filed an automatic shelf registration statement, which immediately became effective under the Securities and Exchange Commission, or 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 Securities Exchange Act of 1934 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 May 22, 2018, 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 May 22, 2018, 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 revolving credit facility, 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 remaining senior convertible notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing our notes that could have the effect of diminishing our ability to make payments on our indebtedness. However, our senior secured credit facility restricts 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. The term of the board authorization of the repurchase program is until December 31, 2019. Any repurchased shares will be available for use in connection with our stock plans and for other corporate purposes. As of March 31, 2018, we have not made any repurchases under this program.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is currently confined to our cash and cash equivalents. We currently do not hedge interest rate exposure or foreign currency exchange exposure, and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, we believe that an increase in market rates would likely not have a significant impact on the realized value of our investments, but any increase in market rates would likely increase the interest expense associated with our debt.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act, 1934, or Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2018, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act that occurred during the quarter ended March 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may be involved in various legal proceedings and claims that arise in or outside the ordinary course of our business. We believe that the outcome of these pending legal proceedings in the aggregate is unlikely to have a material adverse effect on our business, financial condition or results of operations.

Purported Shareholder Class Action Lawsuit filed July 19, 2016

On July 19, 2016, Plaintiff William Sponn, or 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, or 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 alleges, among other things, that the Company 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 is seeking 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 Robins Geller Rudman & Dowd LLP as Lead Counsel. On December 27, 2016, the Plaintiffs filed an amended complaint that cites the same class period, names the same defendants and makes similar allegations to the original complaint. The Company filed a Motion to Dismiss on February 27, 2017. The Plaintiffs filed an opposition brief on April 28, 2017. The Company's Motion to Dismiss was heard and denied on July 6, 2017. The Company filed its answer on July 28, 2017. The parties are currently in the process of exchanging discovery. The Plaintiffs filed an amended motion for

class certification and appointment of Sponn and Geoffrey L. Flagstad as lead plaintiffs on December 20, 2017. A hearing on that motion was heard on May 2, 2018. The Defendants believe that the allegations in the complaint are without merit and intend to defend themselves vigorously against those claims.

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 principal customer, the U.S. government. If the U.S. government's demand for and/or funding for procurement of BioThrax is substantially reduced, our business, financial condition, operating results and cash flow would be materially harmed.

We have derived, and expect for the foreseeable future to derive, a substantial portion of our revenue from sales of BioThrax, our anthrax vaccine licensed by the FDA to the U.S. government. In December 2016, we signed a follow-on procurement contract with the CDC for the delivery of approximately 29.4 million doses of BioThrax for placement into the SNS over a five-year period ending in September 2021. The potential value of this contract is approximately $911 million if all procurement options are exercised.

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

Our submission of NuThrax for EUA pre-approval and eventual FDA licensure may not be approved by the FDA in a timely manner or at all. Delays in our ability to achieve such pre-approval and licensure could prevent us from realizing the full potential value of our BARDA contract for the advanced development and procurement of NuThrax.

In September 2016, we entered into a contract with the U.S. Department of Health and Human Services, or HHS, through BARDA for the advanced development and procurement of NuThrax, our next generation anthrax vaccine candidate. The contract, as modified in March 2017, is valued at up to approximately $1.5 billion.

We intend to submit an application with the FDA for EUA pre-approval of NuThrax this year, and although there can be no assurances, we currently anticipate that the FDA could authorize NuThrax for emergency use as early as 2019, triggering deliveries of NuThrax to the SNS for use in an emergency situation as early as 2019. However, the FDA does not have review deadlines with respect to such submissions and, therefore, the timing of any approval of an EUA pre-approval submission is uncertain. We cannot guarantee that the FDA will review our data in a timely manner, or that the FDA will accept the data when reviewed. The FDA may decide that our data are insufficient for EUA pre-approval and require additional pre-clinical, clinical or other studies and refuse to approve our application. If we are unsuccessful in obtaining EUA pre-approval for NuThrax 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 NuThrax may be limited or not available, and our future business, financial condition, operating results and cash flows could be materially harmed.

Our U.S. government procurement and development contracts require ongoing funding decisions by the U.S. government. Reduced or discontinued funding of these contracts could cause our business, financial condition, operating results and cash flows to suffer materially.

The U.S. government 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 NuThrax product candidate. We anticipate that the U.S. government 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 U.S. government development contracts and grants. Over its lifetime, a U.S. government 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 U.S. government 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 NuThrax 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 NuThrax 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 U.S. government 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 U.S. government upon the expiration of any of our current product procurement contracts.

Our revenue is substantially dependent upon product procurement contracts with the U.S. government 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, although there are remaining deliverables under the contract, 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 GSK expires in 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 U.S. government 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 more costly and 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 U.S. government, 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 U.S. government 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, or 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, or DFARs, and agency-specific regulations supplemental to DFARs, which comprehensively regulate the award, formation, administration and performance of U.S. Department of Defense, or DoD, government contracts;
- the Department of State Acquisition Regulation, or 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;
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- 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.

U.S. government 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 and such audit were to uncover improper or illegal activities, we could be subject to civil and criminal penalties, administrative sanctions, including suspension or debarment from government contracting, and suffer significant reputational harm. Loss of our status as an eligible government contractor would 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 U.S. government 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 U.S. government substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the U.S. government 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 U.S. government's convenience. Under general principles of government contracting law, if the U.S.

government 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 U.S. government 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 U.S. government, are terminable at the U.S. government's convenience with these potential consequences.

In addition, our U.S. government contracts grant the U.S. government 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 U.S. government. Under our U.S. government 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 U.S. government.

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, or BLA, to the FDA. Ordinarily, the FDA requires a company to support a BLA with substantial evidence of the product candidate's safety and efficacy in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted.

However, NuThrax and many of our MCM product candidates, for example, are subject to 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 NuThrax 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 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.

We intend to transfer the manufacturing of Raxibacumab, which we recently 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 Human Genome Sciences, Inc. and GlaxoSmithKline LLC, collectively referred to as 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 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, current good manufacturing practices, or 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. For example, our Lansing Building 55 facility was inspected most recently by the FDA in June 2016, our Lansing Building 12 facility was inspected most recently by the FDA in April 2016, our Winnipeg manufacturing facility was inspected most recently by the FDA in May 2017 and Health Canada in November 2016, our Canton, Massachusetts manufacturing facility was inspected most recently by the FDA in December 2017, our Rockville facility was inspected most recently by the FDA in March 2017, and our Baltimore (Camden) facility was most recently inspected by the Health Products Regulatory Authority of Ireland in February 2017, FDA in January 2017, Health Canada in October 2016 and the Russian Ministry of Health in February 2018. Following several of these inspections, regulatory authorities 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, or 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 U.S. government), 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, 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 recently received market authorization under the MRP to sell BioThrax in France, Italy, the Netherlands, Poland, and the U.K. and are currently awaiting licensure of BioThrax in these five CMS countries. To market our products in foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA in the United States or the MRP in the CMS 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 MRP. 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. We have limited experience in preparing, filing and prosecuting the applications necessary to gain foreign regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process.

Our international operations increase our risk of exposure to potential claims of bribery and corruption.

As we expand our commercialization activities outside of the United States, we are subject to an increased risk of inadvertently conducting activities in a manner that violates the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act, Canada's Corruption of Foreign Public Officials Act, or other similar foreign laws, which prohibit corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. In the course of establishing and expanding our commercial operations and seeking regulatory approvals outside of the United States, we will need to establish and expand business relationships with various third parties and will interact more frequently with foreign

officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be foreign officials under the FCPA or similar foreign laws. If our business practices are found to be in violation of the FCPA or similar foreign laws despite our training and compliance efforts, we and our senior management may be subject to significant civil and criminal penalties, potential debarment from public procurement and reputational damage, which could have a material adverse effect on our business, financial condition, operating results, cash flows and growth prospects.

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 U.S. government 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 our 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; and Canton, Massachusetts; Rockville, Maryland; and Hattiesburg, Mississippi facilities. Any such disruption, damage, or destruction of these facilities could impede our ability to manufacture our 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, and many of our current product candidates, including NuThrax, are biologics. Manufacturing biologic products, especially in large quantities, is complex. The products must be made consistently and in compliance with a clearly defined manufacturing process. Problems during manufacturing may arise for a variety of reasons, including problems with raw materials, equipment malfunction and failure to follow specific protocols and procedures. In addition, slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation, contamination including from particulates among other things, filtration, filling, labeling, packaging, storage and shipping, potency and stability issues and other quality control testing, may result in lot failures or manufacturing shut-downs, delays in the release of lots, product recalls, spoilage or regulatory action. Such deviations may require us to revise manufacturing processes or change manufacturers. Additionally, as our equipment ages, it will need to be replaced. Replacement of equipment has the potential to introduce variations in the manufacturing process that may result in lot failures or manufacturing shut-downs, delay in the release of lots, product recalls, spoilage or regulatory action. Success rates can also vary dramatically at different stages of the manufacturing process, which can reduce yields and increase costs. From time to time, we may experience deviations in the manufacturing process that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation or regulatory action against us, including warning letters and other restrictions on the marketing or manufacturing of a product, or cause the FDA to cease releasing product until the deviations are explained and corrected, any of which could be costly to us, damage our reputation and negatively impact our business.

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

Manufacturing delays, lot failures, shipping deviations, spoilage or other loss during shipping could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in potential clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

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

FDA approval is required for the release of each lot of BioThrax. A "lot" is approximately 181,000 doses. We are not able to sell any lots that fail to satisfy the release testing specifications. For example, we must provide the FDA with the results of certain tests, including potency tests, before lots are released for sale. Potency testing of each lot of BioThrax is performed against a qualified control lot that we maintain. We have one mechanism for conducting this potency testing that is reliant on a unique animal strain for which we currently have no alternative. We continually monitor the status of our reference lot and periodically produce and qualify a new reference lot to replace the existing reference lot. If we are not able to produce and qualify a new reference lot or otherwise satisfy the FDA's requirements for release of BioThrax, our ability to sell BioThrax would be impaired until such time as we become able to meet the FDA's requirements, which would materially harm our business, financial condition, operating results and cash flows.

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

We depend on certain single-source suppliers for key materials and services necessary for the manufacture of BioThrax and our other products and product candidates. For example, we rely on a single-source supplier to provide us with Alhydrogel in sufficient quantities to meet our needs to manufacture BioThrax and NuThrax, and currently rely on a single-source supplier to manufacture Raxibacumab. We also rely on single-source suppliers for the sponge applicator device and the active ingredient used to make RSDL as well as the specialty plasma in our hyperimmune specialty plasma products and certain ingredients for ACAM2000. A disruption in the availability of such materials or services from these suppliers or in the quality of the material provided by such suppliers could require us to qualify and validate alternative suppliers. If we are unable to locate or establish alternative suppliers, our ability to manufacture our products and product candidates could be adversely affected and could harm our revenues, cause us to fail to satisfy contractual commitments, lead to a termination of one or more of our contracts or lead to delays in our clinical trials, any of which could be costly to us and otherwise materially harm our business, financial condition, operating results and cash flows.

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

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

RISKS RELATED TO STRATEGIC ACQUISITIONS AND COLLABORATIONS

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

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

Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote significant resources to potential acquisitions that are

never completed. Even if we are successful in acquiring a company or product, it may not result in a successfully developed or commercialized product or, even if an acquired product is commercialized, competing products or technologies could render a product noncompetitive, uneconomical or obsolete. Moreover, the cost of acquiring other companies or in-licensing products could be substantial, and in order to acquire companies or new products, we may need to incur substantial debt or issue dilutive securities. For example, our recently completed acquisition of the ACAM2000 business required initial payments of $117.5 million and an additional milestone payment of $7.5 million on the achievement of a regulatory event. In addition, our recently completed acquisition of Raxibacumab required a $76 million upfront payment and may require up to $20 million in additional future milestone payments.

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 assets into our operations could adversely affect our ability to realize the benefits of such acquisitions and, therefore, to grow our business.

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

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

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

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 U.S. government'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, or 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 pre-approval. 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, or 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 Emergency Use Authorization. If our product candidates are not selected under this Project BioShield authority, they generally will have to be approved by the FDA through traditional regulatory mechanisms for distribution in the United States.

We may experience unforeseen events or issues during, or as a result of, preclinical testing, clinical trials or animal efficacy studies. These issues and events, which could delay or prevent our ability to receive regulatory approval for a product candidate, include, among others:

§ our inability to manufacture sufficient quantities of materials for use in trials;
§ the unavailability or variability in the number and types of subjects for each study;
§ safety issues or inconclusive or incomplete testing, trial or study results;
§ drug immunogenicity;
§ lack of efficacy of product candidates during the trials;
§ government or regulatory restrictions or delays; and
§ greater than anticipated costs of trials.

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

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

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

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

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

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

INTELLECTUAL PROPERTY RISKS

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

Our success, especially with respect to our small molecule product candidates, will depend, in large part, on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology, products and product candidates. Obtaining and maintaining this protection 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, which 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 or 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 infringement or to otherwise protect or enforce our proprietary rights could be substantial and, from time to time, our patents are subject to opposition proceedings. Some of our competitors may be better able to sustain the costs of complex patent litigation because they may have substantially greater financial resources. Intellectual property lawsuits are expensive and unpredictable and would consume management's time and attention and other resources, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents are not valid, are unenforceable, or must be interpreted narrowly and that we do not have the right to stop another party from using the inventions covered by or incorporating them. There is also a risk that, even if the validity of a patent were upheld, a court would 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 were to 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 Pfizer, Inc. an oligonucleotide adjuvant, CPG 7909, for use in our NuThrax anthrax vaccine product candidate.

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 would 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 may have substantially greater financial resources than us and 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 were 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 the 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 were 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 licensed patents 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, competitors may be able to use this information to develop products that compete with our products, which could materially and adversely impact our business.

FINANCIAL RISKS

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.

We recently entered into a five-year $200 million syndicated senior secured revolving credit facility that replaced our prior $100 million facility, which was scheduled to expire in December 2018. The senior secured credit facility also includes a $100 million accordion feature in revolver or incremental term loans, at our option, which could expand total commitments to up to $300 million subject to certain conditions and requirements under the credit agreement. 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 revolving credit facility, to restrictive covenants that may reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing;
- requiring us to pledge our assets as collateral, which could limit our ability to obtain additional debt financing;
- limiting our flexibility in planning for, or reacting to, general adverse economic and industry conditions; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

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

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 operating results, financial condition and cash flows.

We may require significant additional funding to grow our business, including efforts to acquire other companies or products, in-license and develop additional products, enhance our manufacturing capacity, support commercial marketing activities or otherwise provide additional financial flexibility. We may also require additional funding to support our ongoing operations in the event that our ability to sell BioThrax to the U.S. government is interrupted for an extended period of time, reducing our BioThrax revenues and decreasing our cash balances.

As of March 31, 2018, we had approximately $163.6 million of cash and cash equivalents. Our future capital requirements will depend on many factors, including, among others:

- the level, timing and cost of product sales;
- 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 recently 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. In May 2015, 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 May 22, 2018, 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 May 22, 2018, 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 revolving credit facility, 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, or 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 facility restricts our ability to incur additional indebtedness, including secured indebtedness.

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

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

Although we have been profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. For example, we incurred a net loss in the second quarter of 2016 and in each of the first quarters of 2018, 2015, 2014 and 2013. Our profitability has been substantially dependent on BioThrax product sales, which historically have fluctuated significantly from quarter to quarter, and we expect that they will continue to fluctuate significantly based primarily on the timing of our fulfillment of orders from the U.S. government. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

THE SPIN-OFF OF OUR BIOSCIENCES BUSINESS

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

It was our intention that our distribution on August 1, 2016 of all of the outstanding shares of Aptevo common stock to our stockholders, or 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, or the Code. In anticipation of the Distribution, we received a favorable private letter ruling from the Internal Revenue Service, or 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 restricts 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 is 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 will comply with these restrictions. Failure of Aptevo to satisfy its obligations 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

Pending litigation and legal proceedings and the impact of any finding of liability or damages could adversely impact our business, operating results, financial condition and cash flows.

From time to time, we may be named as a defendant in various legal actions or other proceedings. Certain of these actions include and future actual or threatened legal actions may include, claims for substantial and indeterminate amounts of damages, or may result in other action adverse to us.

For example, a purported class action lawsuit was filed against us and several of our senior officers and directors in the United States District Court for the District of Maryland seeking unspecified damages on behalf of a putative class of persons who purchased or otherwise acquired our common stock between January 11, 2016 and June 21, 2016. The complaint, as amended on December 27, 2016, alleges, among other things, that we made materially false and misleading statements about the government's demand for BioThrax and expectations that our five-year exclusive procurement contract with HHS would be renewed and omitted certain material facts.

The results of this lawsuit and possible other future legal proceedings cannot be predicted with certainty. Accordingly, we cannot determine whether our insurance coverage would be sufficient to cover the costs or potential losses, if any. Regardless of merit, litigation may be both time-consuming and disruptive to our operations and cause significant expense and diversion of management attention. If we do not prevail in the purported class action lawsuit or in other future legal proceedings, we may be faced with significant monetary damages or injunctive relief against us that may adversely affect our business, operating results, financial condition and cash flows.

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

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

One measure of protection against such lawsuits is coverage under the Public Readiness and Emergency Preparedness Act, or 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, or 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 U.S. government, or the U.S. government 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 may occur. 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. 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. If we identify a material weakness in our internal control over financial reporting, it 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 are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial reporting, and the trading price of our common stock could be negatively affected.

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

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to interruption, invasion, computer viruses, destruction, malicious intrusion and additional related disruptions, which may result in the impairment of production and key business processes.

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

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

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

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

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

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

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his substantial beneficial ownership of our common stock. As of April 27, 2018, 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, or Section 203. In general and subject to certain exceptions, Section 203 prohibits a publicly-held corporation from engaging in a business combination with an interested stockholder, generally a person which, together with its affiliates, owns or within the last three years has owned 15% or more of the corporation's voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us.

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

Our Board of Directors may implement a stockholder rights plan without stockholder approval. We previously implemented a stockholder rights plan, which expired on November 14, 2016. Under our prior stockholder rights plan, we issued to each of our stockholders one preferred stock purchase right for each outstanding share of our common stock. Each right, when exercisable, would have entitled its holder to purchase from us a unit consisting of one one-thousandth of a share of series A junior participating preferred stock at a purchase price of $150 in cash, subject to adjustments. Our stockholder rights plan was intended to protect stockholders in the event of an unfair or coercive offer to acquire us and to provide our Board of Directors with adequate time to evaluate unsolicited offers.

Our Board of Directors may implement a new stockholder rights plan, which may have anti-takeover effects, potentially preventing a change in control of us in instances in which some stockholders may believe a change in control is in their best interests. This could cause substantial dilution to a person or group that attempts to acquire us on terms that our Board of Directors does not believe are in our best interests or those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

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

Our stock price has been, and is likely to continue to be, volatile. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this "Risk Factors" section, or for reasons unrelated to our operations, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as industry conditions and general financial, economic and political instability. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through April 27, 2018, our common stock has traded as high as $55.91 per share and as low as $4.40 per share. The stock market in general as well as the market for biopharmaceutical companies in particular has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including, among others:

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contracts, decisions and procurement policies by the U.S. government 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 facility limits and any future debt agreements that we enter into may limit our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 6 million shares of our common stock outstanding as of April 27, 2018, have the right to require us to register these shares of common stock under specified circumstances. In May 2015, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer" under SEC rules, this shelf registration statement, effective until May 2018, would provide for a secondary offering of these shares from time to time.

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

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

Not applicable.

Purchases of Equity Securities

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

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

EXHIBIT INDEX

Exhibit Number	Description
10.1#†	Modification No. 7, effective February 26, 2018, 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 (the "CDC BioThrax Procurement Contract").
10.2#	Modification No. 8, effective March 6, 2018, to the CDC BioThrax Procurement Contract.
10.3	Form of 2018-2020 Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K, filed on February 14, 2018).
12#	Ratio of Earnings to Fixed Charges.
31.1#	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).
31.2#	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).
32.1#	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101. INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Calculation Linksbase Document.
101.DEF	XBRL Taxonomy Definition Linksbase Document.
101.LAB	XBRL Taxonomy Label Linksbase Document.
101.PRE	XBRL Taxonomy Presentation Linksbase Document.

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language):
(i) Condensed Consolidated Statements of Operations for the three months ended March 31, 2018 and 2017;
(ii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three months ended March 31, 2018 and 2017;
(iii) Condensed Consolidated Balance Sheets at March 31, 2018 and December 31, 2017;
(iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2018 and 2017; and
(v) Condensed Consolidated Statement of Changes in Stockholders' Equity for the three months ended March 31, 2018; and
(vi) Notes to Condensed Consolidated Financial Statements.

Filed herewith.
† Confidential treatment requested with the Securities and Exchange Commission as to certain portions. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

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/DANIEL J. ABDUN-NABI
Daniel J. Abdun-Nabi
Chief Executive Officer
(Principal Executive Officer)

Date: May 4, 2018

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

Date: May 4, 2018