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 September 30, 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☑ Yes ☐ No

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

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

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

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

As of October 26, 2018, the registrant had 50,945,056 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 and the ability of our collaborations to protect our intellectual property rights;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- our ability to successfully integrate our acquisitions of PaxVax Holding Company Ltd. and Adapt Pharma Limited, both of which were acquired in October 2018, and realize the benefits of these acquisitions;
- 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 facilities;
- our ability to obtain and maintain regulatory approvals for our product candidates and the timing of any such approvals;
- the procurement of products by 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)

	September 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 339,358	$ 178,292
Restricted cash	1,043	1,043
Accounts receivable	76,955	143,653
Inventories	125,745	142,812
Income tax receivable, net	-	2,432
Prepaid expenses and other current assets	20,047	17,157
Total current assets	563,148	485,389
Property, plant and equipment, net	435,075	407,210
Intangible assets, net	107,861	119,597
Goodwill	49,130	49,130
Deferred tax assets, net	12,652	2,834
Other assets	5,757	6,046
Total assets	$ 1,173,623	$ 1,070,206
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 38,874	$ 41,751
Accrued expenses and other current liabilities	7,425	4,831
Accrued compensation	41,807	37,882
Contingent consideration, current portion	2,954	2,372
Income taxes payable, net	164	-
Deferred revenue, current portion	10,790	13,232
Total current liabilities	102,014	100,068
Contingent consideration, net of current portion	9,003	9,902
Long-term indebtedness	13,495	13,457
Income taxes payable	12,500	12,500
Deferred revenue, net of current portion	65,343	17,259
Other liabilities	4,619	4,675
Total liabilities	206,974	157,861
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at both September 30, 2018 and December 31, 2017	-	-
Common stock, $0.001 par value; 200,000,000 shares authorized, 51,403,585 shares issued and 50,186,299 shares outstanding at September 30, 2018; 50,619,808 shares issued and 49,405,365 shares outstanding at December 31, 2017	51	50
Treasury stock, at cost, 1,217,286 and 1,214,443 common shares at September 30, 2018 and December 31, 2017, respectively	(39,642)	(39,497)
Additional paid-in capital	640,178	618,416
Accumulated other comprehensive loss	(4,666)	(3,698)
Retained earnings	370,728	337,074
Total stockholders' equity	966,649	912,345
Total liabilities and stockholders' equity	$ 1,173,623	$ 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(Unaudited)		(Unaudited)	
Revenues:				
Product sales	$ 133,269	$ 114,296	$ 389,115	$ 259,875
Contract manufacturing	22,172	18,912	71,963	52,700
Contracts and grants	18,212	16,226	50,589	54,489
Total revenues	173,653	149,434	511,667	367,064
Operating expenses:				
Cost of product sales and contract manufacturing	73,232	44,503	220,449	125,449
Research and development	37,006	22,659	90,802	68,886
Selling, general and administrative	42,105	34,503	121,815	101,521
Income from operations	21,310	47,769	78,601	71,208
Other income (expense):				
Interest income	701	637	1,229	1,593
Interest expense	(642)	(1,991)	(1,884)	(5,734)
Other income (expense), net	190	(101)	11	(387)
Total other income (expense), net	249	(1,455)	(644)	(4,528)
Income before provision for income taxes	21,559	46,314	77,957	66,680
Provision for income taxes	614	12,763	11,776	18,028
Net income	$ 20,945	$ 33,551	$ 66,181	$ 48,652
Net income per share - basic	$ 0.42	$ 0.81	$ 1.33	$ 1.19
Net income per share - diluted (1)	$ 0.41	$ 0.68	$ 1.29	$ 1.03
Weighted-average number of shares - basic	50,071,632	41,222,504	49,851,082	40,989,813
Weighted-average number of shares - diluted	51,486,996	50,467,829	51,189,680	50,090,088

(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
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(Unaudited)		(Unaudited)	
Net income	$ 20,945	$ 33,551	$ 66,181	$ 48,652
Foreign currency translations, net of tax	(250)	(296)	(968)	516
Comprehensive income	$ 20,695	$ 33,255	$ 65,213	$ 49,168

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)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:	(Unaudited)	
Net income	$ 66,181	$ 48,652
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	16,664	11,805
Depreciation and amortization	37,106	29,899
Income taxes	12,761	18,618
Change in fair value of contingent consideration	1,917	1,350
Other	1,515	703
Changes in operating assets and liabilities:		
Accounts receivable	66,455	9,411
Inventories	17,067	5,113
Income taxes payable	(10,130)	(5,515)
Prepaid expenses and other assets	(5,921)	(2,157)
Accounts payable	(5,695)	2,965
Accrued expenses and other liabilities	2,457	(2,334)
Accrued compensation	3,925	(1,902)
Deferred revenue	3,262	14,006
Net cash provided by operating activities	207,564	130,614
Cash flows from investing activities:		
Purchases of property, plant and equipment and other	(51,275)	(42,381)
Proceeds from sale of assets	2,624	-
Net cash used in investing activities	(48,651)	(42,381)
Cash flows from financing activities:		
Issuance of common stock upon exercise of stock options	11,402	10,799
Debt issuance costs	-	(1,426)
Taxes paid on behalf of employees for equity activity	(6,303)	(4,184)
Payments of notes payable to Aptevo	-	(20,000)
Contingent consideration payments	(2,234)	(2,744)
Restricted cash	-	(1,043)
Purchase of treasury stock	(145)	(83)
Net cash provided by (used in) financing activities	2,720	(18,681)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(567)	(74)
Net increase in cash, cash equivalents and restricted cash	161,066	69,478
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)	$ 340,401	$ 340,991

(1) As of December 31, 2017 and September 30, 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)	(3,698)	304,547	879,818
Employee equity plans activity	783,777	1	21,762	-	-	-	-	21,763
Treasury stock	-	-	-	(2,843)	(145)	-	-	(145)
Net income	-	-	-	-	-	-	66,181	66,181
Foreign currency translation, net of tax	-	-	-	-	-	(968)	-	(968)
Balance at September 30, 2018	51,403,585	$ 51	$ 640,178	(1,217,286)	$ (39,642)	$ (4,666)	$ 370,728	$ 966,649

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

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 September 30, 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 nine months ended September 30, 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

Recently Adopted

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

In August 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). ASU 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 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 2016-18, *Restricted Cash (Topic 230): Statement of Cash Flows* ("ASU 2016-18"). ASU 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 consists 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 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"). ASU 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.

ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting*

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payments issued to nonemployees for goods and services. ASU No. 2018-07 is intended to reduce cost and complexity and to improve financial reporting for share-based payments issued to nonemployees (for example, service providers, external legal counsel, suppliers, etc.). The standard will be effective after December 15, 2018 for the Company, with early adoption permitted, but no earlier than the Company's adoption date of Topic 606. The Company early adopted the new standard effective April 1, 2018. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

Not Yet Adopted

ASU 2016-02, *Leases (Topic 842)*

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 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, 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's adoption efforts are primarily focused on the review of its existing lease contracts, identification of other contracts that may fall under the scope of the new guidance and performing a gap analysis on the current state of lease-related activities compared with the future state of lease-related activities. The Company has identified the lease agreements that will be impacted by the new standard and is currently evaluating the overall impact on its condensed consolidated financial statements and related disclosures.

ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*

In October 2016, the FASB issued ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory* ("ASU 2016-16"). ASU 2016-16 improves the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. The new standard will require entities to recognize the income tax consequences of an intra-entity transfer of a non-inventory asset when the transfer occurs. The guidance is effective for fiscal years beginning after December 15, 2017, and early adoption is permitted. The Company is currently evaluating the effects of adopting ASU 2016-16

on its condensed consolidated financial statements but the adoption is not expected to have a significant impact as of the filing of this report.

ASU 2017-04, *Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*

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

ASU 2018-02, *Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*

In February 2018, the FASB issued ASU 2018-02, *Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* ("ASU 2018-02"). ASU 2018-02 provides the option to reclassify certain income tax effects related to the Tax Cuts and Jobs Act passed in December of 2017 between accumulated other comprehensive income and retained earnings and also requires additional disclosures. ASU 2018-02 is effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. Adoption of ASU 2018-02 is to be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the tax laws or rates were recognized. The Company is currently evaluating the impact of adopting ASU 2018-02 on its condensed consolidated financial statements.

ASU 2018-11, *Leases (Topic 842)*: *Targeted Improvements*

In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements* ("ASU 2018-11"). In issuing ASU 2018-11, the FASB decided to provide another transition method in addition to the existing transition method by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company is currently evaluating the impact that ASU 2016-02 and ASU 2018-11 will have 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 ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU No. 2014-09"). ASU No. 2014-09 (known as ASC 606) 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 as of January 1, 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 nine months ended September 30, 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 primary source of funding for 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 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 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 at January 1, 2018, the Company determined that there was one performance obligation to provide ongoing manufacturing capability to the U.S. government and would 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.

In September 2018, the Company modified the CIADM contract under which one of the modifications reduced the 17 additional option periods to seven with the contract now scheduled to expire in June 2027. The Company determined the modification will be accounted for prospectively as a termination of the existing contract and the creation of a new contract.

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 September 30, 2018 and December 31, 2017, the Company had $77.0 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 September 30, 2018 and December 31, 2017, the Company had contract assets associated with deferred costs of $4.0 million and $2.9 million, respectively, which is included in prepaid expenses 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	18,384
Recognition of revenue included in beginning of year contract liability	(15,121)
Balance at September 30, 2018	$ 76,133

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 and nine months ended September 30, 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 and nine months ended September 30, 2018, the Company's revenues disaggregated by the major sources was as follows:

(in thousands)	**Three Months Ended September 30, 2018**			**Nine Months Ended September 30, 2018**		
	U.S Government	**Non-U.S. Government**	**Total**	**U.S Government**	**Non-U.S. Government**	**Total**
Product sales	$ 127,332	$ 5,937	$ 133,269	$ 363,254	$ 25,861	$ 389,115
Contract manufacturing	-	22,172	22,172	-	71,963	71,963
Contracts and grants	16,656	1,556	18,212	46,711	3,878	50,589
Total revenues	$ 143,988	$ 29,665	$ 173,653	$ 409,965	$ 101,702	$ 511,667

As of September 30, 2018, the Company had expected future revenues associated with performance obligations that have not been satisfied of approximately $599 million. The Company expects to recognize a majority of these revenues within the next 24 months, with the remainder recognized thereafter. However, the amount and timing of revenue recognition for unsatisfied performance obligations can materially change due to timing of funding appropriations from the U.S. government and the overall success of the Company's development activities associated with its MCM product candidates that are then receiving development funding support from the government under development contracts. In addition, the amount of future revenues associated with unsatisfied performance obligations excludes the value associated with unexercised option periods in the Company's contracts (which are not performance obligations as of September 30, 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 of 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 U.S. Strategic National Stockpile ("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 included 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 allocation of the purchase price based upon the estimated fair values of assets acquired at October 6, 2017. The Company did not assume any liabilities in the acquisition. The Company has finalized the purchase price allocation related to this acquisition.

(in thousands)	
Fair value of tangible assets acquired:	
Inventory	$ 74,876
Property, plant and equipment	19,995
Total fair value of tangible assets acquired	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 and 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 amount of the purchase price paid in the acquisition 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 includes liabilities measured at fair value on a recurring basis. For the three and nine months ended September 30, 2018, the contingent purchase consideration obligations associated with RSDL increased by $0.2 million and $1.8 million, respectively. During the three and nine months ended September 30, 2017, the contingent purchase consideration obligations associated with RSDL increased by $0.9 million and $1.4 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 nine months ended September 30, 2018.

(in thousands)	
Balance at December 31, 2017	$ 12,274
Expense included in earnings	1,917
Settlements	(2,234)
Balance at September 30, 2018	$ 11,957

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 September 30, 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)	September 30, 2018	December 31, 2017
Raw materials and supplies	$ 33,845	$ 36,069
Work-in-process	64,825	76,610
Finished goods	27,075	30,133
Total inventories	$ 125,745	$ 142,812

6. Property, plant and equipment

Property, plant and equipment consisted of the following:

	September 30,	December 31,

(in thousands)	2018	2017
Land and improvements	$ 21,848	$ 21,843
Buildings, building improvements and leasehold improvements	161,175	160,005
Furniture and equipment	217,908	206,819
Software	53,180	50,829
Construction-in-progress	141,348	100,088
Property, plant and equipment, gross	595,459	539,584
Less: Accumulated depreciation and amortization	(160,384)	(132,374)
Total property, plant and equipment, net	$ 435,075	$ 407,210

In the table presented above, as of September 30, 2018 and December 31, 2017, construction-in-progress primarily includes costs related to construction of the Company's CIADM facility.

7. Intangible assets

During the three months ended September 30, 2018 and 2017, the Company recorded amortization expense for intangible assets of $3.9 million and $1.6 million, respectively. During the nine months ended September 30, 2018 and 2017, the Company recorded amortization expense for intangible assets of $11.7 million and $4.7 million, respectively. Amortization expense has been recorded in operating expenses, specifically selling, general and administrative and cost of product sales and contract manufacturing. As of September 30, 2018, the weighted average amortization period remaining for intangible assets was 8.2 years.

8. Equity

During the nine months ended September 30, 2018, the Company granted 0.4 million shares of stock options and 0.4 million shares of restricted stock units under the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "Plan"). The grants vest over three equal annual installments beginning on the day prior to the anniversary of the grant date. On May 24, 2018, the Company's stockholders approved an increase in the number of shares issuable under the Plan by 3.0 million shares, to a total of 21.9 million shares, and extended the plan term to May 23, 2028.

9. Income taxes

The estimated effective annual tax rate for the Company, which excludes discrete adjustments, was 26% and 32% for the nine months ended September 30, 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 nine months ended September 30, 2018 and 2017, the Company recorded a discrete tax benefit of $8.7 million and $3.3 million, respectively, primarily associated with equity awards activity and finalizing positions taken on the Company's 2017 US federal and state income tax filings.

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 nine months ended September 30, 2018, the Company revised certain provisional estimates recognized in 2017 upon the filing of US federal and state income tax filings. As the Internal Revenue Service and state jurisdictions continue to issue and/or clarify guidance, additional work may be necessary for a more detailed analysis of the Company's deferred tax assets and liabilities, its historical foreign earnings, as well as potential correlative adjustments. Any correlative adjustment to these amounts will be recorded to current tax expense in the final quarter of 2018 when the analysis is complete.

10. Earnings per share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except share and per share data)	2018	2017	2018	2017
Numerator:				
Net income	$ 20,945	$ 33,551	$ 66,181	$ 48,652
Interest expense on convertible debt, net of tax	-	704	-	2,445
Amortization of convertible debt issuance costs, net of tax	-	195	-	586
Net income, adjusted	$ 20,945	$ 34,450	$ 66,181	$ 51,683
Denominator:				
Weighted-average number of shares—basic	50,071,632	41,222,504	49,851,082	40,989,813
Dilutive securities—equity awards	1,415,364	1,148,857	1,338,598	1,003,794
Dilutive securities—convertible debt	-	8,096,468	-	8,096,481
Weighted-average number of shares—diluted	51,486,996	50,467,829	51,189,680	50,090,088
Net income per share - basic	$ 0.42	$ 0.81	$ 1.33	$ 1.19
Net income per share - diluted	$ 0.41	$ 0.68	$ 1.29	$ 1.03

For the three and nine months ended September 30, 2018 and 2017, basic earnings per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period.

For the three and nine months ended September 30, 2018, diluted earnings per share was computed using the "treasury method" by dividing the net income 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 and performance stock units.

For the three and nine months ended September 30, 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 and performance stock units along with the assumption of the conversion of the Notes, at the beginning of the period. The Company terminated the conversion rights under the Notes during the fourth

quarter of 2017.

For the three and nine months ended September 30, 2018 and 2017, there were no stock options excluded from the calculation of diluted earnings per share.

11. Litigation

Shareholder Class Action Lawsuit filed July 19, 2016

On July 19, 2016, Plaintiff William Sponn ("Sponn"), filed a putative class action complaint in the United States District Court for the District of Maryland on behalf of purchasers of the Company's common stock between January 11, 2016 and June 21, 2016, inclusive (the "Class Period"), seeking to pursue remedies under the 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 then engaged 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. On June 8, 2018 the Court granted class certification with a shortened class period, May 5, 2016 to June 21, 2016. The Defendants have denied, and continue to deny any and all allegations of fault, liability, wrongdoing, or damages. However, recognizing the risk, time, and expense of litigating any case to trial, on August 27, 2018, the Company reached an agreement in principle with Plaintiffs to settle all of the related claims of any individual plaintiff that purchased Company stock from January 11, 2016 to June 21, 2016, for $6.5 million, an amount that will be paid by the Company's insurance carrier. The settlement requires no payment by any of the Defendants. The Company and Defendants continue to deny any and all liability. The parties executed the settlement agreement on October 16, 2018, and filed the agreement with the court on October 17, 2018. The court granted preliminary approval of the settlement on October 18, 2018 and has scheduled a hearing regarding final approval for January 22, 2019. Although the court has granted preliminary approval, the court could decide not to grant final approval of the settlement or change terms of the settlement, and the law requires that individual plaintiffs have the right to opt-out of the settlement and bring their own, individual claims. The Company, therefore, at this time, cannot predict the results of this lawsuit and possible other legal proceedings with certainty. Defendants continue to believe that the allegations in the complaint are without merit. As of the date of this filing, the range of potential loss cannot be determined or estimated.

12. Subsequent events

Acquisitions

Acquisition of PaxVax

On October 4, 2018, the Company completed the acquisition of PaxVax Holding Company Ltd. ("PaxVax"), a company focused on developing, manufacturing, and commercializing specialty vaccines that protect against existing and emerging infectious diseases. This acquisition includes Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever, Vaxchora® (Cholera Vaccine, Live, Oral), the only FDA-licensed vaccine for the prevention of cholera, an adenovirus 4/7 vaccine candidate being developed for military personnel under contract with the DoD, and additional clinical-stage vaccine candidates targeting chikungunya and other emerging infectious diseases, European-based current good manufacturing practices ("cGMP") biologics manufacturing facilities, and approximately 250 employees including those in research and development, manufacturing, and commercial operations with a specialty vaccines salesforce in the U.S. and in select European countries.

At the closing, the Company paid a cash purchase price of $270 million, using a combination of cash-on-hand and borrowings under the Company's senior secured credit agreement. This transaction will be 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 PaxVax will be recorded as of October 4, 2018, the acquisition date, at their respective fair values, and combined with those of the Company. As of the date of this filing, the Company has not completed the initial accounting for the PaxVax acquisition due to the Company's need to continue to gather data necessary to complete the fair value valuation of the assets acquired and liabilities assumed.

Acquisition of Adapt

On October 15, 2018, the Company completed the acquisition of Adapt Pharma Limited ("Adapt") and its NARCAN® (naloxone HCl) Nasal Spray marketed product, the first and only needle-free formulation of naloxone approved by the FDA and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression. This acquisition includes the NARCAN Nasal Spray marketed product and a development pipeline of new treatment and delivery options to address opioid overdose, and approximately 50 employees, located in the U.S., Canada, and Ireland, including those responsible for supply chain management, research and development, government affairs, and commercial operations.

The Company paid approximately $575 million in cash at the closing (exclusive of closing adjustments) and issued 733,309 shares of Common Stock, based on the volume-weighted average price per share of the Common Stock as reported on the New York Stock Exchange for the ten-trading day period ending two days before closing, or $65.28 per share (an aggregate total of $47.9 million, inclusive of adjustments). The remaining consideration payable for the acquisition consists of up to $100 million in cash based on the achievement of certain sales milestones through 2022. The Company funded the cash portion of the payments made at closing using a combination of cash-on-hand and borrowings under its Amended Credit Agreement, as described in the *Long-term debt* section below.

This transaction will be 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 Adapt will be recorded as of October 15, 2018, the acquisition date, at their respective fair values, and combined with those of the Company. As of the date of this filing, the Company has not completed the initial accounting for the Adapt acquisition due to the Company's need to continue to gather data necessary to complete the fair value valuation of the assets acquired and liabilities assumed.

Legal proceedings associated with the acquisition of Adapt

ANDA Litigation

On September 14, 2018, Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd. (collectively, "Adapt Pharma") and Opiant Pharmaceuticals, Inc. ("Opiant") received notice from Perrigo UK FINCO Limited Partnership ("Perrigo"), that Perrigo had filed an Abbreviated New Drug Application ("ANDA"), with the United States Food and Drug Administration (the "FDA"), seeking regulatory approval to market a generic version of

NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of U.S. Patent Nos. 9,211,253 (the '"253 Patent"), 9,468,747 (the '"747 Patent"), 9,561,177 (the '"177 Patent"), 9,629,965 (the '"965 Patent") and 9,775,838 (the '"838 Patent"). Perrigo's notice letter asserts that its generic product will not infringe any valid and enforceable claim of these patents.

On October 25, 2018, Emergent BioSolutions' Adapt Pharma subsidiaries and Opiant (collectively, the "Plaintiffs") filed a complaint for patent infringement against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo's ANDA filing with the FDA. As a result of timely filing the lawsuit in accordance with the Hatch-Waxman Act, a 30-month stay of approval will be imposed by the FDA on Perrigo's ANDA, which is expected to remain in effect until March 2021 absent an earlier judgment, unfavorable to the Plaintiffs, by the Court. The Plaintiffs seek, among other relief, an order that the effective date of FDA approval of the ANDA be a date no earlier than the expiration of each of the '253 Patent, the '747 Patent, the '177 Patent, the '965 Patent and the '838 Patent, as well as equitable relief enjoining Perrigo from infringing these patents, and monetary relief as a result of any such infringement. Emergent continues to vigorously enforce the intellectual property portfolio related to NARCAN® Nasal Spray.

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

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

In the complaints described in the prior two paragraphs above, the Plaintiffs seek, among other relief, an order that the effective date of FDA approval of the Teva ANDA be a date not earlier than the expiration of the applicable patent, as well as equitable relief enjoining Teva from making, using, offering to sell, selling, or importing the product that is the subject of the Teva ANDA until after the expiration of the applicable patent, and monetary relief as a result of any such infringement.

As of the date of this filing, the range of potential gain cannot be determined or estimated for the above mentioned complaints.

Long-term debt

On September 29, 2017, the Company entered into a senior secured credit agreement (the "2017 Credit Agreement") with four lending financial institutions. The 2017 Credit Agreement provided for a senior secured credit facility of up to $200 million through September 29, 2022. The 2017 Credit Agreement also included a $100 million accordion feature, which provided for an additional $100 million in revolver or incremental term loans, at the option of the Company, resulting in a potential aggregate commitment of up to $300 million. On October 4, 2018, the Company drew down $100 million under the 2017 Credit Agreement to pay for a portion of the purchase price of PaxVax.

On October 15, 2018, the Company entered into an Amended and Restated Credit Agreement, dated as of October 15, 2018 (the "Amended Credit Agreement"), which amended and restated the Company's 2017 Credit Agreement, dated as of September 29, 2017.

The Amended Credit Agreement (i) increased the revolving credit facility (the "Revolving Credit Facility") from $200 million to $600 million, (ii) extended the maturity of the Revolving Credit Facility from September 29, 2022 to October 13, 2023, (iii) provided for a term loan in the original principal amount of $450 million (the "Term Loan Facility," and together with the Revolving Credit Facility, the "Senior Secured Credit Facility"), (iv) added several additional lenders, (v) amended the applicable margin such that borrowings with respect to the Revolving Credit Facility will bear interest at the annual rate described below, (vi) amended the provision relating to incremental credit facilities such that the Company may request one or more incremental term loan facilities, or one or more increases in the commitments under the Revolving Credit Facility (each an "Incremental Loan"), in any amount if, on a pro forma basis, the Company's consolidated secured net leverage ratio does not exceed 2.50 to 1.00 after such incurrence, plus $200 million and (vii) amended the maximum consolidated net leverage ratio financial covenant from 3.50 to 1.0 (subject to 0.50% step up in connection with material acquisitions) to the maximum consolidated net leverage ratio described below.

Prior to entering into the Amended Credit Agreement, the outstanding principal balance under the Revolving Credit Facility was $100 million. On October 15, 2018, the Company borrowed an additional $218 million, bringing the total borrowings under the Revolving Credit Facility to $318 million and the full $450 million under the Term Loan Facility. Such borrowings were used to finance a portion of the consideration for the Adapt acquisition and related fees, costs and expenses and the remainder will be used for general corporate purposes.

The Revolving Credit Facility may be utilized for working capital, permitted acquisitions, capital expenditures and other general corporate purposes. The Revolving Credit Facility is available for borrowing through October 12, 2023 (unless earlier terminated). Borrowings under the Revolving Credit Facility and the Term Loan Facility will bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.25% to 2.00% per annum, depending on the Company's consolidated net leverage ratio or (b) a base rate (which is the highest of the prime rate, the federal funds rate plus 0.50%, and a eurocurrency rate for an interest period of one month plus 1%) plus a margin ranging from 0.25% to 1.00%, depending on the Company's consolidated net leverage ratio.

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

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

The Amended Credit Agreement contains affirmative and negative covenants customary for financings of this type. Negative covenants in the

Amended Credit Agreement, among other things, limit the ability of the Company to: incur indebtedness and liens; dispose of assets; make investments including loans, advances, guarantees, or acquisitions (other than permitted acquisitions, subject to compliance with the financial covenants and certain other conditions); and enter into certain merger or consolidation transactions. The Amended Credit Agreement also contains financial covenants, including (1) a minimum consolidated debt service coverage ratio of 2.50 to 1.00, and (2) a maximum consolidated net leverage ratio of 4.00 to 1.00 through September 29, 2019, 3.75 to 1.00 from September 30, 2019 through September 29, 2020 and 3.50 to 1.00 thereafter, which may be adjusted to 4.00 to 1.00 for a four quarter period in connection with a material permitted acquisition, subject to the terms and conditions of the Amended Credit Agreement. Each of the ratios referred to in the foregoing clauses (1) and (2) is calculated on a consolidated basis for each consecutive four fiscal quarter period.

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. We have a portfolio of eleven products through which we generate our product sales revenue, which accounts for a majority of 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 product candidates.

Our product portfolio includes:

Vaccines and Anti-Infectives

- 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);
- Vaxchora® (Cholera Vaccine, Live, Oral), the only FDA-licensed vaccine for the prevention of cholera (acquired in October 2018); and
- Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever (acquired in October 2018).

Devices

- NARCAN® (naloxone HCl) Nasal Spray, the first and only needle-free formulation of naloxone approved by the FDA and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression (acquired in October 2018);
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only medical device cleared by the FDA to remove or neutralize the following chemical warfare agents from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin; and
- Trobigard™ (atropine sulfate, obidoxime chloride), an auto-injector device designed for intramuscular self-injection of atropine sulfate and obidoxime chloride, as a nerve agent countermeasure. This product is not currently approved or cleared by the FDA or any similar regulatory body, and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

Antibody Therapeutics

- Raxibacumab (Anthrax Monoclonal), the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax (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; and
- VIGIV [Vaccinia Immune Globulin Intravenous (Human)], the only antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination.

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

Vaccines and Anti-Infectives

- NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), a next generation anthrax vaccine;
- 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);
- Live Attenuated Virus, a vaccine that address adenovirus types 4 and 7 (acquired in October 2018); and
- Chikungunya Virus Like Particle (VLP) Platform, vaccine for the prevention of disease caused by the chikungunya virus (acquired in October 2018).

Devices

- 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.

Antibody Therapeutics

- 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; and
- FILOV (NP026), an equine polyclonal antibody therapeutic being developed to treat hemorrhagic fever caused by Filoviruses (Ebola, Marburg and Sudan).

Highlights and Business Accomplishments for 2018

In October 2018, we completed the acquisition of Adapt Pharma Limited, or Adapt, and its marketed product NARCAN® (naloxone HCl) Nasal Spray, the first and only needle-free formulation of naloxone approved by the FDA and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression. This acquisition includes NARCAN Nasal Spray product and a development pipeline of new treatment and delivery options to address opioid overdose, and bring on approximately 50 employees, located in the U.S., Canada, and Ireland, including those responsible for supply chain management, research and development, government affairs, and commercial operations. We paid approximately $575 million in cash at the closing (exclusive of closing adjustments) and issued 733,309 shares of Common Stock, based on the volume-weighted average price per share of the Common Stock as reported on the New York Stock Exchange for the ten-trading day period ending two days before closing, or $65.28 per share (an aggregate total of $47.9 million, inclusive of adjustments). The remaining consideration payable for the acquisition consists of up to $100 million in cash based on the achievement of certain sales milestones through 2022.

In October 2018, we completed the acquisition of PaxVax Holding Company Ltd., or PaxVax, a company focused on developing, manufacturing, and commercializing specialty vaccines that protect against existing and emerging infectious diseases, for an all-cash consideration of $270 million. With the closing of this transaction, we acquired two marketed vaccines – Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever, and Vaxchora® (Cholera Vaccine, Live, Oral), the only FDA-licensed vaccine for the prevention of cholera, a potentially serious intestinal disease, caused by *Vibrio cholerae serogroup O1*. The acquisition broadens our development pipeline with vaccines that address adenovirus types 4 and 7, which are common causes of acute respiratory disease, and chikungunya, a viral disease spread to humans by infected mosquitoes that can cause severely debilitating joint pain. The acquisition also includes approximately 250 employees including those in research and development, manufacturing, and commercial operations with a specialty vaccine salesforce in the U.S. and in select European countries focused on the travelers' market and establishes an international manufacturing footprint with European-based cGMP biologics facilities.

In August 2018, the Coalition for Epidemic Preparedness Innovations, or CEPI, announced a collaboration with us and Profectus BioSciences, Inc., or Profectus, under which the parties will receive up to $36 million to advance the development and manufacture of a vaccine against the Lassa virus. Lassa virus infection—a single-stranded RNA virus belonging to the family Arenaviridae—can cause the acute viral hemorrhagic illness known as Lassa fever. The virus is spread to humans via contact with food or household items that have been contaminated with urine or feces from Mastomys rats. Under the terms of the Framework Partnering Agreement for the collaboration among the three parties, Profectus will receive development funding from CEPI for advancing its Lassa virus vaccine. CEPI will provide $4.3 million to support the first phase of the project, with options to invest up to a total of $36 million over five years, including procurement of the vaccine for stockpiling purposes. We will provide technical and manufacturing support for the CEPI-funded program. Through a separate agreement with Profectus, we have exercised the option to license and to assume control of development activities for the Lassa-virus vaccine from Profectus.

In July 2018, we announced the initiation of a Phase 1 clinical study to evaluate the safety and pharmacokinetics of ZIKV-IG, our anti-Zika virus immune globulin, being developed as a therapeutic intervention against Zika virus disease. ZIKV-IG was granted Fast Track designation by the FDA in December 2017. The FDA's fast track process is designed to facilitate the development and expeditious review of products to treat serious conditions and fill an unmet medical need. The main purpose is to get important new drugs to the patient earlier.

In June 2018, we announced a planned $50 million expansion to our Camden fill/finish facility located in Baltimore, Maryland. The multi-year expansion is expected to be completed in 2021 and will increase our contract development and manufacturing capability and capacity.

In May 2018, CEPI announced a collaboration with us and Profectus under which the parties will receive up to $25 million to advance the development and manufacture of a vaccine against the Nipah virus, or NiV, a bat-borne virus that can spread to both humans and livestock. We, through a separate agreement with Profectus, have an exclusive option to license and assume control of development activities for the NiV vaccine from Profectus. NiV and Hendra virus, or HeV, are closely related Paramyxoviruses that cause respiratory and encephalitis disease in a variety of animal hosts and in humans. There is currently no approved vaccine or therapeutic against either NiV or HeV.

In April 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 Paul-Ehrlich-Institut. Following the positive MRP outcome, national licenses were issued by the five CMS countries.

In February 2018, we announced a contract award by the Centers for Disease Control and Prevention, or CDC, an operating division of the U.S. Department of Health and Human Services, or HHS, 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.

In February 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. Initial data from the trial are expected to be available in late 2018. Upon availability of Phase 1 data, we will have the option to continue the development and commercialization of a Zika vaccine under our 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 for exclusive commercialization rights in Europe.

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 valued at up to $911 million, to supply approximately 29.4 million doses of BioThrax to the SNS through September 2021. We are focused on increasing the sales of our marketed MCMs to U.S. government customers, as well as on expanding the market for our MCM product portfolio to other customers domestically and internationally.

We have received contract and grant funding from the Biomedical Advanced Research and Development Authority, or BARDA, Department of Defense, or DoD, the 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	09/2005 — 04/2021
	BARDA	09/2018	09/2018 — 09/2023
Auto-injector platform	DoD	07/2017	07/2017 — 06/2022
BAT	BARDA	05/2006	05/2006 — 12/2027
CIADM	BARDA	06/2012	06/2012 — 06/2027
GC-072	DTRA	08/2014	08/2014 — 08/2019
NuThrax	NIAID	08/2014	08/2014 — 01/2020
	BARDA	03/2015	03/2015 — 03/2019
	BARDA	09/2016	09/2016 — 09/2021
SIAN	BARDA	09/2017	09/2017 — 09/2022
VIGIV	CDC	02/2018	02/2018 — 02/2019

Critical Accounting Policies and Estimates

During the nine months ended September 30, 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 adopted the requirements of the new standard as of January 1, 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, 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.

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 consideration received can vary based on developmental progression of the product candidate(s). When a contract's transaction price 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 constraints or material changes to our variable consideration estimates during the nine months ended September 30, 2018.

To indicate the transfer of control for our product sales and contract manufacturing services, we 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 we meet the criteria associated with transferring control of the good or service over time.

Results of Operations

Three Months Ended September 30, 2018 Compared to Three Months Ended September 30, 2017

Revenues

	Three Months Ended September 30, 2018			
(in millions)	2018	2017	Change	% Change
Product sales:				
BioThrax	$ 45.9	$ 83.5	$ (37.6)	(45%)
Other	87.4	30.8	56.6	184%
Total Product sales	133.3	114.3	19.0	17%
Contract manufacturing	22.2	18.9	3.3	17%
Contracts and grants	18.2	16.2	2.0	12%
Total revenues	$ 173.7	$ 149.4	$ 24.3	16%

Product sales:

The decrease in BioThrax sales was primarily due to the timing of BioThrax deliveries to the SNS. Substantially all of the BioThrax product sales revenues during the three months ended September 30, 2018 and 2017 consisted of sales to the U.S. government.

The increase in Other product sales relates primarily to:

- sales of ACAM2000 (which was acquired in October 2017) to the CDC;
- sales of Raxibacumab (which was acquired in October 2017) to BARDA;
- sales of RSDL to the DoD; and
- sales of Trobigard to the U.S. Department of State.

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

Contract manufacturing:

The increase in Contract manufacturing revenue was primarily due to manufacturing services at our Camden facility.

Contracts and grants:

The increase in Contracts and grants revenue was primarily due to an increase in R&D activities related to certain ongoing funded development programs, including:

- SIAN primarily related to toxicology/safety studies and manufacturing development;
- ACAM2000 (acquired October 2017) primarily related to development contract closeout activities with the CDC;
- BAT primarily related to the timing of stability testing; and
- D4 primarily related to device concept and feasibility activities.

These increases in Contracts and grants revenue were partially offset by 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:

- CIADM program, primarily due to the adoption of a new revenue accounting standard effective January 1, 2018; and
- NuThrax program related to the timing of clinical trial activities, partially offset by an increase in manufacturing development activities.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $28.7 million, or 64%, to $73.2 million for the three months ended September 30, 2018 from $44.5 million for the three months ended September 30, 2017. The increase was primarily attributable to the increase in Other product sales (primarily for ACAM2000 and Raxibacumab), partially offset by a decrease in BioThrax sales.

Research and Development Expenses

Research and development expenses increased by $14.3 million, or 63%, to $37.0 million for the three months ended September 30, 2018 from $22.7 million for the three months ended September 30, 2017. Net of contracts and grants revenue, during the three months ended September 30, 2018 and 2017, we incurred net research and development expenses of $18.8 million and $6.5 million, respectively.

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

- timing of manufacturing development activities for ACAM2000 (acquired in October 2017);
- timing of a Phase 2 clinical study and related activities for our FLU-IGIV (NP025) program;
- timing of manufacturing development activities for our NuThrax product candidate; and
- timing of manufacturing activities and toxicology/safety studies for our SIAN product candidate.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $7.6 million, or 22%, to $42.1 million for the three months ended September 30, 2018 from $34.5 million for the three months ended September 30, 2017. The increase was primarily attributable to an increase in professional services to support our strategic growth initiatives.

Total Other Income (Expense), Net

Total other income (expense), net increased by $1.7 million, or 113%, to other income, net of $0.2 million for the three months ended September 30, 2018 from other expense, net of $1.5 million for the three months ended September 30, 2017. The increase was primarily attributable to a decrease in interest expense primarily due to the conversion of substantially all of the outstanding debt under our 2.875% Convertible Senior Notes due 2021 into shares of common stock during the fourth quarter of 2017.

Provision for Income Taxes

Provision for income taxes decreased by $12.2 million, to $0.6 million for the three months ended September 30, 2018 from $12.8 million for the three months ended September 30, 2017. The decrease was primarily due to a decrease in pre-tax income of $24.7 million, an increase in the discrete tax benefit, and 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%.

Nine Months Ended September 30, 2018 Compared to Nine Months Ended September 30, 2017

Revenues

	Nine Months Ended September 30, 2018			
(in millions)	**2018**	**2017**	**Change**	**% Change**
Product sales:				
BioThrax	$ 143.7	$ 179.6	$ (35.9)	(20%)
Other	245.4	80.3	165.1	206%
Total Product sales	389.1	259.9	129.2	50%
Contract manufacturing	72.0	52.7	19.3	37%
Contracts and grants	50.6	54.5	(3.9)	(7%)
Total revenues	$ 511.7	$ 367.1	$ 144.6	39%

Product sales:

The decrease in BioThrax sales was primarily due to the timing of BioThrax deliveries to the SNS. Substantially all of the BioThrax product sales revenues during the nine months ended September 30, 2018 and 2017 consisted of sales to the U.S. government.

The increase in Other product sales relates primarily to:

- sales of ACAM2000 (which was acquired in October 2017) to the CDC;
- sales of Raxibacumab (which was acquired in October 2017) to BARDA;
- sales of Trobigard to the U.S. Department of State;
- sales of RSDL to the DoD; and
- sales of Anthrasil to the Canadian National Defence ministry.

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

Contract manufacturing:

The increase in Contract manufacturing revenue was primarily due to the design, construction and validation of manufacturing capability for a third party at our Lansing, Michigan site and manufacturing services at our Canton, Massachusetts facility and manufacturing.

Contracts and grants:

The decrease in Contracts and grants revenue was primarily due to 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:

- CIADM program primarily due to adoption of a new revenue accounting standard effective January 1, 2018. The decrease also includes a decrease in funding for CIADM task orders (related to Ebola and Zika);
- NuThrax program related to the timing of clinical trial activities, partially offset by an increase in manufacturing development activities; and
- large-scale manufacturing of BioThrax, primarily due to the timing of contract close out activities associated with the development contract from BARDA.

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

- SIAN primarily related to toxicology/safety studies and manufacturing development;
- ACAM2000 (acquired October 2017) primarily related to development contract closeout activities with the CDC; and
- D4 primarily related to device concept and feasibility activities.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $95.0 million, or 76%, to $220.4 million for the nine months ended September 30, 2018 from $125.4 million for the nine months ended September 30, 2017. The increase was primarily attributable to the increase in Other product sales (primarily for ACAM2000 and Raxibacumab) and contract manufacturing activities.

These increases were partially offset by a decrease in BioThrax sales along with higher 2017 costs for BioThrax due to an increase in the cost per dose sold associated with decreased production yields in the period in which the doses were produced.

Research and Development Expenses

Research and development expenses increased by $21.9 million, or 32%, to $90.8 million for the nine months ended September 30, 2018 from $68.9 million for the nine months ended September 30, 2017. Net of contracts and grants revenue, during the nine months ended September 30, 2018 and 2017, we incurred net research and development expenses of $40.2 million and $14.4 million, respectively.

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

- technology transfer activities for Raxibacumab (acquired in October 2017), moving the manufacturing from GlaxoSmithKline's facility to our Bayview facility;
- timing of manufacturing development activities for ACAM2000 (acquired in October 2017);
- timing of a Phase 2 clinical study and related activities for our FLU-IGIV (NP025) program; and
- timing of manufacturing activities and toxicology/safety studies for our SIAN product candidate.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $20.3 million, or 20%, to $121.8 million for the nine months ended September 30, 2018 from $101.5 million for the nine months ended September 30, 2017. The increase was primarily attributable to an increase in professional services to support our strategic growth and infrastructure improvement initiatives, along with an increase in compensation related costs.

Total Other Expense, Net

Total other expense, net decreased by $3.9 million, or 87%, to $0.6 million for the nine months ended September 30, 2018 from $4.5 million for the nine months ended September 30, 2017. The decrease was primarily attributable to a decrease in interest expense primarily due to the conversion of substantially all of the outstanding debt under our 2.875% Convertible Senior Notes due 2021 into shares of common stock during the fourth quarter of 2017.

Provision for Income Taxes

Provision for income taxes decreased by $6.2 million, to $11.8 million for the nine months ended September 30, 2018 from $18.0 million for the nine months ended September 30, 2017. The decrease was 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%. In addition, for the nine months ended September 30, 2018 and 2017, we recorded a discrete tax benefit of $8.7 million and $3.3 million, respectively, primarily associated with equity awards activity and finalizing positions taken on the Company's 2017 US federal and state income tax filings.

Liquidity and Capital Resources

Sources of Liquidity

From inception through September 30, 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 September 30, 2018, we had cash and cash equivalents of $339.4 million. As of September 30, 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 nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,	
(in millions)	**2018**	**2017**
Net cash provided by (used in):		
Operating activities(i)	$ 207.0	$ 130.5
Investing activities	(48.7)	(42.4)
Financing activities	2.7	(18.7)
Net increase in cash and cash equivalents	$ 161.0	$ 69.4

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

Operating Activities:

Net cash provided by operating activities of $207.0 million for the nine months ended September 30, 2018 was primarily due to our net income excluding non-cash items of $136.1 million and offset by changes in working capital which resulted in a net cash inflow of $71.4 million. Cash inflow includes a decrease in accounts receivable related to the timing of collection of amounts billed (primarily related to BioThrax, ACAM2000, BAT and VIGIV) and a decrease in inventories primarily due to the timing of deliveries of ACAM2000, BAT and RSDL, partially offset by a decrease in accounts payable and prepaid expenses and other assets.

Net cash provided by operating activities of $130.5 million for the nine months ended September 30, 2017 was primarily due to our net income excluding non-cash items of $111.0 million and changes in working capital which resulted in a net cash inflow of $19.6 million. Cash inflow includes an increase in deferred revenue, a decrease in accounts receivable related to the timing of collection of amounts billed primarily to the CDC, and a decrease in inventories primarily due to the timing of deliveries of BAT and VIGIV, partially offset by income taxes paid and a decrease in accrued expenses and other liabilities.

Investing Activities:

Net cash used in investing activities of $48.7 million for the nine months ended September 30, 2018 reflects infrastructure and equipment investments, including construction at our Baltimore CIADM manufacturing facility, partially offset by net proceeds from the sale of our manufacturing and development facility in Winnipeg, Manitoba.

Net cash used in investing activities of $42.4 million for the nine months ended September 30, 2017 reflects infrastructure and equipment investments, including construction at our Baltimore CIADM manufacturing facility.

Financing Activities:

Net cash provided by financing activities of $2.7 million for the nine months ended September 30, 2018 was primarily due to the $11.4 million in proceeds from the issuance of common stock pursuant to our employee stock option exercises, partially offset by $6.3 million associated with the taxes paid on behalf of employees for equity activity and $2.2 million in contingent obligation payments.

Net cash used in financing activities of $18.7 million for the nine months ended September 30, 2017 was primarily due to the payment of a $20.0 million note payable to Aptevo Therapeutics, Inc. in conjunction with the spin-off, $4.2 million associated with the taxes paid on behalf of employees for equity activity and $2.7 million in contingent obligation payments, partially offset by $10.8 million in proceeds from the issuance of common stock pursuant to our employee stock option exercises.

Long-term debt

2017 Credit Agreement

On September 29, 2017, the Company entered into a senior secured credit agreement, or the 2017 Credit Agreement, with four lending financial institutions. The 2017 Credit Agreement provided for a senior secured credit facility of up to $200 million through September 29, 2022. The 2017 Credit Agreement also included a $100 million accordion feature, which provided an additional $100 million in revolver or incremental term loans, at the option of the Company, resulting in a potential aggregate commitment of up to $300 million. On October 4, 2018, the Company drew down $100 million under the 2017 Credit Agreement to pay for a portion of the purchase price of PaxVax.

Amended and Restated Credit Agreement

On October 15, 2018, we entered into an Amended and Restated Credit Agreement, dated as of October 15, 2018, or the Amended Credit Agreement, which amended and restated our existing 2017 Credit Agreement, dated as of September 29, 2017.

The Amended Credit Agreement (i) increased the revolving credit facility, or the Revolving Credit Facility, from $200 million to $600 million, (ii) extended the maturity of the Revolving Credit Facility from September 29, 2022 to October 13, 2023, (iii) provided for a term loan in the original principal amount of $450 million, or the Term Loan Facility, and together with the Revolving Credit Facility, or the Senior Secured Credit Facility, (iv) added several additional lenders, (v) amended the applicable margin such that borrowings with respect to the Revolving Credit Facility will bear interest at the annual rate described below, (vi) amended the provision relating to incremental credit facilities such that we may request one or more incremental term loan facilities, or one or more increases in the commitments under the Revolving Credit Facility, each an Incremental Loan, in any amount if, on a pro forma basis, our consolidated secured net leverage ratio does not exceed 2.50 to 1.00 after such incurrence, plus $200 million and (vii) amended the maximum consolidated net leverage ratio financial covenant from 3.50 to 1.0 (subject to 0.50% step up in connection with material acquisitions) to the maximum consolidated net leverage ratio described below.

Prior to entering into the Amended Credit Agreement, the outstanding principal balance under the Revolving Credit Facility was approximately $100 million. On October 15, 2018, we borrowed an additional $218 million, bringing the total borrowings under the Revolving Credit Facility to $318 million and the full $450 million under the Term Loan Facility. Such borrowings were used to finance a portion of the consideration for the Adapt acquisition and related fees, costs and expenses and the remainder will be used for general corporate purposes.

The Revolving Credit Facility may be utilized for working capital, permitted acquisitions, capital expenditures and other general corporate purposes and is available for borrowing through October 12, 2023 (unless earlier terminated under the terms of the Credit Agreement). Borrowings under the Revolving Credit Facility and the Term Loan Facility will bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.25% to 2.00% per annum, depending on our consolidated net leverage ratio or (b) a base rate (which is the highest of the prime rate, the federal funds rate plus 0.50%, and a eurocurrency rate for an interest period of one month plus 1%) plus a margin ranging from 0.25 % to 1.00%, depending on our consolidated net leverage ratio.

We are required to make quarterly payments under the Amended Credit Agreement for accrued and unpaid interest on the outstanding principal balance under the Revolving Credit Facility and the Term Loan Facility, based on the above interest rates. In addition, we are required to pay commitment fees ranging from 0.150% to 0.300% per annum, depending on our consolidated net leverage ratio, in respect of the average daily unused commitments under the Revolving Credit Facility. We are to repay the outstanding principal amount of the Term Loan Facility in quarterly installments based on an annual percentage equal to 2.5% of the original principal amount of the Term Loan Facility during each of the first two years of the Term Loan Facility, 5% of the original principal amount of the Term Loan Facility during the third year of the Term Loan Facility and 7.5% of the original principal amount of the Term Loan Facility during each year of the remainder of the term of the Term Loan Facility until the maturity date of the Term Loan Facility, at which time the entire unpaid principal balance of the Term Loan Facility will be due and payable. We have the right to prepay the Term Loan Facility without premium or penalty. The Revolving Credit Facility and the Term Loan Facility mature (unless earlier terminated) on October 13, 2023.

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

The Amended Credit Agreement contains affirmative and negative covenants customary for financings of this type. Negative covenants in the Amended Credit Agreement, among other things, limit the ability of us to: incur indebtedness and liens; dispose of assets; make investments including loans, advances, guarantees, or acquisitions (other than permitted acquisitions, subject to compliance with the financial covenants and certain other conditions); and enter into certain merger or consolidation transactions. The Amended Credit Agreement also contains financial covenants, including (1) a minimum consolidated debt service coverage ratio of 2.50 to 1.00, and (2) a maximum consolidated net leverage ratio of 4.00 to 1.00 through September 29, 2019, 3.75 to 1.00 from September 30, 2019 through September 29, 2020 and 3.50 to 1.00 thereafter, which may be adjusted to 4.00 to 1.00 for a four quarter period in connection with a material permitted acquisition, subject to the terms and conditions of the Amended Credit Agreement. Each of the ratios referred to in the foregoing clauses (1) and (2) is calculated on a consolidated basis for each consecutive four fiscal quarter period.

Funding Requirements

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

- existing cash and cash equivalents;
- net proceeds from the sale of our products and contract manufacturing services;
- development contracts and grants funding; and
- our senior secured credit facilities and any other lines of credit we may establish from time to time.

There are numerous risks and uncertainties associated with product sales and with the development and commercialization of our product candidates. We may seek additional external financing to provide additional financial flexibility. Our future capital requirements will depend on many factors, including (but not limited to):

- the level, timing and cost of product sales and contract manufacturing services;
- the extent to which we acquire or invest in and integrate companies, businesses, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
- the extent to which we repurchase additional common stock under our authorized share repurchase program; and
- the costs of commercialization activities, including product marketing, sales and distribution.

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

If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our senior secured 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 2.875% Convertible Senior Notes due 2021 from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing our notes that could have the effect of diminishing our ability to make payments on our indebtedness. However, our senior secured credit 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 up to $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 September 30, 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 September 30, 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 September 30, 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 September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. ***LEGAL PROCEEDINGS***

ANDA Litigation

On September 14, 2018, Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd., or collectively, Adapt Pharma, and Opiant Pharmaceuticals, Inc., or Opiant, received notice from Perrigo UK FINCO Limited Partnership, or Perrigo, that Perrigo had filed an Abbreviated New Drug Application, or ANDA, with the United States Food and Drug Administration, or FDA, seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of U.S. Patent Nos. 9,211,253, or the '253 Patent, 9,468,747, or the '747 Patent, 9,561,177, or the '177 Patent, 9,629,965, or the '965 Patent, and 9,775,838, or the '838 Patent. Perrigo's notice letter asserts that its generic product will not infringe any valid and enforceable claim of these patents.

On October 25, 2018, Emergent BioSolutions' Adapt Pharma subsidiaries and Opiant, or collectively, Plaintiffs, filed a complaint for patent infringement against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo's ANDA filing with the FDA. As a result of timely filing the lawsuit in accordance with the Hatch-Waxman Act, a 30-month stay of approval will be imposed by the FDA on Perrigo's ANDA, which is expected to remain in effect until March 2021 absent an earlier judgment, unfavorable to the Plaintiffs, by the Court. The Plaintiffs seek, among other relief, an order that the effective date of FDA approval of the ANDA be a date no earlier than the expiration of each of the '253 Patent, the '747 Patent, the '177 Patent, the '965 Patent and the '838 Patent, as well as equitable relief enjoining Perrigo from infringing these patents, and monetary relief as a result of any such infringement. Emergent continues to vigorously enforce the intellectual property portfolio related to NARCAN® Nasal Spray.

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

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

In the complaints described in the prior two paragraphs above, the Plaintiffs seek, among other relief, an order that the effective date of FDA approval of the Teva ANDA be a date not earlier than the expiration of the applicable patent, as well as equitable relief enjoining Teva from making, using, offering to sell, selling, or importing the product that is the subject of the Teva ANDA until after the expiration of the applicable patent, and monetary relief as a result of any such infringement.

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 then engaged 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. On June 8, 2018 the Court granted class certification with a shortened class period, May 5, 2016 to June 21, 2016. The Defendants believe that the allegations in the complaint are without merit and intend to defend themselves vigorously against those claims. But recognizing the risk of litigating any case to trial, on August 27, 2018, the Company has reached an agreement in principle with Plaintiffs to settle all related claims for any individual plaintiff that purchased Company stock from January 11, 2016 to June 21, 2016. The Company continues to deny any and all liability. On August 27, 2018, the Company reached an agreement in principle with Plaintiffs to settle all of the related claims of any individual plaintiff that purchased Company stock from January 11, 2016 to June 21, 2016, for $6.5 million, an amount that will be paid by the Company's insurance carrier. The settlement requires no payment by any of the Defendants. The Company and Defendants continue to deny any and all liability. The parties executed the settlement agreement on October 16, 2018, and filed the agreement with the court on October 17, 2018. The court granted preliminary approval of the settlement on October 18, 2018 and has scheduled a hearing regarding final approval for January 22, 2019. Although the court has granted preliminary approval, the court could decide not to grant final approval of the settlement or change terms of the settlement, and the law requires that individual plaintiffs have the right to opt-out of the settlement and bring their own, individual claims. The Company, therefore, at this time, cannot predict the results of this lawsuit and possible other legal proceedings with certainty. Defendants continue to believe that the allegations in the complaint are without merit.

ITEM 1A. RISK FACTORS

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

GOVERNMENT CONTRACTING RISKS

We currently derive a substantial portion of our revenue from sales of BioThrax to our largest customer, the 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 flows would be materially harmed.

We derive a substantial portion of our current and expected future revenues from sales of BioThrax, our anthrax vaccine licensed by the FDA to the 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 future operating results 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 Emergency Use Authorization, or 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 Human Genome Sciences, Inc. and GlaxoSmithKline LLC, collectively referred to as 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;
- 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.

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

We purchase certain supplies used in our manufacturing processes from single sources due to quality considerations, costs or constraints resulting from regulatory requirements, including device and key packaging components for NARCAN Nasal Spray. Where a particular single-source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation of materials prior to use in our products, and the complex nature of manufacturing processes. In addition, we may lose a sole-source supplier due to, among other things, the acquisition of such a supplier by a competitor (which may cause the supplier to stop selling its products to us) or the bankruptcy of such a supplier, which may cause the supplier to cease operations. Any reduction or interruption by a sole-source supplier of the supply of materials or key components used in the manufacturing of our products or an increase in the price of those materials or components could adversely affect our business, financial condition and results of operations.

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

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 acquired from GSK, to our bulk and fill finish facilities in Baltimore, Maryland, and this transfer of manufacturing operations requires FDA approval.

Under our arrangements with GSK for our acquisition of the Raxibacumab product, we will continue to purchase product from GSK to satisfy deliveries to the SNS under the current BARDA contract, which expires in 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. Following several of these inspections, regulatory authorities have issued inspectional observations, some of which were significant, but all of which are being, or have been, addressed through corrective actions. If, in connection with any future inspection, regulatory authorities find that we are not in substantial compliance with all applicable requirements, or if they are not satisfied with the corrective actions we take, our regulators may undertake enforcement action against us, which may include:

- warning letters and other communications;
- product seizure or withdrawal of the product from the market;
- restrictions on the marketing or manufacturing of a product;
- suspension or withdrawal of regulatory approvals or refusal to approve pending applications or supplements to approved applications;
- fines or disgorgement of profits or revenue; and
- injunctions or the imposition of civil or criminal penalties.

Similar action may be taken against us should we fail to comply with regulatory requirements, or later discover previously unknown problems with our products or manufacturing processes. For instance, our products are tested regularly to determine if they satisfy potency and stability requirements for their required shelf lives. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, 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 licensure of BioThrax in the 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.

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

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

MANUFACTURING RISKS

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

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

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

Providers of PHT countermeasures could be subject to an increased risk of terrorist activities. The 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 these facilities from terrorist efforts determined to disrupt our manufacturing activities.

The factors listed above could also cause disruptions at our other facilities, including our manufacturing facilities in Winnipeg, Manitoba, Canada; other Baltimore, Maryland facilities in Camden; facilities in Canton, Massachusetts; Rockville, Maryland; and Hattiesburg, Mississippi. We do not have any redundant manufacturing facilities for any of our marketed products. Accordingly, any disruption, damage, or destruction of these facilities could impede our ability to manufacture our marketed products, our product candidates and our ability to produce products for external customers, result in losses and delays, including delay in the performance of our contractual obligations or delay in our clinical trials, any of which could be costly to us and materially harm our business, financial condition, operating results and cash flows.

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

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

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

BioThrax, Raxibacumab, ACAM2000, Anthrasil, BAT, VIGIV, Vivotif, Vaxchora, and many of our current product candidates, including 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 and ACAM2000, which may not be obtained on a timely basis or at all.

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

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

We depend on certain single-source suppliers for key materials and services necessary for the manufacture of BioThrax and our other products and product candidates. For example, we rely on a single-source supplier to provide us with Alhydrogel in sufficient quantities to meet our needs to manufacture BioThrax and 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 acquisition of Adapt consisted of an upfront payment of approximately $635 million, exclusive of closing adjustments and holdbacks, and up to $100 million in cash based on achievement of certain sales milestones through 2022 and our 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 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 businesses and/or assets into our operations could adversely affect our ability to realize the benefits of such acquisitions and, therefore, to grow our business.

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

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

- retaining existing customers and attracting new customers;
- retaining key employees;

- diversion of management attention and resources;
- conforming internal controls, policies and procedures, business cultures and compensation programs;
- consolidating corporate and administrative infrastructures;
- successfully executing technology transfers and obtaining required regulatory approvals;
- consolidating sales and marketing operations;
- identifying and eliminating redundant and underperforming operations and assets;
- assumption of known and unknown liabilities;
- coordinating geographically dispersed organizations; and
- managing tax costs or inefficiencies associated with integrating operations.

If we are unable to successfully integrate pending and future acquisitions with our existing businesses, or operate any acquired business profitably, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect the growth of our business, financial condition, operating results and cash flows.

COMPETITIVE AND POLITICAL RISKS

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

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

There are a number of companies with products or product candidates addressing PHT preparedness that are competing with us for both 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, VIGIV, Vivotif and Vaxchora otherwise referred to as our "Biologic Products," may be affected by follow-on biologics, or "biosimilars," in the United States and other jurisdictions. Regulatory and legislative activity in the United States and other countries may make it easier for generic drug manufacturers to manufacture and sell biological drugs similar or identical to our Biologic Products, which might affect the profitability or commercial viability of our Biologic Products. Under the Biologics Price Competition and Innovation Act of 2010, the FDA cannot approve a biosimilar application until the 12-year exclusivity period for the innovator biologic has expired. Regulators in the European Union and in other foreign jurisdictions have already approved biosimilars. The specific regulatory framework for this biosimilar approval path and the extent to which an approved biosimilar would be substituted for the innovator biologic are not yet clear and will depend on many factors. If a biosimilar version of one of our Biologic Products were approved, it could have a material adverse effect on the sales and gross profits of the affected Biologic Product and could adversely affect our business, financial condition, operating results and cash flows.

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

Our marketed product NARCAN Nasal Spray faces substantial competition from other treatments, including injectable naloxone, auto-injectors and improvised nasal kits. In addition, other entrants may seek approval to market generic versions of NARCAN Nasal Spray before the underlying patents expire. For example, in 2016 and 2018 Teva filed, and in 2018 Perrigo filed, ANDAs which seek regulatory approval to market generic versions of NARCAN Nasal Spray before the expiration of certain underlying patents. Any reduction in demand for NARCAN in favor of a competing product, or unsuccessful efforts to defend underlying patents from infringement by generic entrants, could lead to a loss of market share and cause reduced revenues, margins and levels of profitability for us, which could adversely affect our business, financial condition, operating results and cash flows.

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

Products developed to counter the potential impact of PHTs, whether CBRNE or EID, are subject to changing political and social environments. The political responses and social awareness of the risks of these threats on military personnel or civilians may vary over time. If the threat of terrorism were to decline, then the public perception of the risk on public health and safety may be reduced. This perception, as well as political or social pressures, could delay or cause resistance to bringing our products in development to market or limit pricing or purchases of our products, any of which could negatively affect our revenues and our business, financial condition, operating results and cash flows.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Lawsuits brought against us by third parties or activists, even if not successful, could require us to spend significant management time and financial resources defending the related litigation and could potentially damage the public's perception of us and our products. Any publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of our PHT countermeasures and thereby limit the demand for our products, which would adversely affect our business, financial condition, operating results and cash flows.

PRODUCT DEVELOPMENT AND COMMERCIALIZATION RISKS

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

We have invested significant effort and financial resources in the development of our vaccines, therapeutics and medical device product candidates and the acquisition of additional product candidates. In addition to our product sales, our ability to generate revenue is dependent on a number of factors, including the success of our development programs, the 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 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. This is especially relevant with respect to our small molecule 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 may be subjected to opposition proceedings or validity challenges. 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 AV7909 anthrax vaccine product candidate.
Opiant Pharmaceuticals, Inc. formulations of naloxone, for use in our Narcan® Nasal Spray
Pharma Consult GmbH autoinjectors, including the autoinjector used for our Trobigard® atropine sulfate, obidoxime chloride.*

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

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

Third parties may choose to file patent infringement claims against us; defending ourselves from such allegations 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 license and subject us to damages, which may be material.

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

We also rely upon unpatented proprietary technology, processes and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for all of our current products, our only other intellectual property protection for products, other than trademarks, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and unique starting materials. However, these types of confidential information and trade secrets can be difficult to protect. We seek to protect this confidential information, in part, through agreements with our employees, consultants and third parties as well as confidentiality policies and audits, although these may not be successful in protecting our trade secrets and confidential information.

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

FINANCIAL RISKS

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our operations to pay our substantial debt.

As of September 30, 2018 our total consolidated indebtedness was approximately $13.5 million, including approximately $10.6 million of obligations under our senior convertible notes due in 2021. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We may also seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing could have significant adverse consequences for our business, including:

- requiring us to dedicate a substantial portion of any cash flow from operations to payment on our debt, which would reduce the amounts available to fund other corporate initiatives;
- increasing the amount of interest that we have to pay on debt with variable interest rates, if market rates of interest increase;

- subjecting us, as under our senior secured 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.

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

In connection with the acquisition of Adapt, we entered into an amendment and restatement of our 2017 credit agreement to provide for new five-year syndicated senior secured credit facilities that replaced our existing facility. The senior secured credit facilities include a $450 million Term Loan and the ability to borrow up to a $600 million revolver, of which we have drawn down $450 million and $318 million, respectively. We may also seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing could have significant adverse consequences for our business, including:

- the level, timing and cost of product sales and contract manufacturing services;
- the extent to which we acquire or invest in and integrate companies, businesses, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
- the extent to which we repurchase additional common stock under our authorized share repurchase program; and
- the costs of commercialization activities, including product marketing, sales and distribution.

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

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

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

If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our senior secured 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, which expired on August 2, 2018, restricted Aptevo from taking any action that prevents such transactions from being tax-free for U.S. federal income tax purposes. In particular, for the two-year period following the Distribution, Aptevo was restricted from taking certain actions (including restrictions on share issuances, business combinations, sales of assets, amendments to organizational documents and similar transactions) that could cause the Distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes. There can be no assurance that Aptevo adequately complied with these restrictions. If a finding is made by the IRS through a tax audit that Aptevo failed to satisfy its obligations, this could have a substantial impact on our tax obligations, consolidated financial condition and cash flows.

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

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

OTHER BUSINESS RISKS

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

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

One measure of protection against such lawsuits is coverage under the 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. Additionally, potential product liability claims related to our commercial products, including NARCAN Nasal Spray, Vivotif and Vaxchora, may be made by patients, health care providers or others who sell or consume these products. Such claims may be made even with respect to those products that possess regulatory approval for commercial sale. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition, operating results and cash flows.

The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. 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, or the internal controls of other companies we may acquire, are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial reporting, and the trading price of our common stock could be negatively affected.

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

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

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

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

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

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

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

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

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his substantial beneficial ownership of our common stock. As of October 26, 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 October 26, 2018, our common stock has traded as high as $67.24 per share and as low as $4.40 per share. The stock market in general as well as the market for biopharmaceutical companies in particular has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including, among others:

- contracts, decisions and procurement policies by the 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 October 26, 2018, have the right to require us to register these shares of common stock under specified circumstances.

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

Recent Sales of Unregistered Securities

On October 15, 2018, in connection with our acquisition of Adapt, 733,309 shares of Common Stock were issued to stockholders of Adapt (based on the volume-weighted average price per share of the Common Stock as reported on the New York Stock Exchange for the ten-trading day period ending two days before closing, or $65.28 per share) in a private placement in reliance upon the exemption from the registration requirements set forth in Section 4(a)(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

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***

The information set forth below is included herein for the purpose of providing disclosure under "Item 8.01 Other Events" of Form 8-K.

On or about October 26, 2018, Emergent BioSolutions' Adapt subsidiaries (collectively Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd.) and Opiant Pharmaceuticals, Inc. received a second Paragraph IV certification notice letter from Perrigo UK FINCO Limited Partnership, related to Perrigo's Abbreviated New Drug Application previously filed with the FDA. Perrigo is seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray prior to the expiry of the six patents listed in the FDA's Orange Book. Perrigo's first notice letter related to five of the listed patents. Perrigo's second notice letter alleges that its generic product will not infringe any valid and enforceable claim of the recently listed sixth patent, U.S. Patent No. 10,085,937.

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
2.1†	Share Purchase Agreement, dated August 28, 2018, by and among Emergent BioSolutions Inc., the Sellers identified therein, Seamus Mulligan and Adapt Pharma Limited (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on October 15, 2018).
2.2†	Merger Agreement, dated August 8, 2018, by and among Emergent BioSolutions Inc., PaxVax Holding Company Ltd., Panama Merger Sub Ltd., and PaxVax SH Representative LLC (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on October 5, 2018).
10.1	Amended and Restated Credit Agreement, dated October 15, 2018, by and among Emergent BioSolutions Inc., the lenders party thereto from time to time, and Wells Fargo Bank, National Association, as the Administrative Agent (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K, filed on October 15, 2018).
10.2#†	Modification No. 13, effective September 21, 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.
10.3#†	Modification No. 2, effective August 29, 2018 to the Award/Contract, effective September 30, 2016, from the BioMedical Advanced Research and Development Authority to Emergent Product Development Gaithersburg, Inc.
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 and nine months ended September 30, 2018 and 2017;
(ii) Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2018 and 2017;
(iii) Condensed Consolidated Balance Sheets at September 30, 2018 and December 31, 2017;
(iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and 2017; and
(v) Condensed Consolidated Statement of Changes in Stockholders' Equity for the nine months ended September 30, 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: November 1, 2018

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

Date: November 1, 2018

EXHIBIT 10.2

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES 1 2
2. AMENDMENT/MODIFICATION NO. 0013	3. EFFECTIVE DATE 09/21/2018	4. REQUISITION/PURCHASE REQ. NO. 0000HCGE-2018-28775	5. PROJECT NO. *(If applicable)*

6. ISSUED BY CODE 2543	7. ADMINISTERED BY *(If other than Item 6)* CODE 2543
Centers for Disease Control and Prevention Office of Acquisition Services (OAS) 2920 Brandywine Rd, RM 3000 Atlanta, GA 30341-5539	Centers for Disease Control and Prevention Office of Acquisition Services (OAS) 2920 Brandywine Rd, RM 3000 Atlanta, GA 30341-5539

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)* (□)		9A. AMENDMENT OF SOLICITATION NO. 9B. DATED *(See Item 11)* 10A. MODIFICATION OF CONTRACT/ORDER NO. 200-2017-92634 10B. DATED *(See Item 13)*
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 3500 N MARTIN LUTHER KING JR BLVD LANSING, MI 48906-2933	X	
CODE 026489018	FACILITY CODE	12/08/2016

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers __ is extended, __ is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning __copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEGMENT
TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter,
provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

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

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

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

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

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
This modification is issued to:

1. Correct the total funding figure from Modification 12 (error occurred in Mod 2 and carried forth to subsequent funding mods) to $[**]
2. Exercise alternate SubCLIN 2006 from Optional CLIN 0002;
3. Increase and fund [**] doses on CLIN 2006 in the amount of $[**];
4. Total funding for this contract has increased by $[**] from $[**]

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME OF CONTRACTING OFFICER Sherrie N Randall	
15B. CONTRACTOR/OFFEROR _____ *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY /s/Sherrie N Randall *(Signature of Contracting Officer)*	16C. DATE SIGNED 09/21/2018

NSN 7540-01-152-8070 **STANDARD FORM 30 (REV. 10-83)**
PREVIOUS EDITION UNUSABLE **30-105**
Prescribed by GSA **FAR (48 CFR) 53.243**

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
2006	BioThrax [**] product [**] upon date of delivery: [**] product at a unit price of $[**] Delivery Address: Contractor's Facility Delivery to be NLT [**]	[**] Doses	$ [**]	$ [**]
Line(s) Of Accounting: 9390BBG 2642 2018 75-18-0943 5623RF1101 $[**] 9390BPZ 2642 2018 75-18-0943 5623RF1101 $[**] 939ZWUX 2642 2018 75-X-0956 5664711101 $[**]				

EXHIBIT 10.3

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Triple asterisks denote omissions.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES 1 5

2. AMENDMENT/MODIFICATION NO. 0002	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS226613	5. PROJECT NO. *(If applicable)*

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

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

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended.

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)* Net Increase: $[***]

2018.199TWNP.25106

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

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

E. IMPORTANT: Contractor is not, x is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
Tax ID Number: [***]
DUNS Number: [***]
The purpose of this modification is to modify ARTICLES B.3. OPTION PRICES, B.5. ADVANCE UNDERSTANDINGS, C.1. STATEMENT OF WORK, G.3. KEY PERSONNEL, and SECTION J – LIST OF
ATTACHMENTS.

Funds Obligated Prior to this Modification: $198,705,042

Funds Obligated with Mod #2: $[***]

Total Funds Obligated to Date: $[***]
Continued ...
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)* Abigail Jenkins SVP BU HEAD VAI		16A. NAME OF CONTRACTING OFFICER CHRISTOPHER SCOTT	
15B. CONTRACTOR/OFFEROR /s/ Abigail Jenkins *(Signature of person authorized to sign)*	15C. DATE SIGNED Aug 28, 2018	16B. UNITED STATES OF AMERICA BY /s/ Christopher Scott *(Signature of Contracting Officer)*	16C. DATE SIGNED 08/29/2018

NAME OF OFFEROR OR CONTRACTOR
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. 1365869

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	EXPIRATION DATE: September 29, 2021 (Unchanged) Delivery: 08/28/2018 Delivery Location Code: HHS/OS/ASPR HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201 US Appr. Yr.: 2018 CAN: 199 TWNP Object Class: 25106 FOB: Destination Period of Performance: 09/30/2016 to 09/29/2021 Add Item 5 as follows:				
5	ASPR-18-04521 – Base period funds to support a Phase II Drug-Drug Interaction study Obligated Amount: $[***]				[***]

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

CLIN	Period of Performance	Supplies/ Services	Total Est. Cost	Fixed Fee	Total Cost Plus Fixed Fee ($)
		COST REIMBURSEMENT			
0001A (Option)	[***]	Phase II [**] Study or studies required by the FDA [**]	[***]	[***]	[***]
0012	**08/29/18-09/29/21**	**Doxycycline Arm & Redundant Contract Filler**	[***]	[***]	[***]
CLIN	**Period of Performance**	**Supplies/ Services**	**Total Est. Cost**	**Fixed Fee**	**Total Cost Plus Fixed Fee ($)**
		FIXED PRICE			
0003 (Option)	[***]	Phase IV post marketing commitments /Requirements (This is an option that may or may not be exercised during the base period as determined by the need and as established by the FDA)	N/A	N/A	[***]

CLIN	Period of Performance	Supplies/ Services	Units (# of Product)	FY 2018 Unit Price ($)	Total ($)
0004 (Option)	[***]	Additional Surge Capacity (EUA)	7,500,000 to [***]	[***]	[***]
0005 (Option)	[***]	Additional Surge Capacity (Licensure)	7,500,000 to [***]	[***]	[***]
0006 (Option)	[***]	Additional Surge Capacity (EUA)	[***]	[***]	[***]
0007 (Option)	[***]	Additional Surge Capacity (Licensure)	[***]	[***]	[***]
0008 (Option)	[***]	Additional Surge Capacity (EUA)	[***]	[***]	[***]
0009 (Option)	[***]	Additional Surge Capacity (Licensure)	[***]	[***]	[***]
0010 (Option)	[***]	Additional Surge Capacity (EUA)	[***]	[***]	[***]
0011 (Option)	[***]	Additional Surge Capacity (Licensure)	[***]	[***]	[***]

[***]

****CLIN 0012 is funded with this modification**

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

h. Option CLINS

If procurement for CLINs 4-11 occurs after FY 2018, the following chart illustrates the dose prices to be used:

Units (# of Doses)	FY 2019 Unit Price ($)	FY 2020 Unit Price ($)	FY 2021 Unit Price ($)
7,500,000 to [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

[***]

The USG reserves the right to re-negotiate the option CLINS based on availability of funds and feedback received from the FDA.

ARTICLE C.1. STATEMENT OF WORK is hereby modified as follows:

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work dated August 29, 2018 set forth in SECTION J - List of Attachments, attached hereto and made a part of the contract.

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

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

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

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

***Bold indicated changes in this modification**

SECTION J - LIST OF ATTACHMENTS is hereby modified as follows:

1. **Statement of Work, dated August 29, 2018, 10 Pages**

ATTACHMENT 1: STATEMENT OF WORK

NEXT GENERATION ANTHRAX VACCINE
RFP 16-100-SOL-0015
AV7909 Anthrax Vaccine

1.0 Contractual Statement of Work

Preamble to the Statement of Work

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work submitted in response to RFP 16-100-SOL-00015.

1.1 Scope

The scope of work for this contract includes AV7909 development activities through licensure that fall into the following areas: program management, nonclinical, clinical, regulatory, and chemistry, manufacturing, and controls (CMC). The scope of work also includes activities to support post-marketing requirements.

1.2 Objective

The objective of this Statement of Work (SOW) is to conduct all necessary activities to advance the development of AV7909 through Biologics License Application (BLA) submission and approval and post-marketing requirements. Activities to meet the objective of this SOW fall in three separate contract line item number (CLIN):

- CLIN 0001 - Approval of Emergency Use Authorization (EUA), licensure, approval, and clearance of product through the FDA (Base)
- CLIN 0001A - Conduct of a Phase 2 clinical [***] study or other studies required by the FDA [***] (Option)
- CLIN 0002 - Initial purchase, storage, and delivery of product (Base)
- CLIN 0003 - Phase 4 post marketing requirements (Option)
- CLIN 0004 - Surge Capacity - Additional procurement of product (Option)

1.3 CLIN 0001 - Approval of Emergency Use Authorization (EUA) licensure, approval, and clearance of product through the EDA (Base)

This section identifies representative tasks and sub-tasks for CLIN 0001 with associated WBS code for each task or subtask.

[***] Program Management

Emergent shall provide program management activities. The activities shall include but are not limited to:

- Identification of and management to, distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Integrated Product Development Plan.
- Establishment of and tracking of milestones and timelines for the initiation conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- Ongoing evaluation of qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.
- Maintaining and managing staff (in-house and contracted) to assure the necessary expertise and dedicated effort to perform the work.

- Directing and overseeing subcontractors and consultants to assure successful performance of planned activities within the cost and schedule constraints of the contract.

- Conducting performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both Emergent and subcontractors on a real time basis.

- Manage contract activities in accordance with Earned Value Management. In this regard, Emergent shall:

    - Provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support product approval. The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/No-Go" decision criteria and a contract Work Breakdown Structure (due within 90 days of contract award with updates as requested by the Contracting Officer's Representative (COR).

    - Submit an updated Integrated Master Schedule in an approved format.

    - Use principles of Earned Value Management System (EVMS) in the management of this contract.

    - Submit a plan for a Performance Measurement Baseline Review (PMBR) electronically via email to the Contracting Officer (CO) and COR for a PBMR to occur within 90 days of contract award.

- Develop and maintain a risk management plan.

- Participate in regular meetings to coordinate and oversee the contracting effort.

[***] Non-Clinical Toxicology

Emergent shall conduct safety and toxicology of AV7909 using animal models following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations, 21CFR Part 58), as appropriate. The activities shall include but are not limited to:

[***]

[***] Non-Clinical Efficacy

Emergent shall conduct efficacy, pharmacokinetics/pharmacodynamics, bioavailability, solubility, formulation, dose, route and schedule of the medical countermeasure using both in vitro and animal models following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations, 21 CFR Part 58), as appropriate. The activities shall include but are not limited to:

[***]

[***] Clinical Evaluation

Emergent shall design and conduct Phase 2 and Phase 3 clinical studies in accordance with all Federal regulations and Good Clinical Practice (GCP) guidelines. The activities shall include but are not limited to:

[***]

[***] Regulatory Activities

Emergent shall conduct all required regulatory activities to support submission of BLA licensure for AV7909. The activities shall include but are not limited to:

[***]

[***] - Chemistry and Manufacturing Controls (CMC)

Emergent shall complete the manufacturing activities necessary to support BLA submission. The activities shall include but are not limited to:

[***]

1.4 CLIN 0001A - Conduct of a Phase 2 clinical [***] study or other studies required by the FDA [***] (Option)

This section identifies representative tasks and sub-tasks for CLIN 0001A with associated WBS code for each task or subtask.

[***] Program Management

Emergent shall provide program management activities. The activities shall include but are not limited to:

- Identification of and management to, distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Integrated Product Development Plan.
- Establishment of and tracking of milestones and timelines for the initiation conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- Ongoing evaluation of qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.
- Maintaining and managing staff (in-house and contracted) to assure the necessary expertise and dedicated effort to perform the work.
- Directing and overseeing subcontractors and consultants to assure successful performance of planned activities within the cost and schedule constraints of the contract.
- Conducting performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both Emergent and subcontractors on a real time basis.
- Manage contract activities in accordance with Earned Value Management. In this regard, Emergent shall:
    - Provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support product approval. The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/ No Go" decision criteria and a contract Work Breakdown Structure (due within 90 days of contract award with updates as requested by the Contracting Officer's Representative (COR).
    - Submit an updated Integrated Master Schedule in an approved format.
    - Use principles of Earned Value Management System (EVMS) in the management of this contract.
    - Submit a plan for a Performance Measurement Baseline Review (PMBR) electronically via email to the Contracting Officer (CO) and COR for a PBMR to occur within 90 days of contract award.
- Develop and maintain a risk management plan.
- Participate in regular meetings to coordinate and oversee the contracting effort.

[***] Clinical Evaluation

Emergent shall design and conduct a Phase 2 clinical study in accordance with all Federal regulations and Good Clinical Practice (GCP) guidelines unless other studies are required by the FDA [***]. The activities shall include, but are not limited to:

- [***] - AVA.214 Phase 2 [***] Study

[***] - Chemistry and Manufacturing Controls (CMC)

Emergent shall complete the manufacturing activities necessary to support AVA.214 Phase 2 [***] Study. The activities below are specific to conducting a Phase 2 [***] clinical study. If the FDA requires an alternate strategy for [***], the activities below may no longer be applicable. Upon new guidance from the FDA, Emergent will update the SOW accordingly.

[***]

1.5 CLIN 0002 - Initial purchase, storage, and delivery of product (Base)

Emergent shall deliver 2,000,000 doses of AV7909 within [***] after EUA pre-authorization approval by FDA.

1.6 CLIN 0003 - Phase 4 post marketing requirements (Option)

[***].

Program Management

Emergent shall provide program management activities. The activities shall include but are not limited to:

- Identification of and management to, distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Integrated Product Development Plan.
- Establishment of and tracking of milestones and timelines for the initiation conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- Ongoing evaluation of qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.
- Maintaining and managing staff (in-house and contracted) to assure the necessary expertise and dedicated effort to perform the work.
- Directing and overseeing subcontractors and consultants to assure successful performance of planned activities within the cost and schedule constraints of the contract.
- Conducting performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both Emergent and subcontractors on a real time basis.
- Manage contract activities in accordance with Earned Value Management. In this regard, Emergent shall:
    - Provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support product approval. The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/No Go" decision criteria and a contract Work Breakdown Structure (due within 90 days of contract award with updates as requested by the Contracting Officer's Representative (COR).
    - Submit an updated Integrated Master Schedule in an approved format.
    - Use principles of Earned Value Management System (EVMS) in the management of this contract.
    - Submit a plan for a Performance Measurement Baseline Review (PMBR) electronically via email to the Contracting Officer (CO) and COR for a PBMR to occur within 90 days of contract award.
- Develop and maintain a risk management plan.
- Participate in regular meetings to coordinate and oversee the contracting effort.

[***]

1.7 CLINs 0004 - 0011 Surge Capacity - Additional procurement of product (Option)

Emergent shall deliver up to 25 million dose regimens (equivalent to 50 million doses of AV7909). This option may be triggered after EUA pre-authorization approval by FDA, which is currently linked to release of PPQ lots, and deliveries will start within [***] after trigger.

1.8 Reporting Requirements and Deliverables Reports

As part of the work to be performed under this contract, Emergent will prepare and deliver the following reports throughout the period of performance.

Monthly Technical Progress Reports

On the fifteenth (15) day of each month for the previous calendar month, Emergent will submit to the COR and the CO a Technical Progress Report covering the previous calendar month. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period will consist of each calendar month. The frequency of Technical Progress Reporting will be determined by the CO and COR during negotiations of the contract. The format and type of Technical Progress Report and Executive Summary will be provided by the COR. The Technical Progress Reports will summarize progress for the reporting period, such as: management and administrative updates, technical progress, issues, proposed work, manufacturing and supply chain management, and a summary of invoices. A Technical Progress Report will not be required for the period when the same month Annual Progress Reports or a Final Report are due. Emergent will submit one copy of the Technical Progress Report electronically via e-mail to the CO and COR.

Annual Progress Reports

On the thirtieth (30th) calendar day following the last day of each reporting period, Emergent will submit to the COR and the CO an Annual Progress Report. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year. Annual Progress Reports will summarize progress for the reporting period, such as: management and administrative updates, technical progress, issues, proposed work, manufacturing and supply chain management, and a summary of invoices. An Annual Progress Report will not be required for the period when the Final Technical Progress Report is due.

Draft Final Report and Final Report

Emergent will submit the Draft Final Progress Report forty-five (45) calendar days prior to the expiration date of the contract and the Final Progress Report on or before the expiration date of the contract. These reports will include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report will be in sufficient detail to describe comprehensively the results achieved. An electronic copy of the Draft Final Report and Final Report will be submitted to the COR and CO.

FDA Regulatory Agency Correspondence, Meeting Summaries, and Submissions

With regard to interactions with the FDA, Emergent shall:

- Forward the initial draft minutes to BARDA within five business days of any formal meeting with the FDA or other regulatory agency, and forward the final minutes when available.
- Forward the initial draft minutes to BARDA within five business days of any informal meeting with the FDA or other regulatory agency, and forward the final minutes when available and if applicable.
- Forward the dates and times of any meeting with the FDA and other regulatory agencies to BARDA as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings.
- Provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. Emergent will provide BARDA with five (5) business days in which to review and provide comments prior to Emergent's submission to the FDA.

Emergent will notify the COR and CO within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency and provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). Emergent will provide the COR and CO copies of the plan for addressing areas of non-conformance to FDA regulations for Good Laboratory Practice (GLP) guidelines as identified in the audit report, status updates during the plans execution, and a copy of all final responses to the FDA. Emergent will also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. Emergent will make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.

Key Deliverables

A summary of Key Deliverables for this contract follow

No.	Deliverable	Description	Due Date
01	Monthly Progress Report	Shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.	Due on or before the 15th day of each month following the end of each reporting period. Monthly progress reports are not required in the same month Annual Progress reports or a Final Report are due.
02	Annual Progress Report	Shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.	Due on or before the 30th calendar day following the end of each reporting period.
03	Draft Final Progress Report	To include a summation of the work performed and results obtained for execution of various studies or technical work packages during entire contract period of performance. Shall be in sufficient detail to describe comprehensively the results achieved.	Due 45 Calendar days prior to the expiration date of the contract.
04	Final Progress Report	To include a summation of the work performed and results obtained for execution of various studies or technical work packages during entire contract period of performance. Shall be in sufficient detail to describe comprehensively the results achieved.	Due on/before the expiration date of the contract.
05	FDA/Regulatory Agency Correspondence and Meeting Minutes	The Contractor shall forward initial draft minutes and final draft minutes of any formal or informal meeting with the FDA or other regulatory agency. The contractor shall forward the dates and times of any meeting with the FDA and other regulatory agencies as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings. The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. The Contractor shall forward SOPs upon request from the COR. The contractor shall notify the COR and CO within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency, and provide copies of any associated reports, documentation, or communication.	Due within 5 business days of each meeting for Contractor's minutes, upon receipt of minutes from FDA/ regulatory agency, and upon request from the COR or Co-COR.
06	Integrated Master Project Plan (Critical Path Milestones, Work Breakdown Structure, Risk Mitigation Plan/ Matrix)	The contractor shall provide an Integrated Master Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to annual deliverables (key, critical path milestones, with "Go/No Go" decision criteria) and Work Breakdown Structure (WBS) elements that shall be discernable and consistent. The contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans.	Due within 90 days of contract award. Updates are due as requested by the COR or Co-COR.

07	Technology Packages	Technology packages developed under the contract that includes complete protocols must be submitted at the request of the BARDA COR.	Due upon request from the COR or Co-COR.
08	Experimental Protocols	The Contractor shall submit to the COR all study/experiment/test plans, designs, and protocols prior to execution for BARDA approval or upon request by the COR or Co-COR when required.	Due upon request from the COR or Co-COR.
09	Annual/Final Invention Report	All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification. If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the CO.	Annual Invention Report Due on or before the 30th calendar day after the completion of each reporting period. Final Invention Report due on or before the expiration of the contract.
10	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission.	Due within 30 calendar days for manuscripts prior to publication and 15 calendar days for abstracts.
11	Press Releases	The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the CO has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.	Reports/Notices due for approval to the CO not less than five (5) business days prior to the issuance of any potential press release.
12	Security Report	The contractor shall report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products	Due within 24 hours after occurrence of an activity or incident.
13	Earned Value Management System Requirements	Subject to the requirements under FAR 52.234-4 Earned Value Management System, the Contract shall use principles of Earned Value Management System (EVMS) in the management of this contract (include this plan as part of the monthly, annual, and final reports). The Contractor shall also submit a Performance Measurement Baseline Review plan electronically via email to the CO and COR for a PMBR to occur within 90 days of contract award, and an Integrated Master Schedule electronically via email as outlined in a format agreed upon by BARDA to the COR and CO. The Offeror shall deliver an Earned Value Contract Performance Report on a monthly basis.	As detailed in Section F.3.2 Subpart F.

	Milestone #	WBS #	Milestone	Deliverables Summary (Details as specified in the Deliverables)	Quantity	Estimated Completion Date
CLIN 0001	1	[***]	[***]	[***]	1 Electronic Copy to Contract Officer Representative (COR); 1 Electronic Copy to Contracting Officer (CO)	[***]
	2	[***]	[***]	[***]	See Above	[***]
	3	[***]	[***]	[***]	See Above	[***]
	4	[***]	[***]	[***]	See Above	[***]
	5	[***]	[***]	[***]	See Above	[***]
	6	[***]	[***]	[***]	See Above	[***]
	7	[***]	[***]	[***]	See Above	[***]
	8	[***]	[***]	[***]	See Above	[***]
	9	[***]	[***]	[***]	See Above	[***]
	10	[***]	[***]	[***]	See Above	[***]
	11	[***]	[***]	[***]	See Above	[***]
	12	[***]	[***]	[***]	See Above	[***]
CLIN 0002	16	[***]	[***]	[***]	See Above	[***]

EXHIBIT 12

Ratio of Earnings to Fixed Charges

(in thousands)	Year to Date September 30, 2018	Year Ended December 31, 2017	2016	2015	2014	2013
Pretax income from continuing operations (1)	$ 77,957	$ 118,633	$ 99,221	$ 135,716	$ 84,194	$ 83,439
Fixed charges						
Interest expense	1,824	6,987	8,270	7,834	7,480	1,973
Debt issuance cost	285	1,759	1,526	1,564	3,290	319
Total fixed charges (2)	2,109	8,746	9,796	9,398	10,770	2,292
Noncontrolling interest in pretax income (3)	-	-	-	-	-	876
Capitalized interest (4)	225	2,156	2,179	2,875	2,530	1,973
Earnings ((1) + (2) -(3) -(4))	79,841	125,223	106,838	142,239	92,434	82,882
Fixed charges	2,109	8,746	9,796	9,398	10,770	2,292
Ratio of earnings to fixed charges	37.9	14.3	10.9	15.1	8.6	36.2

EXHIBIT 31.1

CERTIFICATION

I, Daniel J. Abdun-Nabi, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 1, 2018

/s/DANIEL J. ABDUN-NABI
Daniel J. Abdun-Nabi
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Richard S. Lindahl, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 1, 2018

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

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Daniel Abdun-Nabi, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 1, 2018

/s/DANIEL J. ABDUN-NABI
Daniel J. Abdun-Nabi
Chief Executive Officer

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Richard S. Lindahl, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 1, 2018

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