Emergent BioSolutions Inc.
Form 10-Q
August 04, 2017
UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q
(Mark
One)

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

For the quarterly period ended June 30, 2017

OR

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

For the transition period from to

Commission file number: 001-33137
EMERGENT BIOSOLUTIONS INC.
(Exact Name of Registrant as Specified in Its Charter)

| | |
|---|---|
| Delaware | 14-1902018 |
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| 400 Professional Drive, Suite 400 Gaithersburg, Maryland | 20879 |
| (Address of Principal Executive Offices) | (Zip Code) |

(240) 631-3200
(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

(Do not check if a smaller reporting company)

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

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

As of July 28, 2017, the registrant had 41,211,567 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 "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 countermeasure products;
- our ability to perform under our contracts with the U.S. government related to BioThrax, including the timing of deliveries;
- our ability to obtain Emergency Use Authorization pre-approval for NuThrax from the U.S. Food and Drug Administration;
- the availability of funding for our U.S. government grants and contracts;
- uncertainties as to the satisfaction of closing conditions with respect to our recently announced acquisitions of the ACAM2000 smallpox business from Sanofi Pasteur Biologics, LLC and raxibacumab from GlaxoSmithKline LLC, such as the timing and receipt of antitrust regulatory clearance;
- our ability to successfully execute our growth strategy and achieve our financial and operational goals;
- our ability to successfully integrate and develop the products or product candidates, programs, operations and personnel of any entities or businesses that we acquire;
- our ability to identify and acquire companies or in-license products or late-stage product candidates that satisfy our selection criteria;
- our ability to realize synergies and benefits from acquisitions or in-licenses within expected time periods or at all;
- 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 to obtain and maintain intellectual property protection for our products and product candidates;
- our ability and plans to expand and utilize our manufacturing facilities and capabilities;
- our ability and the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices and other regulatory obligations;
- the results of regulatory inspections;
- the operating and financial restrictions placed on us and our subsidiaries under our senior secured credit facility;
- the outcome of the class action lawsuit filed against us and possible other future material legal proceedings;
- the rate and degree of market acceptance and clinical utility of our products;
-

- the success of our ongoing and planned development programs, non-clinical activities and clinical trials of our product candidates;
- our ability to obtain and maintain regulatory approvals for our product candidates and the timing of any such approvals;
- 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
Consolidated Balance Sheets
(in thousands, except share and per share data)

| | June 30, 2017 (unaudited) | December 31, 2016 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $315,627 | $271,513 |
| Accounts receivable, net | 102,511 | 138,478 |
| Inventories | 70,529 | 74,002 |
| Income tax receivable, net | 6,119 | 9,996 |
| Prepaid expenses and other current assets | 14,955 | 16,229 |
| Total current assets | 509,741 | 510,218 |
| | | |
| Property, plant and equipment, net | 380,240 | 376,448 |
| Intangible assets, net | 30,756 | 33,865 |
| Goodwill | 41,001 | 41,001 |
| Deferred tax assets, net | 5,022 | 6,096 |
| Other assets | 3,723 | 2,483 |
| Total assets | $970,483 | $970,111 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $29,604 | $34,649 |
| Accrued expenses and other current liabilities | 1,874 | 6,368 |
| Accrued compensation | 24,326 | 34,537 |
| Notes payable | - | 20,000 |
| Contingent consideration, current portion | 1,710 | 3,266 |
| Deferred revenue, current portion | 15,412 | 7,036 |
| Total current liabilities | 72,926 | 105,856 |
| | | |
| Contingent consideration, net of current portion | 9,503 | 9,919 |
| Long-term indebtedness | 248,693 | 248,094 |
| Deferred revenue, net of current portion | 17,092 | 8,433 |
| Other liabilities | 1,670 | 1,604 |
| Total liabilities | 349,884 | 373,906 |
| | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at both June 30, 2017 and December 31, 2016 | - | - |
| Common stock, $0.001 par value; 200,000,000 shares authorized, 41,532,614 shares issued and 41,107,065 shares outstanding at June 30, 2017; 40,996,890 shares issued and 40,574,060 | 41 | 41 |

| | | |
|---|---|---|
| shares outstanding at December 31, 2016 | | |
| Treasury stock, at cost, 425,549 and 422,830 common shares at June 30, 2017 and December 31, 2016, respectively | (6,503) | (6,420) |
| Additional paid-in capital | 360,999 | 352,435 |
| Accumulated other comprehensive loss | (3,519) | (4,331) |
| Retained earnings | 269,581 | 254,480 |
| Total stockholders' equity | 620,599 | 596,205 |
| Total liabilities and stockholders' equity | $970,483 | $970,111 |

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

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2017 (Unaudited) | 2016 | 2017 (Unaudited) | 2016 |
| Revenues: | | | | |
| Product sales | $63,610 | $48,333 | $145,579 | $112,087 |
| Contract manufacturing | 16,160 | 10,156 | 33,788 | 17,743 |
| Contracts and grants | 21,002 | 32,752 | 38,263 | 64,375 |
| Total revenues | 100,772 | 91,241 | 217,630 | 194,205 |
| Operating expenses: | | | | |
| Cost of product sales and contract manufacturing | 34,624 | 29,465 | 80,946 | 53,466 |
| Research and development | 25,751 | 27,893 | 46,227 | 53,985 |
| Selling, general and administrative | 31,868 | 35,925 | 67,018 | 67,639 |
| Income from operations | 8,529 | (2,042) | 23,439 | 19,115 |
| Other income (expense): | | | | |
| Interest income | 583 | 219 | 956 | 406 |
| Interest expense | (1,805) | (1,510) | (3,743) | (3,033) |
| Other income (expense), net | (586) | 24 | (286) | 57 |
| Total other expense, net | (1,808) | (1,267) | (3,073) | (2,570) |
| Income (loss) from continuing operations before provision for (benefit from) income taxes | 6,721 | (3,309) | 20,366 | 16,545 |
| Provision for (benefit from) income taxes | 2,105 | (1,267) | 5,265 | 6,698 |
| Net income (loss) from continuing operations | 4,616 | (2,042) | 15,101 | 9,847 |
| Net loss from discontinued operations | - | (8,905) | - | (16,803) |
| Net income (loss) | $4,616 | $(10,947) | $15,101 | $(6,956) |
| Net income (loss) per share from continuing operations - basic | $0.11 | $(0.05) | $0.37 | $0.25 |
| Net loss per share from discontinued operations - basic | - | (0.22) | - | (0.42) |
| Net income (loss) per share - basic | $0.11 | $(0.27) | $0.37 | $(0.17) |
| Net income (loss) per share from continuing operations - diluted | $0.11 | $(0.05) | $0.35 | $0.24 |
| Net loss per share from discontinued operations - diluted | - | (0.22) | - | (0.34) |
| Net income (loss) per share - diluted (1) | $0.11 | $(0.27) | $0.35 | $(0.10) |
| Weighted-average number of shares - basic | 41,013,764 | 40,202,821 | 40,871,540 | 39,872,738 |
| Weighted-average number of shares - diluted | 50,078,594 | 40,202,821 | 49,899,291 | 48,784,339 |

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

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

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| | (Unaudited) | | (Unaudited) | |
| Net income (loss) | $4,616 | $(10,947) | $15,101 | $(6,956) |
| Foreign currency translations, net of tax | 228 | 1,072 | 812 | (367) |
| Comprehensive income (loss) | $4,844 | $(9,875) | $15,913 | $(7,323) |

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

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

| | Six Months Ended June 30, | |
|---|---|---|
| | 2017 | 2016 |
| Cash flows from operating activities: | (Unaudited) | |
| Net Income (loss) | $ 15,101 | $ (6,956) |
| Adjustments to reconcile to net cash provided by (used in) operating activities: | | |
| Stock-based compensation expense | 8,018 | 9,945 |
| Depreciation and amortization | 20,097 | 17,770 |
| Income taxes | 4,951 | 547 |
| Change in fair value of contingent obligations | 433 | 935 |
| Impairment of long-lived assets | - | 1,114 |
| Excess tax benefits from stock-based compensation | - | (10,442) |
| Other | 464 | 775 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 36,160 | 53,933 |
| Inventories | 3,473 | (19,738) |
| Income taxes | - | (10,064) |
| Prepaid expenses and other assets | 276 | (1,713) |
| Accounts payable | 4,245 | 11,287 |
| Accrued expenses and other liabilities | (4,386) | (3,533) |
| Accrued compensation | (10,194) | (4,966) |
| Provision for chargebacks | - | 274 |
| Deferred revenue | 17,035 | 1,007 |
| Net cash provided by operating activities | 95,673 | 40,175 |
| Cash flows from investing activities: | | |
| Purchases of property, plant and equipment | (29,605) | (39,246) |

| | | |
|---|---|---|
| Net cash used in investing activities | (29,605) | (39,246) |
| Cash flows from financing activities: | | |
| Issuance of common stock upon exercise of stock options | 4,605 | 14,524 |
| Excess tax benefits from stock-based compensation | - | 10,442 |
| Taxes paid on behalf of employees for equity activity | (4,059) | (4,492) |
| Payments of notes payable | (20,000) | - |
| Contingent obligation payments | (2,405) | (971) |
| Purchase of treasury stock | (83) | - |
| Net cash (used in) provided by financing activities | (21,942) | 19,503 |
| Effect of exchange rate changes on cash and cash equivalents | (12) | 168 |
| Net increase in cash and cash equivalents | 44,114 | 20,600 |
| Cash and cash equivalents at beginning of period | 271,513 | 312,795 |
| Cash and cash equivalents at end of period | $ 315,627 | $ 333,395 |

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

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

1. Summary of significant accounting policies

Basis of presentation and consolidation

The accompanying unaudited 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, 2016, as filed with the SEC.

During the six months ended June 30, 2017, 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, 2016, as filed with the SEC, except for revenue recognition associated with the new Biomedical Advanced Research and Development Authority ("BARDA") contract for BioThrax and the modification of the Company's contract for the NuThrax product candidate with BARDA ("the BARDA NuThrax Contract").

The BARDA NuThrax Contract was entered into on September 30, 2016. This contract is a service arrangement that includes multiple elements. The deliverables under the BARDA NuThrax Contract are the completion of development for NuThrax and the procurement of NuThrax for the Strategic National Stockpile ("SNS"). The Company has determined that the procurement of NuThrax under the BARDA NuThrax Contract is a contingent deliverable, as it is dependent upon successful completion of development; therefore the Company has excluded this from the allocation of the contract consideration. The Company allocated the value of the contract to the development for NuThrax based on best estimate of selling price ("BESP"). BESP methodology for the development deliverable was developed using a cost build-up for internal and external costs, plus a specified mark-up. The Company has allocated $147.5 million to the development services deliverable and will recognize revenue as the services are provided.

On March 16, 2017, the Company entered into a contract with BARDA, valued at $100 million, for the delivery of BioThrax to the Strategic National Stockpile ("SNS") over a two-year period of performance ("the BARDA BioThrax Contract"). In conjunction with the signing of this contract, the Company entered into a modification to its BARDA NuThrax Contract that increases the number of doses of NuThrax to be delivered under the base period from two million to three million doses with a commensurate reduction in dose price for the initial deliveries. The modification also provides for a discount on the sales price for doses to be procured during the option period by up to $100 million. As a result of the modification of the BARDA NuThrax Contract in conjunction with execution of the BARDA BioThrax Contract, the Company has determined that the two agreements are linked under the provisions of Topic 605, Revenue Recognition. The Company analyzed these agreements and determined that the units of accounting under the linked agreements are:

·development services for the NuThrax product candidate under the BARDA NuThrax Contract; and
·procurement of BioThrax under the BARDA BioThrax Contract.

The Company's allocation of contract consideration for the development services was updated based on the services provided prior to March 17, 2017. The allocation of contract consideration for the BioThrax doses to be sold under the BARDA BioThrax Contract was determined based on similar pricing provided to other customers. The Company determined the amount of contract consideration to be allocated to the discounts was based on an undiscounted probability adjusted model based on the expected timing of regulatory approval for NuThrax, expected levels of procurement of NuThrax upon regulatory approval and the market conditions for these types of medical countermeasures. The Company allocated the contract consideration to the two units of accounting as follows:

·development services for the NuThrax product candidate under the BARDA NuThrax Contract was $137.1 million
·procurement of BioThrax under the BARDA BioThrax Contract was $93.6 million

The Company will defer a portion of the consideration received for doses delivered under the BARDA BioThrax Contract and the development services for the NuThrax product candidate. The Company will recognize the deferred revenue upon the delivery of NuThrax doses under the BARDA NuThrax Contract, or upon the future extinguishment of the Company's obligation to deliver NuThrax doses to which the discount applies.

The Company has classified the results of operations of Aptevo Therapeutics Inc. ("Aptevo") as discontinued operations for the three and six months ended June 30, 2016. The historical financial statements and footnotes have been revised accordingly. See Note 2. "Discontinued operations" for further details regarding the spin-off. For financial reporting purposes, in the periods following the spin-off, the Company reports financial information as one business segment.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature and are necessary to present fairly the financial position of the Company as of June 30, 2017. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Recently issued accounting standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("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 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 standard will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. The Company will adopt this standard effective January 1, 2018 and intends to use the modified retrospective method when adopting ASU No. 2014-09. The Company has completed an initial impact analysis, including reviewing the terms and conditions of its contracts. The Company is in the process of finalizing its accounting policy. Once the accounting policy is finalized, the Company will design and implement necessary changes to processes and controls in order to account for revenue under the new standard beginning on the adoption date. The Company believes that there could be changes to the revenue recognition related to the Company's multiple element contracts, primarily those with the U.S. government. Based on the Company's timeline and planned resources, the Company anticipates completing its implementation by the adoption date.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718) ("ASU No. 2016-09"). ASU No. 2016-09 simplifies several aspects of the accounting for share-based payment award transactions, including: (1) the income tax consequences, (2) classification of awards as either equity or liabilities, and (3) classification on the statement of cash flows. As of January 1, 2017, the Company adopted and performed the evaluation required by the standard and did not identify any conditions or events that would have a material impact on the current disclosures in the financial statements. The Company has retrospectively adjusted the operating and financing sections within the statement of cash flows for the classification of employee taxes paid associated with equity award activities for the six months ended June 30, 2016. In addition, the Company prospectively adopted the provisions related to the excess tax benefits, and as a result prior periods were not adjusted. If the Company had adopted this provision retrospectively, there would have been no change to the estimated effective annual tax rate for the three and six months ended June 30, 2016, but there would have been a tax benefit associated with stock option activity of $1.2 million and $3.5 million, respectively, recorded in the provision for income taxes on the Company's statement of operations.

In January 2017, the FASB issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business ("ASU No. 2017-01"). ASU No. 2017-01 provides clarification for the definition of a business with the objective of adding guidance and providing a more robust framework to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The new standard will be effective for all annual periods beginning after December 15, 2017. Early adoption is permitted. The Company will be assessing the impact of this standard on potential acquisitions in 2017.

In January 2017, the FASB issued ASU No. 2017-04, Intangibles - Goodwill and Other (Topic 250): Simplifying the Test for Goodwill Impairment ("ASU No. 2017-04"). The standard eliminates the second step in the goodwill impairment test, which requires an entity to determine the implied fair value of the reporting unit's goodwill. Instead, an entity should recognize an impairment loss if the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, with the impairment loss not to exceed the amount of goodwill allocated to the reporting unit. The standard is effective for annual and interim goodwill impairment tests conducted in fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company does not believe that the new standard will have a material impact on its 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. Discontinued operations

On August 1, 2016, the Company completed the spin-off of Aptevo through the distribution of 100% of the outstanding shares of common stock of Aptevo to the Company's shareholders (the "Distribution"). The Distribution was made to the Company's shareholders of record as of the close of business on July 22, 2016 (the "Record Date"), and provided for such shareholders to receive one share of Aptevo common stock for every two shares of Emergent common stock held as of the Record Date. The Distribution was intended to qualify as a tax-free distribution for federal income tax purposes in the United States. In the aggregate, approximately 20.2 million shares of Aptevo common stock were distributed to the Company's shareholders of record as of the Record Date in the Distribution. After the Distribution, the Company no longer holds shares of Aptevo's common stock. In addition, on August 1, 2016, the Company entered into a non-negotiable, unsecured promissory note with Aptevo to provide an additional $20 million in funding, which the Company paid in January 2017.

The historical statements of operations of Aptevo have been presented as discontinued operations in the consolidated financial statements and the prior period has been restated. Discontinued operations include results of Aptevo's business except for certain allocated corporate overhead costs and certain costs associated with transition services provided by the Company to Aptevo. These allocated costs remain part of continuing operations. Due to differences between the basis of presentation for discontinued operations and the basis of presentation as a stand-alone company,

the financial results of Aptevo included within discontinued operations for the Company may not be indicative of actual financial results of Aptevo.

The following table summarizes results from discontinued operations of Aptevo included in the consolidated statements of operations:

| (in thousands) | Three Months Ended June 30, 2016 | Six Months Ended June 30, 2016 |
|---|---|---|
| Revenues: | | |
| Product sales | $10,212 | $18,165 |
| Collaborations | 34 | 119 |
| Total revenues | 10,246 | 18,284 |
| Operating expense: | | |
| Cost of product sales | 6,147 | 10,649 |
| Research and development | 7,454 | 15,515 |
| Selling, general and administrative | 8,221 | 16,292 |
| Loss from operations | (11,576) | (24,172) |
| Other income (expense), net: | (5) | 75 |
| Loss from discontinued operations before benefit from income taxes | (11,581) | (24,097) |
| Benefit from income taxes | (2,676) | (7,294) |
| Net loss from discontinued operations | $(8,905) | $(16,803) |

The following table summarizes the cash flows of Aptevo included in the June 30, 2016 consolidated statements of cash flows:

| (in thousands) | Six Months Ended June 30, 2016 |
|---|---|
| Net cash used in operating activities | $(9,134) |
| Net cash used in investing activities | (2,139) |
| Net cash provided by financing activities | 12,277 |
| Net increase in cash and cash equivalents | $1,004 |

3. Fair value measurements

Contingent consideration are liabilities measured at fair value on a recurring basis. As of June 30, 2017 and December 31, 2016, the fair value of contingent consideration was $11.2 million and $13.2 million, respectively.

On January 29, 2014, the Company issued $250.0 million aggregate principal amount of 2.875% Convertible Senior Notes due 2021 (the "Notes"). The Notes mature on January 15, 2021, unless earlier purchased by the Company or

converted. The Notes are subject to the fair value disclosure requirements. The estimated fair value of the Notes at June 30, 2017 was $323.2 million. The fair value of the Notes was determined via broker quote.

For the three months ended June 30, 2017, the contingent consideration obligation associated with the EV-035 series of molecules and the broad spectrum antiviral platform program increased by a nominal amount. For the six months ended June 30, 2017 and the three and six months ended June 30, 2016, the contingent consideration obligation associated with the EV-035 series of molecules and the broad spectrum antiviral platform program decreased by $0.1 million, $0.4 million and $0.4 million, respectively. The changes are primarily due to the estimated timing and probability of success for certain development and regulatory milestones of the EV-035 series of molecules and the broad spectrum antiviral platform program, which are inputs that have no observable market (Level 3). These changes are classified in the Company's statement of operations as both selling, general and administrative expense and research and development expense.

For the three and six months ended June 30, 2017, the contingent purchase consideration obligations associated with RSDL increased by $0.2 million and $0.5 million, respectively. For the three and six months ended June 30, 2016, the contingent purchase consideration obligations associated with RSDL increased by $0.5 million and $1.3 million, respectively. The fair value of the RSDL contingent consideration obligations increased primarily due to the expected 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 six months ended June 30, 2017.

| (in thousands) | |
|---|---|
| Balance at December 31, 2016 | $13,185 |
| Expense included in earnings | 433 |
| Settlements | (2,405 ) |
| Purchases, sales and issuances | - |
| Transfers in/(out) of Level 3 | - |
| Balance at June 30, 2017 | $11,213 |

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 June 30, 2017, the Company had no assets or liabilities that were measured at fair value on a non-recurring basis. As of June 30, 2016, the in-process research and development asset for EV-035 series of molecules was measured at fair value on a non-recurring basis.

4. Inventories

Inventories consisted of the following:

| (in thousands) | June 30, 2017 | December 31, 2016 |
|---|---|---|
| Raw materials and supplies | $33,619 | $ 30,687 |
| Work-in-process | 25,594 | 19,821 |
| Finished goods | 11,316 | 23,494 |
| Total inventories | $70,529 | $ 74,002 |

5. Property, plant and equipment

Property, plant and equipment consisted of the following:

| (in thousands) | June 30, 2017 | December 31, 2016 |
|---|---|---|
| Land and improvements | $20,357 | $20,340 |
| Buildings, building improvements and leasehold improvements | 150,416 | 147,130 |
| Furniture and equipment | 194,140 | 190,157 |
| Software | 52,616 | 52,564 |
| Construction-in-progress | 90,095 | 77,813 |
| Property, plant and equipment, gross | 507,624 | 488,004 |
| Less: Accumulated depreciation and amortization | (127,384) | (111,556) |
| Total property, plant and equipment, net | $380,240 | $376,448 |

As of June 30, 2017 and December 31, 2016, construction-in-progress primarily includes costs related to the build out of the Company's Center for Innovation in Advanced Development and Manufacturing ("CIADM") facility.

6. Intangible assets

For the three months ended June 30, 2017 and 2016, the Company recorded amortization expense of $1.6 million and $1.8 million, respectively. For the six months ended June 30, 2017 and 2016, the Company recorded amortization expense of $3.1 million and $3.7 million, respectively. The amortization expense for intangible assets has been recorded in operating expenses, specifically selling, general and administrative and cost of product sales and contract manufacturing. As of June 30, 2017, the weighted average amortization period remaining for intangible assets is 70 months.

7. Equity

As of June 30, 2017, the Company had one equity awards plan, the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan"), which includes both stock options and restricted stock units.

The following is a summary of stock option award activity under the 2006 Plan:

| | 2006 Plan | | |
|---|---|---|---|
| | Number of Shares | Weighted-Average Exercise Price | Aggregate Intrinsic Value |
| Outstanding at December 31, 2016 | 2,559,331 | $ 22.94 | $25,348,245 |
| Granted | 398,058 | 30.59 | |
| Exercised | (243,400) | 19.29 | |
| Forfeited | (23,796) | 27.92 | |
| Outstanding at June 30, 2017 | 2,690,193 | $ 24.35 | $25,707,213 |

The following is a summary of restricted stock unit award activity under the 2006 Plan:

| | Number of Shares | Weighted-Average Grant Price | Aggregate Intrinsic Value |
|---|---|---|---|
| Outstanding at December 31, 2016 | 875,584 | $ 28.94 | $28,754,179 |
| Granted | 428,810 | 30.55 | |

| | | | |
|---|---|---|---|
| Vested | (403,992) | 20.72 | |
| Forfeited | (31,148 ) | 28.78 | |
| Outstanding at June 30, 2017 | 869,254 | $ 30.20 | $29,476,403 |

8. Earnings per share

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| (in thousands, except share and per share data) | 2017 | 2016 | 2017 | 2016 |
| Numerator: | | | | |
| Net income (loss) from continuing operations | $4,616 | $(2,042 ) | $15,101 | $9,847 |
| Interest expense, net of tax | 835 | - | 1,742 | 1,302 |
| Amortization of debt issuance costs, net of tax | 195 | - | 391 | 391 |
| Net income (loss), adjusted from continuing operations | 5,646 | (2,042 ) | 17,234 | 11,540 |
| Net loss from discontinued operations | - | (8,905 ) | - | (16,803 ) |
| Net income (loss), adjusted | $5,646 | $(10,947 ) | $17,234 | $(5,263 ) |
| | | | | |
| Denominator: | | | | |
| Weighted-average number of shares—basic | 41,013,764 | 40,202,821 | 40,871,540 | 39,872,738 |
| Dilutive securities—equity awards | 968,354 | - | 931,263 | 1,191,076 |
| Dilutive securities—convertible debt | 8,096,476 | - | 8,096,488 | 7,720,525 |
| Weighted-average number of shares—diluted | 50,078,594 | 40,202,821 | 49,899,291 | 48,784,339 |
| | | | | |
| Net income (loss) per share from continuing operations - basic | $0.11 | $(0.05 ) | $0.37 | $0.25 |
| Net loss per share from discontinued operations - basic | - | (0.22 ) | - | (0.42 ) |
| Net income (loss) per share - basic | $0.11 | $(0.27 ) | $0.37 | $(0.17 ) |
| | | | | |
| Net income (loss) per share from continuing operations - diluted | $0.11 | $(0.05 ) | $0.35 | $0.24 |
| Net loss per share from discontinued operations - diluted | - | (0.22 ) | - | (0.34 ) |
| Net income (loss) per share - diluted | $0.11 | $(0.27 ) | $0.35 | $(0.10 ) |

For the three and six months ended June 30, 2017 and 2016, 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 six months ended June 30, 2017, along with the six months ended June 30, 2016, 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 Notes by the weighted average number of shares of common stock outstanding during the period. The weighted average number of shares is adjusted for the potential dilutive effect of the exercise of stock options and the vesting of restricted stock units along with the assumption of the conversion of the Notes, at the beginning of the period.

For the three months ended June 30, 2016, basic and diluted earnings per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. No adjustment to the net loss was computed under the "if-converted" method as the effect would have been anti-dilutive.

For the three and six months ended June 30, 2017, approximately 0.4 million stock options were excluded from the calculation of diluted earnings per share due to the fact that the exercise prices were in excess of the average per share closing price during the period. For the three months ended June 30, 2016, outstanding equity awards to purchase approximately 3.6 million shares of common stock were excluded from the calculation of diluted earnings per share. In addition, for the three months ended June 30, 2016, approximately 7.7 million shares of common stock related to the Company's Notes were excluded from the calculation of diluted earnings per share. All outstanding equity awards to purchase common stock and shares of common stock related to the Company's Notes were excluded from the calculation of diluted earnings per share in the periods in which the Company incurred a net loss.

9. Restructuring

In August 2016, the Company adopted a plan to restructure and reprioritize the operations of one of its facilities at the Emergent BioDefense Operations Lansing LLC ("EBOL") site. This plan was initiated as a result of the Company's large-scale manufacturing facility at the EBOL site commencing manufacturing operations. Severance and other related costs and asset-related charges are reflected within the Company's consolidated statement of operations as a component of selling, general and administrative expense.

The Company has completed the EBOL restructuring. The costs of the restructuring as of June 30, 2017 are detailed below:

| (in thousands) | Incurred in 2017 | Inception to Date |
|---|---|---|
| Termination benefits | $ 40 | $ 5,286 |
| Abandonment of equipment | - | 3,749 |
| Other costs | - | 691 |
| Total | $ 40 | $ 9,726 |

During the year ended December 31, 2016, the Company abandoned certain equipment and associated assets at its EBOL facility related to the manufacturing process at Building 12 ("manufacturing process") asset group. During the third quarter of 2016, the Company recorded a charge for the manufacturing process asset group of $3.7 million. The additional expense is classified in the Company's statements of operations as selling, general and administrative expense.

The following is a summary of the activity for the liabilities related to the restructuring:

| (in thousands) | Termination Benefits |
|---|---|
| Balance at December 31, 2016 | $ 4,357 |
| Expenses incurred | 40 |
| Amount paid | (3,602) |
| Other adjustments | - |
| Balance at June 30, 2017 | $ 795 |

10. Litigation

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 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 the U.S. Department of Health and Human Services 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 Defendants believe that the allegations in the complaint are without merit and intend to defend themselves vigorously against those claims. As of the date of this filing, the range of potential loss cannot be determined or estimated.

11. Subsequent events

On July 19, 2017, the Company entered into an agreement with GSK to acquire raxibacumab, a fully human monoclonal antibody approved by the FDA for the treatment and prophylaxis of inhalational anthrax. The all-cash transaction consists of a $76 million upfront payment and up to $20 million in product sale and manufacturing-related milestone payments, all of which would likely become due in 2019. The Company also plans to assume responsibility for a multi-year contract with BARDA, valued at up to approximately $130 million, to supply the product to the SNS. The Company expects to purchase product from GSK to fulfill deliveries to the SNS under the current BARDA contract and plans to transfer raxibacumab manufacturing to existing Emergent facilities in Baltimore, Maryland in 2020. This transaction, which is subject to customary closing conditions including antitrust regulatory approval, is expected to close in 2017.

On July 14, 2017, the Company entered into an agreement to acquire the ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live) business of Sanofi Pasteur Biologics, LLC ("Sanofi") and Acambis Research Ltd. ("Acambis") in an all-cash transaction with a total value of up to $125 million, consisting of $97.5 million upfront and up to $27.5 million in near-term contingent regulatory and manufacturing-related milestones. Upon the closing of this transaction, the Company will acquire ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live), the only vaccine licensed by the Food and Drug Administration ("FDA") for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection, an existing 10-year contract with the Centers for Disease Control and Prevention ("CDC") originally valued at up to $425 million with a remaining value of up to approximately $160 million for deliveries of ACAM2000 to the SNS and a current good manufacturing practices ("cGMP") bulk manufacturing facility and a lease to a cGMP fill/finish facility. This transaction, which is subject to customary closing conditions including antitrust regulatory approval, is expected to close in 2017.

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 seeking to protect and enhance life by focusing on providing specialty products for civilian and military populations that address accidental, intentional and naturally emerging public health threats. Our company is focused on developing, manufacturing and commercializing medical countermeasures, or MCMs, that address public health threats, or PHTs. The PHTs we are addressing fall into two categories: (1) Chemical, Biological, Radiological and Nuclear, or CBRN; and (2) Explosives and Emerging Infectious Diseases, or EID. We have a portfolio of six revenue-generating products, as well as a pipeline of various investigational stage product candidates addressing select aspects of CBRN and EID threats. 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 marketed MCMs are:

- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or the FDA, for the general use prophylaxis and post-exposure prophylaxis of anthrax disease. BioThrax is also licensed by the Paul-Ehrlich-Institut of the German Federal Ministry of Health for general use prophylaxis of anthrax disease;
- Anthrasil® [Anthrax Immune Globulin Intravenous (Human)], the only polyclonal antibody therapeutic licensed by the FDA for the treatment of inhalational anthrax;
- BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)- (Equine)], the only heptavalent therapeutic licensed by the FDA and Health Canada for the treatment of botulinum disease;
- VIGIV [Vaccinia Immune Globulin Intravenous (Human)], the only therapeutic licensed by the FDA to address certain complications from smallpox vaccination;
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only device cleared by the FDA intended to remove or neutralize chemical warfare agents and T-2 toxin from the skin; and
- Trobigard™ (atropine sulfate, obidoxime chloride), an auto-injector device designed for intramuscular self-injection of atropine sulfate and obidoxime chloride, a nerve agent countermeasure. This product has not been approved by the FDA or any other regulatory agency, is not promoted or distributed in the U.S., and is only sold to non-U.S. authorized government buyers.

Our lead investigational stage MCMs candidates are:

- NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), a next generation anthrax vaccine;
- UV-4B, a novel antiviral being developed for dengue and influenza infections;
- GC-072, the lead compound in the EV-035 series of broad spectrum antibiotics, being developed for Burkholderia pseudomallei;
- FLU-IG (NP025), a human polyclonal antibody therapeutic being developed to treat seasonal influenza;
- ZIKA-IG (NP024), a human polyclonal antibody therapeutic being developed as a prophylaxis for Zika infections; and
- FILOV (NP026), an equine polyclonal antibody therapeutic being developed to treat Ebola infections.

A unique attribute of our investigational stage product portfolio is that many of our candidates are under an active development contract with significant funding from the U.S. government.

We also have programs that leverage our proven manufacturing infrastructure and expertise. We have responded to specific Task Order Requests issued by the Biomedical Advanced Research and Development Authority, or BARDA, for the development and manufacture of specific countermeasures as part of our Center for Innovation in Advanced Development and Manufacturing, or CIADM, program focused on imminent public health threats.

In addition, we provide contract manufacturing services to third-party customers. The majority of these services are performed at our Camden and Bayview facilities located in Baltimore, Maryland. At these facilities we perform pharmaceutical product development and filling services for injectable and other sterile products, as well as process design, technical transfer, manufacturing validation, laboratory support, aseptic filling, lyophilization, final packaging

and accelerated and ongoing stability studies. At our Camden facility we manufacture both vial and pre-filled syringe formats for a wide variety of third-party owned drug products - small molecule and biological - in all stages of development and commercialization. This facility produces finished units of clinical and commercial drugs for a variety of customers ranging from small biopharmaceutical companies to major multinationals. The facility is an approved or inspected manufacturing facility under the regulatory regimes in the United States, Canada, Japan, Brazil, the Middle East and several countries in the European Union.

Highlights and Recent Business Accomplishments for 2017

On July 31, 2017, we were awarded approximately $23 million to develop a novel multi-drug auto-injector for nerve agent antidote delivery from the Department of Defense, or DoD. Our device is being designed for intramuscular self- or buddy-administration of antidotes for use in military environments and for civilian emergencies.

On July 26, 2017, we announced a licensing agreement with Valneva SE, or Valneva, for global exclusive rights to Valneva's Zika vaccine technology, ZIKV. We will co-develop ZIKV-VLA1601, a highly purified inactivated vaccine candidate against the Zika virus, from preclinical development through completion of a Phase 1 safety and immunogenicity clinical trial. ZIKV-VLA1601, which has shown to elicit functional antibody responses, is based on Valneva's established inactivated, whole virus manufacturing platform on which its licensed Japanese Encephalitis vaccine was developed and produced. Phase 1 clinical trial is expected to commence in late 2017 or early 2018.

On July 19, 2017, we entered into an agreement with Human Genome Sciences, Inc. and GlaxoSmithKline LLC, which we collectively refer to as GSK, to acquire raxibacumab, a fully human monoclonal antibody approved by FDA for the treatment and prophylaxis of inhalational anthrax. The all-cash transaction consists of a $76 million upfront payment and up to $20 million in product sale and manufacturing-related milestone payments, all of which would likely become due in 2019. We also plan to assume responsibility for a multi-year contract with BARDA, valued at up to approximately $130 million, to supply the product to the Strategic National Stockpile, or SNS. We expect to purchase product from GSK to fulfill deliveries to the SNS under the current BARDA contract and plan to transfer raxibacumab manufacturing to our existing facilities in Baltimore, Maryland in 2020. This transaction, which is subject to customary closing conditions including antitrust regulatory approval, is expected to close in 2017.

On July 14, 2017, we entered into an agreement to acquire the ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live) business of Sanofi Pasteur Biologics, LLC, or Sanofi, and Acambis Research Ltd., or Acambis, in an all-cash transaction with a total value of up to $125 million, consisting of $97.5 million upfront and up to $27.5 million in near-term contingent regulatory and manufacturing-related milestones. Upon the closing of this transaction, we will acquire ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live), the only vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection, an existing 10-year contract with the Centers for Disease Control and Prevention, or CDC, originally valued at up to $425 million with a remaining value of up to approximately $160 million for deliveries of ACAM2000 to the SNS, and a current good manufacturing practices, or cGMP, bulk manufacturing facility and a lease to a cGMP fill/finish facility. This transaction, which is subject to customary closing conditions including antitrust regulatory approval, is expected to close in 2017.

On March 31, 2017, we signed a modification to our contract with BARDA to manufacture and store bulk drug substance for our botulism antitoxin, BAT, valued at approximately $53 million with a five-year period of performance. This modification to the contract is intended to enable future filling and deliveries of final drug product to the SNS. BAT is indicated for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients.

On March 16, 2017, we entered into a contract with BARDA, valued at $100 million, for the delivery of BioThrax to the Strategic National Stockpile, or SNS, over a two-year period of performance. In conjunction with the signing of the $100 million contract for delivery of BioThrax with BARDA, we entered into a modification to our previously

disclosed multi-year contract with BARDA for the advanced development and delivery of the leading next generation anthrax vaccine candidate, NuThrax. The modification increases the number of doses of NuThrax to be delivered under the base period from two million to three million doses with a commensurate reduction in dose price for the initial deliveries. The modification also reduces the purchase price for doses to be procured during the option period by $100 million thereby reducing the total contract value to be up to $1.5 billion.

On February 13, 2017, we received a task order from BARDA valued at up to $30.5 million to develop monoclonal antibody therapeutics for viral hemorrhagic fever. This task order will utilize our CIADM facility located in Baltimore, Maryland. Using monoclonal antibodies from Mapp Biopharmaceutical Inc., we will conduct technology transfer of process materials and information, perform process and analytical method development, execute small-scale production runs, and perform current good manufacturing practices, or cGMP, cell banking leading to cGMP manufacture of bulk drug substance. The task order consists of a 36-month period of performance with a base task order valued at $7.4 million and options that, if executed, will bring the total task order value over three years to up to $30.5 million.

On January 27, 2017, we received from the Paul-Ehrlich-Institute, or PEI, the regulatory agency under the German Federal Ministry of Health, approval for our large-scale manufacturing facility, Building 55, located in Lansing, Michigan. This approval allows us to market in Germany BioThrax manufactured in Building 55.

Aptevo Spin-off

On August 1, 2016, we completed the spin-off of Aptevo Therapeutics Inc., or Aptevo. As a result of the spin-off, the operating results of Aptevo have been reflected as discontinued operations for the three and six months ended June 30, 2016. Unless otherwise stated, financial results herein reflect continuing operations for the three and six months ended June 30, 2016.

Litigation

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, or the Court, on behalf of purchasers of our common stock between January 11, 2016 and June 21, 2016, inclusive, or the Class Period, seeking to pursue remedies under the Securities Exchange Act of 1934 against us and certain of our senior officers and directors, collectively, the Defendants. The complaint alleges, among other things, that we made materially false and misleading statements about the government's demand for BioThrax and expectations that our five-year exclusive procurement contract with the U.S. Department of Health and Human Services, or 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. We filed a Motion to Dismiss on February 27, 2017. The Plaintiffs filed an opposition brief on April 28, 2017. Our Motion to Dismiss was heard and denied on July 6, 2017. The Company filed its answer on July 28, 2017. The Defendants believe that the allegations in the complaint are without merit and intend to defend themselves vigorously against those claims.

Financial Operations Overview

Revenues

We have derived a majority of our historical product sales revenues from BioThrax sales to the U.S. government. We are a party to a contract with the CDC, an operating division of HHS, valued at up to $911 million, to supply approximately 29.4 million doses of BioThrax to the SNS through September 2021. Through June 30, 2017, we have

delivered and recognized revenue on approximately 3.4 million doses, representing approximately $100 million in revenue under this contract. We are focused on increasing the sales of our products in our product portfolio to U.S. government customers as well as expanding the market for our entire product portfolio to other customers domestically and internationally.

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

| Development Programs | Funding Source | Award Date | Performance Period |
|---|---|---|---|
| Anthrasil | BARDA | 09/2005 | 9/2005 — 4/2021 |
| | BARDA | 09/2013 | 9/2013 — 9/2018 |
| Auto-injector platform | DoD | 7/2017 | 7/2017 — 6/2022 |
| BAT | BARDA | 05/2006 | 5/2006 — 12/2027 |
| CIADM | BARDA | 06/2012 | 6/2012 — 6/2037 |
| GC-072 | DTRA | 08/2014 | 8/2014 — 3/2018 |
| Large-scale manufacturing for BioThrax | BARDA | 07/2010 | 7/2010 — 7/2017 |
| NuThrax | NIAID | 08/2014 | 8/2014 — 10/2019 |
| | BARDA | 03/2015 | 3/2015 — 12/2017 |
| | BARDA | 09/2016 | 9/2016 — 9/2021 |
| UV-4B | NIAID | 09/2011 | 9/2011 — 8/2018 |
| VIGIV | CDC | 08/2012 | 8/2012 — 8/2017 |

Critical Accounting Policies and Estimates

During the six months ended June 30, 2017, 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, 2016, as filed with the Securities and Exchange Commission.

Results of Operations

Three Months Ended June 30, 2017 Compared to Three Months Ended June 30, 2016

Revenues

| | Three Months Ended June 30, | | | |
|---|---|---|---|---|
| (in thousands) | 2017 | 2016 | Change | % Change |
| Product sales: | | | | |
| BioThrax | $52,321 | $40,038 | $12,283 | 31 % |
| Other | 11,289 | 8,295 | 2,994 | 36 % |
| Total Product sales | 63,610 | 48,333 | 15,277 | 32 % |
| Contract manufacturing | 16,160 | 10,156 | 6,004 | 59 % |
| Contracts and grants | 21,002 | 32,752 | (11,750) | (36 %) |
| Total revenues | $100,772 | $91,241 | $9,531 | 10 % |

Product sales:

The increase in Product sales was primarily due to the timing of BioThrax deliveries to the SNS. The increase in other product sales was primarily due to international sales for VIGIV.

Contract manufacturing:

The increase in Contract manufacturing is primarily due to increased fill/finish services provided to third parties, along with bulk manufacturing services performed for Aptevo.

Contracts and grants:

The decrease in Contracts and grants was primarily due to:

- decreased development funding of $7.5 million for VIGIV related to the timing of plasma collection; and
- decreased development funding of $6.3 million related to our CIADM program, which includes a decrease of $2.9 million for CIADM task orders primarily related to Ebola.

These decreases in Contracts and grants were partially offset by an increase in development funding of $2.5 million for NuThrax related to non-clinical studies and manufacturing activities.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $5.1 million, or 17%, to $34.6 million for the three months ended June 30, 2017 from $29.5 million for the three months ended June 30, 2016. The increase was primarily attributable to the increase in BioThrax sales to the SNS and increased contract manufacturing activities.

Research and Development Expenses

Research and development expenses decreased by $2.1 million, or 8%, to $25.8 million for the three months ended June 30, 2017 from $27.9 million for the three months ended June 30, 2016. This decrease primarily reflects lower contract service costs. Net of contracts and grants revenues, during the three months ended June 30, 2017 we incurred net research and development expenses of $4.8 million and during the three months ended June 30, 2016 our research and development expenses were fully funded, resulting in a net contribution from funded development programs of $4.9 million.

Our principal research and development expenses for the three months ended June 30, 2017 and 2016 are shown in the following table:

| | Three Months Ended June 30, | | | |
|---|---|---|---|---|
| (in thousands) | 2017 | 2016 | Change | % Change |
| NuThrax | $10,102 | $5,280 | $4,822 | 91 % |
| FLU-IG (NP025) | 2,329 | - | 2,329 | N/A |
| UV-4B | 1,342 | 879 | 463 | 53 % |
| CIADM task orders | 1,084 | 2,475 | (1,391) | (56 %) |
| BAT | 737 | 1,095 | (358) | (33 %) |
| Auto-injector platform | 719 | 2,498 | (1,779) | (71 %) |
| EV-035 series of molecules | 477 | 839 | (362) | 43 % |
| BioThrax related programs | 348 | 898 | (550) | (61 %) |
| Anthrasil | 279 | 166 | 113 | 68 % |
| VIGIV | 227 | 3,368 | (3,141) | 93 % |

| | | | | |
|---|---|---|---|---|
| Large-scale manufacturing for BioThrax | 195 | 998 | (803) | (80%) |
| Other | 7,912 | 9,397 | (1,485) | (16%) |
| Total | $25,751 | $27,893 | $(2,142) | (8%) |

The increase in expense for NuThrax was primarily due to the timing of non-clinical animal studies and manufacturing activities. The expense for FLU-IG (NP025) was primarily due to clinical trial preparation. The increase in expense for UV-4B was primarily due to clinical trial activity to evaluate safety and tolerability. The decrease in expense for CIADM task orders was due to the timing of manufacturing development for Ebola monoclonal antibodies and Zika. The decrease in expense for our BAT program was primarily related to the timing of stability testing. The decrease in expense for our Auto-injector platform was due to the timing of device concept and design evaluation activities. The decrease in expense for our EV-035 series of molecules was primarily due to the timing of formulation development activities, along with screening of molecules within the series. The decrease in expense for BioThrax related programs was primarily related to the timing of clinical studies to support applications for label expansion for BioThrax. The spending for our Anthrasil program was primarily for non-clinical activities. The decrease in expense for VIGIV was primarily due to the timing of plasma collection. The decrease in expense for large-scale manufacturing of BioThrax was primarily due to the completion of development work and the licensure of the large-scale manufacturing facility in August 2016. The decrease in spending for our Other activities was primarily due to decreased expense related to our funded pre-clinical product candidates and manufacturing development activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $4.0 million, or 11%, to $31.9 million for the three months ended June 30, 2017 from $35.9 million for the three months ended June 30, 2016. The decrease is primarily due to decreased costs associated with the timing of professional services to support our strategic growth initiatives and fixed asset impairments during the second quarter of 2016.

Provision for (Benefit from) Income Taxes

Provision for (benefit from) income taxes increased by $3.4 million to a provision for income taxes of $2.1 million for the three months ended June 30, 2017 from a benefit from income taxes of $1.3 million for the three months ended June 30, 2016. The increase was primarily due to the increase in our income before provision for (benefit from) income taxes of $10.0 million.

Six Months Ended June 30, 2017 Compared to Six Months Ended June 30, 2016

Revenues

| | Six Months Ended June 30, | | | |
|---|---|---|---|---|
| (in thousands) | 2017 | 2016 | Change | % Change |
| Product sales: | | | | |
| BioThrax | $96,135 | $99,139 | $(3,004) | (3)% |
| Other | 49,444 | 12,948 | 36,496 | 282% |
| Total Product sales | 145,579 | 112,087 | 33,492 | 30% |
| Contract manufacturing | 33,788 | 17,743 | 16,045 | 90% |
| Contracts and grants | 38,263 | 64,375 | (26,112) | (41)% |
| Total revenues | $217,630 | $194,205 | $23,425 | 12% |

Product sales:

The increase in Product sales was primarily due to the increase in other product sales due to the timing of BAT deliveries to the SNS and the timing of RSDL shipments to the DoD. These increases were partially offset by a decrease in BioThrax sales due to the timing of BioThrax deliveries to the SNS.

Contract manufacturing:

The increase in Contract manufacturing is primarily due to the expansion of our fill/finish services provided to third parties and bulk manufacturing services performed for Aptevo.

Contracts and grants:

The decrease in Contracts and grants was primarily due to:

- decreased development funding of $15.6 million for VIGIV related to the timing of plasma collection; and
- decreased development funding of $10.3 million related to our CIADM program, which includes a decrease of $7.1 million for CIADM task orders related to Ebola.

These decreases in Contracts and grants were partially offset by an increase in development funding of $4.3 million for NuThrax related to non-clinical studies and manufacturing activities.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $27.4 million, or 51%, to $80.9 million for the six months ended June 30, 2017 from $53.5 million for the six months ended June 30, 2016. The increase was attributable to increased costs associated with the increase in Other product sales and increased costs associated with the expansion of our contract manufacturing business, as well as costs for routine maintenance shutdown activities.

Research and Development Expenses

Research and development expenses decreased by $7.8 million, or 14%, to $46.2 million for the six months ended June 30, 2017 from $54.0 million for the six months ended June 30, 2016. This decrease primarily reflects lower contract service costs. Net of contracts and grants revenues, we incurred net research and development expenses of $7.9 million during the three months ended June 30, 2017. Net of contracts and grants revenues, our research and development expenses were fully funded during the three months ended June 30, 2016, resulting in a net contribution from funded development programs of $10.4 million.

Our principal research and development expenses for the six months ended June 30, 2017 and 2016 are shown in the following table:

| | Six Months Ended June 30, | | | |
|---|---|---|---|---|
| (in thousands) | 2017 | 2016 | Change | % Change |
| NuThrax | $16,580 | $9,666 | $6,914 | 72 % |
| FLU-IG (NP025) | 3,357 | - | 3,357 | N/A |
| UV-4B | 3,256 | 2,032 | 1,224 | 60 % |
| CIADM task orders | 2,181 | 5,299 | (3,118) | (59)% |
| BAT | 1,671 | 2,151 | (480) | (22)% |

| | | | | |
|---|---|---|---|---|
| Auto-injector platform | 1,443 | 5,170 | (3,727) | (72)% |
| EV-035 series of molecules | 1,084 | 1,641 | (557) | (34)% |
| BioThrax related programs | 357 | 1,690 | (1,333) | (79)% |
| Anthrasil | 491 | 448 | 43 | 10 % |
| VIGIV | 837 | 5,955 | (5,118) | 86 % |
| Large-scale manufacturing for BioThrax | 821 | 3,379 | (2,558) | (76)% |
| Other | 14,149 | 16,554 | (2,405) | (15)% |
| Total | $46,227 | $53,985 | $(7,758) | (14)% |

The increase in expense for NuThrax was primarily due to the timing of non-clinical animal studies and manufacturing activities. The expense for FLU-IG (NP025) was primarily due to clinical trial preparation. The increase in expense for UV-4B was primarily due to clinical trial activity to evaluate safety and tolerability. The decrease in expense for CIADM task orders was due to the timing of manufacturing development for Ebola monoclonal antibodies and Zika. The decrease in expense for our BAT program was primarily related to the timing of stability testing. The decrease in expense for our Auto-injector platform was due to the timing of device concept and design evaluation activities. The decrease in expense for our EV-035 series of molecules was primarily due to the timing of formulation development activities, along with screening of molecules within the series. The decrease in expense for BioThrax related programs was primarily related to the timing of clinical studies to support applications for label expansion for BioThrax. The spending for our Anthrasil program was primarily for non-clinical activities. The decrease in expense for VIGIV was primarily due to the timing of plasma collection. The decrease in expense for large-scale manufacturing of BioThrax was primarily due to the completion of development work and the licensure of the large-scale manufacturing facility in August 2016. The decrease in spending for our Other activities was primarily due to decreased expense related to our funded pre-clinical product candidates and manufacturing development activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $0.6 million, or 1%, to $67.0 million for the six months ended June 30, 2017 from $67.6 million for the six months ended June 30, 2016.

Provision for Income Taxes

Provision for income taxes decreased by $1.4 million, or 21%, to $5.3 million for the six months ended June 30, 2017 from $6.7 million for the six months ended June 30, 2016. The decrease was primarily due to non-cash charges associated with tax planning and restructuring activities in 2016, partially offset by an increase in our income before provision for income taxes of $3.8 million.

Liquidity and Capital Resources

Sources of Liquidity

From inception through June 30, 2017, we have funded our cash requirements principally with a combination of product sales revenues, 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, 2016. As of June 30, 2017, we had cash and cash equivalents of $315.6 million.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2017 and 2016:

Six Months Ended

| (in thousands) | June 30, 2017 | 2016 |
|---|---|---|
| Net cash provided by (used in): | | |
| Operating activities(i) | $95,661 | $40,343 |
| Investing activities | (29,605) | (39,246) |
| Financing activities | (21,942) | 19,503 |
| Net increase in cash and cash equivalents | $44,114 | $20,600 |

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

Operating Activities:

Net cash provided by operating activities of $95.7 million for the six months ended June 30, 2017 was primarily due to our net income of $15.1 million, a $36.2 million decrease in accounts receivable related to the timing of collection of amounts billed primarily to the CDC, a $17.0 million increase in deferred revenue, non-cash charges of $20.1 million for depreciation and amortization and $8.0 million in stock-based compensation expense.

Net cash provided by operating activities of $40.3 million for the six months ended June 30, 2016 was primarily due to our net loss of $7.0 million, an increase in inventories of $19.7 million primarily due to the timing of deliveries of BioThrax to the CDC and a net decrease of $9.5 million in income taxes related to quarterly estimated tax payments to federal and state tax jurisdictions, partially offset by a $53.9 million decrease in accounts receivable related to the timing of collection of amounts billed primarily to the CDC, along with non-cash charges of $17.8 million for depreciation and amortization and $9.9 million in stock-based compensation expense.

Investing Activities:

Net cash used in investing activities of $29.6 million for the six months ended June 30, 2017 was due to infrastructure and equipment investments, including the construction of a third manufacturing suite at our Baltimore CIADM manufacturing facility.

Net cash used in investing activities of $39.2 million for the six months ended June 30, 2016 was due to infrastructure and equipment investments, including construction at our Baltimore CIADM manufacturing facility.

Financing Activities:

Net cash used in financing activities of $21.9 million for the six months ended June 30, 2017 was primarily due to the payment of a $20.0 million note payable to Aptevo in conjunction with the spin-off, $4.0 million associated with the taxes paid on behalf of employees for equity activity and $2.4 million in contingent obligation payments, partially offset by $4.6 million in proceeds from the issuance of common stock pursuant to our employee equity awards plan.

Net cash provided by financing activities of $19.5 million for the six months ended June 30, 2016 was primarily due to $14.5 million in proceeds from the issuance of common stock pursuant to employee equity plans and $10.4 million in excess tax benefits from exercise of stock options, partially offset by $4.5 million associated with the taxes paid on behalf of employees for equity activity.

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures, debt service requirements and any future repurchase of our common stock from the following sources: existing cash and cash equivalents; revenues from product sales; development contracts and grants funding; contract manufacturing services and our revolving credit facility and any other lines of credit we may establish from time to time. There are numerous risks and

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

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

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements. In May 2015, we filed an automatic shelf registration statement, which immediately became effective under the Securities and Exchange Commission, or SEC, rules. For so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer" under SEC rules, this shelf registration statement, effective until May 2018, allows us to issue an unrestricted amount of equity, debt and certain other types of securities through one or more future primary or secondary offerings. If we do not file a new automatic shelf registration statement prior to May 2018, the existing shelf registration statement will expire and we will not be able to publicly raise capital or issue debt until a new shelf registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatic shelf registration statement at a future date when we need to raise funds publicly.

If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our senior secured revolving credit facility, which could limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities, buying back shares or declaring dividends. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

We are not restricted under the terms of the indenture governing our senior convertible notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing our notes that could have the effect of diminishing our ability to make payments on our indebtedness. However, our credit facility restricts our ability to incur additional indebtedness, including secured indebtedness.

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

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 June 30, 2017. 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 June 30, 2017, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act that occurred during the quarter ended June 30, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

Purported Shareholder Class Action Lawsuit filed July 19, 2016

On July 19, 2016, Plaintiff William Sponn, or Sponn, filed a putative class action complaint in the United States District Court for the District of Maryland on behalf of purchasers of the Company's common stock between January 11, 2016 and June 21, 2016, inclusive, or the Class Period, seeking to pursue remedies under the 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. On February 27, 2017 the Company filed a motion to dismiss the Plaintiff's amended complaint. 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 Defendants believe that the allegations in the complaint are without merit and intend to defend themselves vigorously against those claims.

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors in addition to the other information in this Quarterly Report on Form 10-Q when evaluating our business because these risk factors may have a significant impact on our business, financial condition, operating results or cash flows. If any of the risks described below or in subsequent reports we file with the SEC actually occur, they may materially harm our business, financial condition, operating results or cash flow. 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 the majority of our revenue from sales of BioThrax to our principal customer, the U.S. government. If the U.S. government's demand for and/or funding for procurement of BioThrax is substantially reduced, our business, financial condition, operating results and cash flow would be materially harmed.

We have derived, and expect for the foreseeable future to derive, the majority of our revenue from sales of BioThrax, our anthrax vaccine licensed by the U.S. Food and Drug Administration, or the FDA, to the U.S. government. In December 2016, we signed a follow-on procurement contract with the Centers for Disease Control and Prevention, or the CDC, for the delivery of approximately 29.4 million doses of BioThrax for placement into the Strategic National Stockpile, or 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. In March 2017, we signed a procurement contract with the Biomedical Advanced Research and Development Authority, or BARDA, a division within the Office of the Assistant Secretary of Preparedness and Response at the U.S. Department of Health and Human Services, or HHS, for the delivery of approximately $100 million of BioThrax into the SNS over a two-year period. This contract is separate from and in addition to the follow-on procurement contract with the CDC.

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 would be materially harmed. The success of our business and our operating results for the foreseeable future are significantly dependent on funding for the procurement of BioThrax and the terms of our BioThrax sales to the U.S. government, including the price per dose, the number of doses and the timing of deliveries.

Our 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 flow to suffer materially.

The U.S. government is the principal customer for our public health threat-focused medical countermeasures BioThrax, BAT, Anthrasil, VIGIV and RSDL, 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 medical countermeasures that we successfully develop within our existing product development pipeline, as well as those we successfully acquire. 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 business, revenues and operating results would suffer.

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 a number of 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 public health threats, 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 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 relationship with the U.S. government, which could have a material adverse effect on our business, financial condition and operating results.

As a manufacturer and supplier of medical countermeasures to the U.S. government addressing public health threats, we must comply with numerous laws and regulations relating to the procurement, formation, administration and

performance of government contracts. 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;
- 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. 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.

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.

Some of 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 and operating results.

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.

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 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 with 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 devote greater resources to market or sell 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 public health threat 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.

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 and operating results.

Our Biologic Products may face risks of competition from biosimilar manufacturers.

Competition for BioThrax, BAT, Anthrasil, and VIGIV, otherwise referred to as our "Biologic Products," may be affected by follow-on biologics, or "biosimilars," in the United States and other jurisdictions. Regulatory and legislative activity in the United States and other countries may make it easier for generic drug manufacturers to manufacture and sell biological drugs similar or identical to our Biologic Products, which might affect the profitability

or commercial viability of our Biologic Products. Under the Biologics Price Competition and Innovation Act of 2010, the FDA cannot approve a biosimilar application until the 12-year exclusivity period for the innovator biologic has expired. Regulators in the European Union and in other foreign jurisdictions have already approved biosimilars, although the European Medicines Agency has expressly excluded blood or plasma-derived products and their recombinant alternatives from the biosimilar pathway for a period of time. Vaccine and allergen products are considered on a case-by-case basis. The specific regulatory framework for this new approval path, whether the FDA will permit biosimilars for blood products and vaccines, 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 that are currently unknown. 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 and operating results.

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 public health threats, whether Chemical, Biological, Radiological and Nuclear, or CBRN, threats, or Explosives and Emerging Infectious Diseases, 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 marketed products, any of which could negatively affect our revenues and our financial condition and operating results.

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 public health threat countermeasures and thereby limit the demand for our products, which would adversely affect our business, financial condition and operating results.

REGULATORY AND COMPLIANCE RISKS

Our submission of NuThrax for Emergency Use Authorization, or 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 delivery of NuThrax.

In September 2016, we entered into a contract with HHS through BARDA for the advanced development and delivery 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 in 2018 with the FDA for EUA pre-approval of NuThrax, and although there can be no assurances, we currently anticipate that the FDA could authorize NuThrax for emergency use as early as 2018, 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 flow.

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

Our long-term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize product candidates and, if we are not successful, our business, financial condition and operating results 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. We have limited experience in preparing, filing and prosecuting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process.

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 or any of our medical countermeasure 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. This is known as the FDA's "Animal Rule." We cannot guarantee that the FDA will permit us to proceed with licensure of NuThrax or any of our public health threat countermeasure 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.

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

the market.

Any vaccine, therapeutic product or medical device for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies. Our approved products are subject to these requirements and ongoing review. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP, requirements relating to quality control, quality assurance, restrictions on advertising and promotion, import and export restrictions and recordkeeping requirements. In addition, various state laws require that companies that manufacture and/or distribute drug products within the state obtain and maintain a manufacturer or distributor license, as appropriate. Because of the breadth of these laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Our regulators enforce cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect domestic manufacturing facilities without prior notice at reasonable times and in a reasonable manner. Health Canada may conduct similar inspections of our facilities where Canadian marketed products are produced, or related formulation and filling operations are conducted. The FDA, Health Canada, and other foreign regulatory agencies conduct periodic inspections of our facilities. For example, our Lansing Building 55 facility was inspected most recently by the FDA in June 2016, our Lansing Building 12 facility was inspected most recently by the FDA in April 2016, our Winnipeg manufacturing facility was inspected most recently by the FDA in May 2017 and Health Canada in November 2016, and our Baltimore (Camden) facility was most recently inspected by the Health Products Regulatory Authority of Ireland in February 2017, FDA in January 2017 and Health Canada in October 2016. Following several of these inspections, regulatory authorities issued inspectional observations, some of which were significant, but all of which are being, or have been, addressed through corrective actions. If, in connection with any future inspection, regulatory authorities find that we are not in substantial compliance with all applicable requirements, or if they are not satisfied with the corrective actions we take, our regulators may undertake enforcement action against us, which may include:

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

Similar action may be taken against us should we fail to comply with regulatory requirements, or later discover previously unknown problems with our products or manufacturing processes. 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 and operating results could be materially and adversely affected.

Additionally, companies may not promote drugs for "off-label" uses-that is, 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 financial condition and results of operations, 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. To market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by 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. We and our collaborators may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and therefore we may be unable to 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, results of operations and growth prospects.

MANUFACTURING RISKS

Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture BioThrax or our other products, which would harm our business, financial condition and operating results.

An interruption in manufacturing operations at Building 55, our FDA-approved large-scale manufacturing facility on our Lansing, Michigan campus, could result in our inability to produce BioThrax 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 public health threat countermeasures could be subject to an increased risk of terrorist activities. The U.S. government has designated both our Lansing, Michigan and our bulk manufacturing facility in Baltimore, Maryland as facilities requiring additional security. Although we continually evaluate and update security measures, there can be

no assurance that any additional security measures would protect our facilities from terrorist efforts determined to disrupt our manufacturing activities.

The factors listed above could also cause disruptions at our other facilities, including our manufacturing facility in Winnipeg, Manitoba, Canada. Any such disruption, damage, or destruction of these facilities could impede our ability to manufacture our Biologic 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 and operating results.

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 could be adversely affected..

Our marketed products and our product candidates are complex to manufacture and ship, which could cause us to experience delays in product manufacturing or development and cause delays in revenues.

BioThrax, BAT, Anthrasil, VIGIV, and many of our current product candidates, including NuThrax, are biologics. Manufacturing biologic products, especially in large quantities, is complex. The products must be made consistently and in compliance with a clearly defined manufacturing process. Problems during manufacturing may arise for a variety of reasons, including problems with raw materials, equipment malfunction and failure to follow specific protocols and procedures. In addition, slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation, contamination including from, among other things, particulates, filtration, filling, labeling, packaging, storage and shipping, and quality control testing, may result in lot (as defined below) failures or manufacturing shut-down, 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-down, 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.

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

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

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

If we are unable to obtain supplies for the manufacture of our marketed 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 marketed 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. 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. 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 and operating results.

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 and results of operations. 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.

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.

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 could materially and adversely affect our financial resources, results of operations and cash flows.

Before obtaining regulatory approval for the sale of our product candidates, we and our collaborative partners, where applicable, must conduct extensive 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 CBRN 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 the Project BioShield Act of 2004, or Project BioShield, the Secretary of HHS can contract to purchase countermeasures 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.

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, results of operations 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 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, results of operations and cash flows could be materially harmed.

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

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

The cost of litigation to uphold the validity of patents to prevent infringement or to otherwise protect or enforce our proprietary rights could be substantial and, from time to time, our patents are subject to opposition proceedings. Some of our competitors may be better able to sustain the costs of complex patent litigation because they may have substantially greater financial resources. Intellectual property lawsuits are expensive and unpredictable and would consume management's time and attention and other resources, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other 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 anthrax vaccine product candidate NuThrax.

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, which could materially harm our business, financial condition, operating results and cash flows.

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

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

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

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for any of our current products, our only intellectual property protection for these 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 trade secrets can be difficult to protect. We seek to protect this confidential information, in part, through agreements with our employees, consultants and third parties as well as confidentiality policies and audits, although these may not be successful in protecting our trade secrets and confidential information.

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

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, in part to fund our acquisition of Cangene Corporation, we issued $250 million of senior convertible notes in January 2014. Our pending purchase of certain assets and liabilities relating to the ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) will require an initial payment of $97.5 million and milestone payments of up to $27.5 million in the aggregate, tied to the achievement of certain regulatory and manufacturing-related milestones. Also, our agreement to acquire raxibacumab, a fully human monoclonal antibody which is FDA-approved for the treatment and prophylaxis of inhalational anthrax, requires us to make a $76 million upfront payment and up to $20 million in milestone payments, all of which would likely become due in 2019. Both transactions are subject to certain closing conditions, including (1) expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (2) receipt of consents under certain material contracts and (3) certain other customary conditions.

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 financial condition and operating results.

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

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

Issues that could delay or prevent successful integration or cost synergies of an acquired business 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;
§ 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 and our financial condition and operating results.

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 June 30, 2017, our total consolidated indebtedness was approximately $253 million, including approximately $250 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, including the senior convertible notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

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 addition to our current debt, we also have a senior secured revolving credit facility with available capacity of up to $100 million, effective until December 11, 2018 (or such earlier date to the extent required by the terms of this facility). We may 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, if any, 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.

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

As of June 30, 2017, we had approximately $315.6 million of cash and cash equivalents. Our future capital requirements will depend on many factors, including, among others:

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

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements. In May 2015, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer" under SEC rules, this shelf registration statement, effective until May 2018, 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 automatic shelf registration statement prior to May 2018, the existing shelf registration statement will expire and we will not be able to publicly raise capital or issue debt until a new shelf registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatic shelf registration statement at a future date when we 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 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 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, results of operations and financial condition 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 2015, 2014, 2013 and 2012. 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, together with certain related transactions, 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 Emergent and Aptevo contained in a tax matters agreement and certain representations contained in representation letters provided by Emergent, Aptevo and certain stockholders to such counsel, including representations and covenants relating to the past and future conduct of Emergent, 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 shareholders exceeded our tax basis in the Aptevo shares and (ii) each of our shareholders 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 shareholder.

Under the tax matters agreement that we entered into with Aptevo in connection with the spin-off, Aptevo may be required to indemnify us against any tax liabilities and related expenses resulting from the failure of the Distribution, together with certain related transactions, to qualify as a transaction described under Sections 355 and 368(a)(1)(D) of

the Code to the extent that the failure to so qualify is attributable to actions, events or transactions relating to Aptevo's stock, assets or business, or a breach of the relevant representations or covenants made by Aptevo in the tax matters agreement or the IRS private letter ruling or in the representation letters provided to our counsel for purposes of their opinion. Any such indemnity obligations could be material, and there can be no assurance that Aptevo will be able to pay any such indemnification.

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

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

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

OTHER BUSINESS RISKS

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

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

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

The results of this lawsuit and possible other future legal proceedings cannot be predicted with certainty. Accordingly, we cannot determine whether our insurance coverage would be sufficient to cover the costs or potential losses, if any. Regardless of merit, litigation may be both time-consuming and disruptive to our operations and cause significant expense and diversion of management attention. If we do not prevail in the purported class action lawsuit or in other

future legal proceedings, we may be faced with significant monetary damages or injunctive relief against us that may adversely affect our business, financial condition and results of operations.

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 immunity 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 immunity from all claims under federal or state law for loss arising out of the administration or use of a covered countermeasure. The Secretary of HHS has issued PREP Act declarations identifying certain of our products, namely BioThrax, BAT, Anthrasil 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, BAT, Anthrasil and VIGIV and SAFETY Act protection for BioThrax and RSDL in addition to our insurance coverage to help mitigate our product liability exposure for these products. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. If we identify a material weakness in our internal control over financial reporting, it could have an adverse effect on our business and financial results and our ability to meet our reporting obligations could be negatively affected, each of which could negatively affect the trading price of our common stock.

Internal control over financial reporting can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements and may not prevent or detect misstatements. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Failure to maintain effective internal control over financial reporting, or lapses in disclosure controls and procedures, could impact our financial information and disclosures, require significant resources to remediate, and expose us to legal or regulatory proceedings.

We regularly review and update our internal controls and disclosure controls and procedures. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Our system of internal controls, however well-designed, can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial reporting, and the price of our common stock could be negatively affected.

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

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

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

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

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

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel. If we are unable to retain the services of one or more of the principal members of senior management or other key employees, our ability to implement our business strategy could be materially harmed. We face intense competition for qualified employees from biopharmaceutical companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. We believe

part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including equity incentive awards. If we cannot offer a competitive compensation package to attract and retain the qualified personnel necessary for the continued development of our business, we may not be able to maintain our operations or grow our business.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

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

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his substantial beneficial ownership of our common stock. As of July 28, 2017, Mr. El-Hibri was the beneficial owner of approximately 13% 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 reinstate our stockholder rights plan or 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 reinstate the prior stockholder rights plan or implement a new stockholder rights plan, which may have anti-takeover effects, potentially preventing a change in control of us in instances in which some stockholders may believe a change in control is in their best interests. This could cause substantial dilution to a person or group that attempts to acquire us on terms that our Board of Directors does not believe are in our best interests or those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

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

Our stock price has been, and is likely to continue to be, volatile. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this "Risk Factors" section, or for reasons unrelated to our operations, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as industry conditions and general financial, economic and political instability. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through July 28, 2017, our common stock has traded as high as $44.38 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;
- announcements relating to 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 July 28, 2017, have the right to require us to register these shares of common stock under specified circumstances. In May 2015, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer" under SEC rules, this shelf registration statement, effective until May 2018, would provide for a secondary offering of these shares from time to time.

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

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

Not applicable.

Purchases of Equity Securities

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

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

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
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 3, 2017

By: /s/ROBERT G. KRAMER, SR.
Robert G. Kramer, Sr.
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Date: August 3, 2017

EXHIBIT INDEX

| Exhibit Number | Description |
|---|---|
| 2.1†† | Asset Purchase Agreement, dated July 14, 2017, by and between Sanofi Pasteur Biologics, LLC, Acambis Research Ltd. and Emergent BioSolutions Inc. (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on July 14, 2017). |
| 2.2†† | Asset Purchase Agreement, dated July 19, 2017, by and between Human Genome Sciences, Inc., GlaxoSmithKline LLC, and Emergent BioSolutions Inc. (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on July 24, 2017). |
| 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 six months ended June 30, 2017 and 2016;
(ii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and six months ended June 30, 2017 and 2016;
(iii) Condensed Consolidated Balance Sheets at June 30, 2017 and December 31, 2016;
(iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2017 and 2016; and
(v) Notes to Consolidated Financial Statements.

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