Emergent BioSolutions Inc.
Form 10-Q
November 09, 2016
UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q
(Mark
One)

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

For the quarterly period ended September 30, 2016

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<br>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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

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

As of October 31, 2016, the registrant had 40,498,025 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 includes 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 or any of its 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 a new procurement contract for BioThrax on favorable terms;
- our ability to obtain Emergency Use Authorization pre-approval for NuThrax from the FDA;
- the availability of funding for our U.S. government grants and contracts;
- 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 utilize the full manufacturing capacity of Building 55, our large-scale vaccine manufacturing facility in Lansing, Michigan;
- whether the operational, marketing and strategic benefits of the spin-off of our biosciences business can be achieved and the timing of any such benefits;
- 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 our manufacturing facilities and capabilities;
- our ability and the ability of our contractors and suppliers to maintain compliance with cGMP and other regulatory obligations;
- the results of regulatory inspections;
- the operating and financial restrictions placed on us and our subsidiaries under our senior secured credit facility;
- the outcome of the purported class action lawsuit 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)

| | September 30, 2016 (unaudited) | December 31, 2015 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $298,932 | $308,304 |
| Accounts receivable, net | 69,633 | 113,906 |
| Inventories | 81,160 | 60,887 |
| Income tax receivable, net | 11,831 | 6,573 |
| Prepaid expenses and other current assets | 18,439 | 18,458 |
| Current assets of discontinued operations | - | 29,282 |
| Total current assets | 479,995 | 537,410 |
| | | |
| Property, plant and equipment, net | 362,544 | 327,808 |
| In-process research and development | - | 701 |
| Intangible assets, net | 35,419 | 40,758 |
| Goodwill | 41,001 | 41,001 |
| Deferred tax assets, net | 11,286 | 11,286 |
| Other assets | 1,781 | 2,155 |
| Non-current assets of discontinued operations | - | 76,365 |
| Total assets | $932,026 | $1,037,484 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $46,342 | $37,970 |
| Accrued expenses and other current liabilities | 4,279 | 6,207 |
| Accrued compensation | 32,102 | 31,998 |
| Notes payable | 20,000 | - |
| Contingent consideration, current portion | 2,759 | 2,109 |
| Deferred revenue, current portion | 4,824 | 3,979 |
| Current liabilities of discontinued operations | - | 17,348 |
| Total current liabilities | 110,306 | 99,611 |
| | | |
| Contingent consideration, net of current portion | 20,169 | 23,046 |
| Long-term indebtedness | 247,793 | 246,892 |
| Deferred revenue, net of current portion | 4,695 | 3,426 |
| Other liabilities | 1,440 | 1,258 |
| Non-current liabilities of discontinued operations | - | 3,234 |
| Total liabilities | 384,403 | 377,467 |
| | | |
| | - | - |

| | | |
|---|---|---|
| Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at both September 30, 2016 and December 31, 2015 | | |
| Common stock, $0.001 par value; 200,000,000 shares authorized, 40,910,479 shares issued and 40,487,649 shares outstanding at September 30, 2016; 100,000,000 shares authorized, 39,829,408 shares issued and 39,406,578 shares outstanding at December 31, 2015 | 41 | 40 |
| Treasury stock, at cost, 422,830 common shares at both September 30, 2016 and December 31, 2015 | (6,420) | (6,420) |
| Additional paid-in capital | 342,888 | 317,971 |
| Accumulated other comprehensive loss | (3,572) | (2,713) |
| Retained earnings | 214,686 | 351,139 |
| Total stockholders' equity | 547,623 | 660,017 |
| Total liabilities and stockholders' equity | $932,026 | $1,037,484 |

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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2016 (Unaudited) | 2015 | 2016 (Unaudited) | 2015 |
| Revenues: | | | | |
| Product sales | $96,698 | $117,512 | $208,785 | $204,563 |
| Contract manufacturing | 14,712 | 11,341 | 32,455 | 32,443 |
| Contracts and grants | 31,504 | 29,525 | 95,879 | 92,541 |
| Total revenues | 142,914 | 158,378 | 337,119 | 329,547 |
| Operating expenses: | | | | |
| Cost of product sales and contract manufacturing | 39,560 | 35,240 | 93,025 | 73,083 |
| Research and development | 27,188 | 34,179 | 81,173 | 93,833 |
| Selling, general and administrative | 40,688 | 25,800 | 108,328 | 86,263 |
| Income from operations | 35,478 | 63,159 | 54,593 | 76,368 |
| Other income (expense): | | | | |
| Interest income | 358 | 104 | 764 | 459 |
| Interest expense | (2,049) | (1,635) | (5,082) | (4,923) |
| Other income (expense), net | (234) | 519 | (176) | 669 |
| Total other expense, net | (1,925) | (1,012) | (4,494) | (3,795) |
| Income from continuing operations before provision for income taxes | 33,553 | 62,147 | 50,099 | 72,573 |
| Provision for income taxes | 13,165 | 20,059 | 19,861 | 23,648 |
| Net income from continuing operations | 20,388 | 42,088 | 30,238 | 48,925 |
| Income (loss) from discontinued operations (net of tax) | 952 | (5,145) | (15,854) | (19,402) |
| Net income | $21,340 | $36,943 | $14,384 | $29,523 |
| Net income per share - basic: | | | | |
| Income from continuing operations | $0.50 | $1.08 | $0.75 | $1.28 |
| Income (loss) from discontinued operations | 0.02 | (0.14) | (0.40) | (0.51) |
| Net income per share - basic | $0.52 | $0.94 | $0.35 | $0.77 |
| Net income per share - diluted (1): | | | | |
| Income from continuing operations | $0.43 | $0.90 | $0.68 | $1.11 |
| Income (loss) from discontinued operations | 0.02 | (0.11) | (0.32) | (0.42) |
| Net income per share - diluted | $0.45 | $0.79 | $0.36 | $0.69 |
| Weighted-average number of shares - basic | 40,465,423 | 38,831,341 | 40,071,730 | 38,423,715 |
| Weighted-average number of shares - diluted | 49,440,313 | 47,784,550 | 48,826,597 | 46,958,179 |

(1) See Note 10 "Earnings per share" 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
(in thousands)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| | (Unaudited) | | (Unaudited) | |
| Net income | $21,340 | $36,943 | $14,384 | $29,523 |
| Foreign currency translations, net of tax | (492) | (495) | (859) | (1,144) |
| Comprehensive income | $20,848 | $36,448 | $13,525 | $28,379 |

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

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2016 | 2015 |
| Cash flows from operating activities: | (Unaudited) | |
| Net Income | $ 14,384 | $ 29,523 |
| Adjustments to reconcile to net cash provided by (used in) operating activities: | | |
| Stock-based compensation expense | 14,527 | 11,802 |
| Depreciation and amortization | 28,155 | 25,859 |
| Income taxes | 4,814 | 15,904 |
| Change in fair value of contingent obligations | (1,253) | (10,898) |
| Impairment of intangible assets (including IPR&D) | - | 9,827 |
| Abandonment of long-lived assets | 3,749 | - |
| Excess tax benefits from stock-based compensation | (10,825) | (8,002) |
| Other | 2,467 | 197 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 45,035 | 1,749 |
| Inventories | (16,183) | (14,396) |
| Income taxes | (14,662) | (22,707) |
| Prepaid expenses and other assets | (3,146) | 1,010 |
| Accounts payable | (1,305) | 1,902 |
| Accrued expenses and other liabilities | (1,699) | (2,060) |
| Accrued compensation | (152) | (1,688) |
| Provision for chargebacks | 103 | (296) |
| Deferred revenue | (1,348) | 3,663 |
| Net cash provided by operating activities | 62,661 | 41,389 |
| Cash flows from investing activities: | | |

| | | |
|---|---|---|
| Purchases of property, plant and equipment | (56,243) | (33,631) |
| Net cash used in investing activities | (56,243) | (33,631) |
| Cash flows from financing activities: | | |
| Proceeds from long-term debt obligations | - | 2,000 |
| Issuance of common stock upon exercise of stock options | 14,981 | 15,902 |
| Excess tax benefits from stock-based compensation | 10,825 | 8,002 |
| Distribution of Aptevo | (45,000) | - |
| Contingent obligation payments | (1,226) | (5,427) |
| Net cash (used in) provided by financing activities | (20,420) | 20,477 |
| Effect of exchange rate changes on cash and cash equivalents | 139 | (16) |
| Net (decrease) increase in cash and cash equivalents | (13,863) | 28,219 |
| Cash and cash equivalents at beginning of period | 312,795 | 280,499 |
| Cash and cash equivalents at end of period | $ 298,932 | $ 308,718 |

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

On August 6, 2015, Emergent BioSolutions Inc. (the "Company" or "Emergent"), announced its plan to separate into two independent publicly-traded companies. On August 1, 2016, the Company accomplished this plan through the completion of the spin-off of Aptevo Therapeutics Inc. ("Aptevo"), a biotechnology company focused on novel oncology and hematology therapeutics to meaningfully improve patients' lives. Emergent remains as a global specialty life sciences company focused on providing specialty products for civilian and military populations that address intentional and naturally emerging public health threats.

In anticipation of the spin-off, the Company realigned certain components of its biosciences business to the new Aptevo segment to be consistent with how the Company's chief operating decision maker ("CODM") allocates resources and makes decisions about the operations of the Company. Effective January 1, 2016, the Company changed its segment presentation to reflect this new structure, and recast all prior periods presented to conform to the new presentation. On August 1, 2016, the Company completed the spin-off of Aptevo. Aptevo is now an independent public company trading under the symbol "APVO" on the NASDAQ Global Select Market ("NASDAQ"). The results of operations and financial position of Aptevo are reflected as discontinued operations for all periods presented through the date of the spin-off. The historical financial statements and footnotes have been revised accordingly. See Note 2. "Discontinued operations" for further details regarding the spin-off. For periods following the spin-off, the Company reports financial results under one business segment.

The accompanying unaudited consolidated financial statements include the accounts of Emergent and its 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, 2015, as filed with the SEC.

During the nine months ended September 30, 2016 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, 2015, as filed with the SEC. In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, except for the adjustments associated with the spin-off of Aptevo, and are necessary to present fairly the financial position of the Company as of September 30, 2016, specifically: the results of operations and comprehensive income for the three and nine months ended September 30, 2016 and 2015; and cash flows for the nine months ended September 30, 2016 and 2015. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

We analyze our multiple element revenue-generating arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. An item can generally be considered a

separate unit of accounting if both of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis and (2) if the arrangement includes a general right of return and delivery or performance of the undelivered item(s) is considered probable and substantially in our control. Items that cannot be divided into separate units are combined with other units of accounting, as appropriate. Consideration received is allocated among the separate units based on the unit's relative selling price and is recognized in full when the appropriate revenue recognition criteria are met. We deem services to be rendered if no continuing obligation exists on our part. As of September 30, 2016, the Company has determined that its US Government contracts for Anthrasil™ (Anthrax Immune Globulin Intravenous (Human), BAT™ (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-Equine and VIGIV (Vaccinia Immune Globulin Intravenous (Human)) are multiple element arrangements.

Recent accounting standards

In April 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-08, Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity ("ASU No. 2014-08"). ASU No. 2014-08 limits discontinued operations reporting to disposals of components of an entity that represent strategic shifts that have (or will have) a major effect on an entity's operations and financial results. ASU No. 2014-08 also requires expanded disclosures for discontinued operations and disposals of individually significant components of an entity that do not qualify for discontinued operations reporting. ASU No. 2014-08 was effective for disposals and components classified as held-for-sale that occurred within annual periods beginning on or after December 15, 2014, and interim periods within those years. Early adoption was permitted. The new guidance is effective for the Company prospectively for all disposals of components of an entity that occurred after January 1, 2015. The spin-off of Aptevo by the Company on August 1, 2016 meets the definition of a discontinued operation under the new guidance and, as a result, the Company reflected the provisions of the new guidance in the third quarter of 2016.

In May 2014, the FASB issued ASU No. 2014-09, Summary and Amendments That Create Revenue from Contracts with Customers (Topic 606) and Other Assets and Deferred Costs—Contracts with Customers (Subtopic 340-40). 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 FASB has deferred ASU No. 2014-09 for one year, and with that deferral, the standard will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, which for the Company will be its 2018 first quarter. The Company is permitted to use either the retrospective or the modified retrospective method when adopting ASU No. 2014-09. The Company is still assessing the potential impact that ASU No. 2014-09 will have on its financial statements and disclosures, but believes that there could be changes to the revenue recognition for government contracts.

In April 2015, the FASB issued ASU No. 2015-03, Interest - Imputation of Interest (Subtopic 835-30), which simplifies the presentation of debt issuance costs. ASU No. 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. Prior to the issuance of ASU 2015-03, debt issuance costs were required to be presented as an asset on the balance sheet. ASU No. 2015-03 is effective for interim and annual periods beginning after December 15, 2015. The Company has adopted the guidance and has applied the guidance on a retrospective basis.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718). 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. ASU No. 2016-09 is effective for the annual reporting period beginning after December 15, 2016, including interim periods within that reporting period, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU No. 2016-09 will have on the consolidated financial statements and related disclosures.

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"), who received 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 within six to twelve months following the Distribution.

The historical balance sheet and statements of operations of Aptevo have been presented as discontinued operations in the consolidated financial statements and prior periods have 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.

In conjunction with the spin-off, the Company entered into a Separation and Distribution Agreement with Aptevo to effect the separation of Aptevo from the Company (the "Separation"). The Company also entered into various other agreements to provide a framework for its relationship with Aptevo after the Separation, including a manufacturing services agreement, transition services agreement, a tax matters agreement and an employee matters agreement.

The Separation and Distribution Agreement with Aptevo sets forth, among other things, the assets that were transferred, the liabilities assumed, and the contracts that were assigned to each of Aptevo and the Company as part of the Separation of the Company into two companies, and provided for when and how these transfers, assumptions and assignments were to occur.

Under the terms of the manufacturing services agreement, the Company agreed to provide contract manufacturing services for certain of Aptevo's products commencing on the date of the Distribution. The contract has a term of ten years. For the three and nine months ended September 30, 2016, there has been no revenue under this agreement.

Under the terms of the transition services agreement, the Company agreed to provide on an interim, transitional basis, various services, including, but not limited to, accounts payable administration, information technology services, regulatory and clinical support, general administrative services and other support services commencing on the date of the Distribution and terminating up to two years following the date of the Distribution. During the three and nine months ended September 30, 2016, approximately $0.5 million of transition services revenue associated with the provision of services to Aptevo.

The tax matters agreement governs the respective rights, responsibilities and obligations of Aptevo and the Company with respect to taxes (including taxes arising in the ordinary course of business and taxes, if any, incurred as a result of any failure of the Distribution and certain related transactions to qualify as tax-free for U.S. federal income tax purposes), tax attributes, tax returns, tax proceedings and certain other tax matters.

The employee matters agreement governs certain compensation and employee benefit obligations and allocates liabilities and responsibilities relating to employment matters, employee compensation and benefit plans and programs and other related matters, including the transfer or assignment of employees from the Company to Aptevo.

The following table represents the carrying value of Aptevo's assets and liabilities distributed as part of the Separation on August 1, 2016:

| (in thousands) | August 1, 2016 |
|---|---|
| Assets: | |
| Cash and cash equivalents | $45,000 |
| Accounts receivable, net | 4,465 |
| Inventories | 11,959 |
| Other current assets | 4,870 |
| Current assets of discontinued operations | 66,294 |
| | |
| Property, plant and equipment, net | 6,128 |
| In-process research and development | 41,800 |
| Intangible assets, net | 15,402 |
| Goodwill | 13,902 |
| Non-current assets of discontinued operations | 77,232 |
| Total assets of discontinued operations | $143,526 |
| | |
| Liabilities: | |
| Accounts payable | $6,285 |
| Accrued expenses and other current liabilities | 64 |
| Accrued compensation | 2,456 |
| Contingent consideration | 191 |
| Provisions for chargebacks | 2,341 |
| Deferred revenue, current portion | 433 |
| Current liabilities of discontinued operations | 11,770 |
| | |
| Deferred revenue, net of current portion | 3,232 |
| Other liabilities | 91 |
| Non-current liabilities of discontinued operations | 3,323 |
| Total liabilities of discontinued operations | $15,093 |

The following table represents Aptevo's assets and liabilities presented as discontinued operations and classified as held-for-disposition as of December 31, 2015:

| (in thousands) | December 31, 2015 |
|---|---|
| Assets: | |
| Cash and cash equivalents | $4,492 |

| | |
|---|---|
| Accounts receivable, net | 6,861 |
| Inventories | 16,049 |
| Prepaid expenses and other current assets | 1,880 |
| Current assets of discontinued operations | 29,282 |
| | |
| Property, plant and equipment, net | 4,046 |
| In-process research and development | 41,800 |
| Intangible assets, net | 16,617 |
| Goodwill | 13,902 |
| Non-current assets of discontinued operations | 76,365 |
| Total assets of discontinued operations | $105,647 |
| | |
| Liabilities: | |
| Accounts payable | $8,134 |
| Accrued expenses and other current liabilities | 22 |
| Accrued compensation | 2,684 |
| Contingent consideration, current portion | 306 |
| Provisions for chargebacks | 2,238 |
| Deferred revenue, current portion | 3,964 |
| Current liabilities of discontinued operations | 17,348 |
| | |
| Deferred revenue, net of current portion | 3,163 |
| Other liabilities | 71 |
| Non-current liabilities of discontinued operations | 3,234 |
| Total liabilities of discontinued operations | $20,582 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| (in thousands) | 2016 | 2015 | 2016 | 2015 |
| Revenues: | | | | |
| Product sales | $3,019 | $6,441 | $21,183 | $19,704 |
| Collaborations | 68 | 121 | 187 | 5,434 |
| Total revenues | 3,087 | 6,562 | 21,370 | 25,138 |
| | | | | |
| Operating expense: | | | | |
| Cost of product sales | 907 | 3,270 | 11,556 | 11,442 |
| Research and development | 2,509 | 7,689 | 18,024 | 27,678 |
| Selling, general and administrative | 7,499 | 5,756 | 23,792 | 16,239 |
| Loss from operations | (7,828) | (10,153) | (32,002) | (30,221) |
| | | | | |
| Other income (expense), net: | (116) | 83 | (41) | (464) |
| | | | | |
| Loss from discontinued operations before benefit from income taxes | (7,944) | (10,070) | (32,043) | (30,685) |
| Benefit from income taxes | (8,896) | (4,925) | (16,189) | (11,283) |
| Net loss from discontinued operations | $952 | $(5,145) | $(15,854) | $(19,402) |

The following table summarizes the cash flows of Aptevo included in the September 30, 2016 and 2015 consolidated statements of cash flows:

| | Nine Months Ended September 30, | |
|---|---|---|
| (in thousands) | 2016 | 2015 |
| Net cash (used in) provided by operating activities | $(17,813) | $1,414 |
| Net cash used in investing activities | (1,925) | (970) |
| Net cash provided by (used in) financing activities | 15,247 | (679) |
| Net increase (decrease) in cash and cash equivalents | $(4,491) | $(235) |

3. Fair value measurements

The following table represents the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis:

| | September 30, 2016 | | | |
|---|---|---|---|---|
| (in thousands) | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Investment in money market funds (1) | $10 | $ - | $- | $10 |
| Total assets | $10 | $ - | $- | $10 |
| | | | | |
| Liabilities: | | | | |
| Contingent consideration | $- | $ - | $22,928 | $22,928 |
| Total liabilities | $- | $ - | $22,928 | $22,928 |

| | December 31, 2015 | | | |
|---|---|---|---|---|
| (in thousands) | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Investment in money market funds (1) | $3,323 | $ - | $- | $3,323 |
| Total assets | $3,323 | $ - | $- | $3,323 |
| | | | | |
| Liabilities: | | | | |
| Contingent consideration | $- | $ - | $25,155 | $25,155 |
| Total liabilities | $- | $ - | $25,155 | $25,155 |

(1) Included in cash and cash equivalents in the accompanying consolidated balance sheets.

During the nine months ended September 30, 2016, the Company did not have any transfers between Level 1 and Level 2 assets or liabilities.

For the three months ended September 30, 2016, the contingent consideration obligation associated with the EV-035 series of molecules increased by $0.1 million. For the nine months ended September 30, 2016, the contingent consideration obligation associated with the EV-035 series of molecules decreased by $0.3 million. For the three and nine months ended September 30, 2015, the contingent consideration obligation decreased by $9.9 million and $9.5 million, respectively. These changes are primarily due to the estimated timing and probability of success for certain

development and regulatory milestones and the estimated timing and volume of potential future sales of the EV-035 series of molecules and the broad spectrum antiviral platform, which are inputs that have no observable market (Level 3), along with the novation of the Defense Threat Reduction Agency ("DTRA") contract for the EV-035 series of molecules. These decreases and increases in the contingent consideration were classified in the Company's statement of operations as both selling, general and administrative expense and research and development expense. During the nine months ended September 30, 2015, the Company received novation of the DTRA contract and paid the $4.0 million milestone to Evolva in the second quarter of 2015.

For the three and nine months ended September 30, 2016, the contingent purchase consideration obligations associated with RSDL decreased by $2.3 million and $1.0 million, respectively. For the three and nine months ended September 30, 2015, the contingent consideration obligations associated with RSDL decreased by $1.9 million and $1.8 million, respectively. The fair value of the RSDL contingent consideration obligations decreased as a result of management's assessment of the assumed and actual achievement of future net sales, which are inputs that have no observable market (Level 3). These changes are classified in the Company's statement of operations as cost of product sales and contract manufacturing.

The following table is a reconciliation of the beginning and ending balance of the liabilities, consisting only of contingent consideration, measured at fair value using significant unobservable inputs (Level 3) during the nine months ended September 30, 2016.

| (in thousands) | |
|---|---|
| Balance at December 31, 2015 | $25,155 |
| Income included in earnings | 1,263 |
| Settlements | (964) |
| Purchases, sales and issuances | - |
| Transfers in/(out) of Level 3 | - |
| Balance at September 30, 2016 | $22,928 |

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a non-recurring basis. As of September 30, 2016, the in-process research and development asset for the EV-035 series of molecules was measured at fair value on a non-recurring basis.

4. Inventories

Inventories consisted of the following:

| (in thousands) | September 30, 2016 | December 31, 2015 |
|---|---|---|
| Raw materials and supplies | $ 31,239 | $ 21,275 |
| Work-in-process | 24,459 | 32,709 |
| Finished goods | 25,462 | 6,903 |
| Total inventories | $ 81,160 | $ 60,887 |

5. Property, plant and equipment

Property, plant and equipment consisted of the following:

| (in thousands) | September 30, 2016 | December 31, 2015 |
|---|---|---|

| | | |
|---|---|---|
| Land and improvements | $20,391 | $16,520 |
| Buildings, building improvements and leasehold improvements | 141,322 | 108,908 |
| Furniture and equipment | 191,529 | 129,933 |
| Software | 52,744 | 39,683 |
| Construction-in-progress | 64,885 | 126,531 |
| Property, plant and equipment, gross | 470,871 | 421,575 |
| Less: Accumulated depreciation and amortization | (108,327) | (93,767 ) |
| Total property, plant and equipment, net | $362,544 | $327,808 |

6. Intangible assets and in-process research and development

Intangible assets consisted of the following:

| (in thousands) | |
|---|---|
| Cost basis | |
| Balance at December 31, 2015 | $57,099 |
| Additions | - |
| Balance at September 30, 2016 | $57,099 |
| | |
| Accumulated amortization | |
| Balance at December 31, 2015 | $(16,343) |
| Amortization | (5,337 ) |
| Balance at September 30, 2016 | $(21,680) |
| | |
| Net balance at September 30, 2016 | $35,419 |

In September 2015, the Company received data for the leading molecule in the EV-035 series of molecules, GC-072, that indicated a potential toxicity issue. The Company considered this information an indicator of impairment of the related EV-035 series of molecules in-process research and development ("IPR&D") asset, and completed an impairment assessment of this asset. Based on this assessment, the Company recorded a non-cash impairment charge of $9.8 million, which is included in the Company's statement of operations as research and development expense. The impairment assessment was performed using the income approach which discounts expected future cash flows to present value. The projected cash flows for the EV-035 series of molecules were based on key assumptions including: estimates of revenues and operating profits considering its stage of development; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate, such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential for alternative treatments in any future target markets.

For the three months ended September 30, 2016 and 2015, the Company recorded amortization expense of $1.7 million and $1.8 million, respectively. For the nine months ended September 30, 2016 and 2015, the Company recorded amortization expense of $5.3 million and $5.5 million, respectively, for intangible assets, which has been recorded in operating expenses, specifically selling, general and administrative and cost of product sales and contract manufacturing. As of September 30, 2016, the weighted average amortization period remaining for intangible assets is 78 months.

7. Long-term debt

As of December 31, 2015, the Company reclassified debt issuance costs of $1.2 million and $4.9 million from prepaid expenses and other current assets and other assets, respectively, as a reduction to long-term debt.

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 original conversion rate was equal to 30.8821 shares of common stock per $1,000 principal amount of notes (which is equivalent to a conversion price of approximately $32.38 per share of common stock). The conversion rate is subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest. As of August 1, 2016, certain conversion features were triggered due to the completion of the Aptevo spin-off. The conversion rate under the Notes was adjusted in accordance with the terms of the indenture. Effective August 12, 2016, the conversion rate was adjusted to 32.3860 shares of common stock per $1,000 principal amount of notes (which is equivalent to a conversion price of approximately $30.88 per share of common stock).

8. Equity

As of September 30, 2016, the Company had two stock-based employee compensation plans, the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan") and the Emergent BioSolutions Employee Stock Option Plan (the "2004 Plan"). The Company refers to both plans together as the "Emergent Plans." On May 19, 2016, at the Company's annual meeting, the Company's shareholders approved the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan, and the issuance of 3.8 million shares thereunder. In addition, the Company's shareholders approved an increase in the number of authorized shares of common stock to 200 million shares from 100 million shares.

In connection with the Separation, on August 1, 2016 and in accordance with the employee matters agreement and the Emergent Plans, the Company made certain adjustments to the exercise price and number of equity awards. Continuing Emergent employees with equity awards issued prior to Distribution received an equitable adjustment reflecting a revised exercise price and number of equity awards granted. Continuing Aptevo employees who had been granted Emergent equity awards had their grants canceled and reissued as Aptevo equity awards with an adjusted exercise price.

The following is a summary of stock option award activity:

| | 2006 Plan | | 2004 Plan | | |
|---|---|---|---|---|---|
| | Number of Shares | Weighted-Average Exercise Price | Number of Shares | Weighted-Average Exercise Price | Aggregate Intrinsic Value |
| Outstanding at December 31, 2015 | 2,964,237 | $ 22.73 | 29,699 | $ 10.28 | $52,119,607 |
| Granted | 403,978 | 33.70 | - | - | |
| Exercised | (750,293) | 19.56 | (29,699) | 10.28 | |
| Forfeited | (62,441) | 27.48 | - | - | |
| Canceled | (146,986) | 28.33 | - | - | |
| Equitable adjustment | 236,313 | 22.90 | - | - | |
| Outstanding at September 30, 2016 | 2,644,808 | 22.84 | - | - | 22,976,804 |
| Exercisable at September 30, 2016 | 1,558,840 | $ 19.51 | - | $ - | $18,732,937 |

The following is a summary of restricted stock unit award activity:

| | Number of Shares | Weighted-Average Grant Price | Aggregate Intrinsic Value |
|---|---|---|---|
| Outstanding at December 31, 2015 | 889,004 | $ 26.86 | $35,569,048 |
| Granted | 488,738 | 34.36 | |
| Vested | (416,289) | 24.68 | |

| | | | |
|---|---|---|---|
| Forfeited | (46,994) | 29.84 | |
| Canceled | (107,514) | 30.90 | |
| Equitable adjustment | 79,339 | 28.86 | |
| Outstanding at September 30, 2016 | 886,284 | $ 28.95 | $24,922,306 |

On July 14, 2016, the Company's board of directors authorized management to repurchase, from time to time, up to an aggregate of $50 million of the Company's common stock under a board-approved share repurchase program. The timing, amount, and price of any repurchases will be made pursuant to one or more 10b5-1 plans. The term of the board authorization of the repurchase program is until December 31, 2017. The plan will permit shares to be repurchased when the Company might otherwise be precluded from doing so under insider trading laws. The repurchase program may be suspended or discontinued at any time. Any repurchased shares will be available for use in connection with the Company's stock plans and for other corporate purposes. As of September 30, 2016, the Company has neither implemented a repurchase plan nor repurchased any shares under this program.

9. Income taxes

The estimated effective annual tax rate for continued operations, which excludes discrete adjustments, was 37% and 29%, respectively, for the nine months ended September 30, 2016 and 2015. The increase in the estimated effective annual tax rate on continuing operations was primarily related to tax on the sale, within the Emergent consolidated group, of assets from Canadian subsidiaries to U.S. subsidiaries in preparation of the spin-off of Aptevo and a valuation allowance charge related to Aptevo net deferred tax assets prior to the Distribution, partially offset by a release of valuation allowances associated with Canadian Scientific Research and Experimental Development tax credits.

10. Earnings per share

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| (in thousands, except share and per share data) | 2016 | 2015 | 2016 | 2015 |
| Numerator: | | | | |
| Net income from continuing operations | $20,388 | $42,088 | $30,238 | $48,925 |
| Interest expense, net of tax | 934 | 786 | 2,234 | 2,378 |
| Amortization of debt issuance costs, net of tax | 183 | 215 | 569 | 671 |
| Net income, adjusted from continuing operations | 21,505 | 43,089 | 33,041 | 51,974 |
| Income (loss) from discontinued operations | 952 | (5,145) | (15,854) | (19,402) |
| Net income, adjusted | $22,457 | $37,944 | $17,187 | $32,572 |
| | | | | |
| Denominator: | | | | |
| Weighted-average number of shares—basic | 40,465,423 | 38,831,341 | 40,071,730 | 38,423,715 |
| Dilutive securities—equity awards | 878,390 | 1,232,684 | 658,367 | 813,939 |
| Dilutive securities—convertible debt | 8,096,500 | 7,720,525 | 8,096,500 | 7,720,525 |
| Weighted-average number of shares—diluted | 49,440,313 | 47,784,550 | 48,826,597 | 46,958,179 |
| | | | | |
| Net income per share-basic from continuing operations | $0.50 | $1.08 | $0.75 | $1.28 |
| Income (loss) per share-basic from discontinued operations | 0.02 | (0.14) | (0.40) | (0.51) |
| Net income per share-basic | $0.52 | $0.94 | $0.35 | $0.77 |
| | | | | |
| Net income per share-diluted from continuing operations | $0.43 | $0.90 | $0.68 | $1.11 |

| | | | | |
|---|---|---|---|---|
| Income (loss) per share-diluted from discontinued operations | 0.02 | (0.11) | (0.32) | (0.42) |
| Net income per share-diluted | $0.45 | $0.79 | $0.36 | $0.69 |

For the three and nine months ended September 30, 2016 and 2015, basic earnings per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period.

For the three and nine months ended September 30, 2016 and 2015, 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 Company's 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 September 30, 2016, approximately 0.4 million stock options were excluded from the calculation of diluted earnings per share. For the three and nine months ended September 30, 2015, along with the nine months ended September 30, 2016, substantially all of the outstanding stock options to purchase shares of common stock were included in the calculation of diluted earnings per share.

11. Restructuring

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

The Company has completed this restructuring. The costs of the restructuring as of September 30, 2016 are detailed below:

| (in thousands) | Incurred in 2016 | Inception to Date Costs Incurred | Total Expected to be Incurred |
|---|---|---|---|
| Termination benefits | $ 2,488 | $ 2,488 | $ 5,264 |
| Abandonment of equipment | 3,749 | 3,749 | 3,749 |
| Other costs | 691 | 691 | 691 |
| Total | $ 6,928 | $ 6,928 | $ 9,704 |

During the nine months ended September 30, 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. 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. As of September 30, 2016, the Company has determined that there were no indications of impairment for the remaining assets groups at the EBOL site.

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

| | Termination |
|---|---|

| (in thousands) | Benefits |
|---|---|
| Balance at December 31, 2015 | $ - |
| Expenses incurred | 2,488 |
| Amount paid | - |
| Other adjustments | - |
| Balance at September 30, 2016 | $ 2,488 |

In addition to the above restructuring costs, the Company also recorded a charge of $1.7 million during the nine months ended September 30, 2016 related to retention payments for certain employees at the EBOL site.

12. Related party transactions

In November 2015, the Company entered into a consulting arrangement with a member of the Company's Board of Directors, amended in July 2016, to provide assistance in connection with the planned spin-off of Aptevo. The total compensation under the agreement was approximately $0.2 million. The consulting agreement terminated on August 1, 2016.

13. Segment information

On August 6, 2015, the Company announced its plan to separate into two independent publicly-traded companies. In anticipation of the spin-off, the Company realigned certain components of its biosciences business to the new Aptevo segment to be consistent with how the CODM allocates resources and makes decisions about the operations of the Company. Effective January 1, 2016, the Company changed its segment presentation to reflect this new structure, and recast all prior periods presented to conform to the new presentation. On August 1, 2016, the Company completed the spin-off of Aptevo. The results of operations and financial position of Aptevo are reflected as discontinued operations for all periods presented through the date of the spin-off.

For financial reporting purposes, in the periods following the spin-off of Aptevo, the Company reports financial information for one business segment.

For the three and nine months ended September 30, 2016 and 2015, substantially all of the Company's revenues are from the United States government.

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

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this quarterly report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, including information with respect to our plans and strategy for our business and financing, includes forward-looking statements that involve risks and uncertainties. You should carefully review the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this quarterly report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Product Portfolio

Emergent BioSolutions Inc., or Emergent, is a specialty biopharmaceutical business focused on countermeasures that address public health threats, specifically Chemical, Biological, Radiological, Nuclear and Explosive, or CBRNE, threats as well as emerging infectious diseases, or EID. The U.S. government is the primary purchaser of our products and historically provided us with substantial funding for the development of our product candidates. We develop, manufacture, and deliver a portfolio of medical countermeasures primarily for government agencies in the areas of biological and chemical threats and emerging infectious diseases. Operations include manufacturing, regulatory affairs, quality assurance, quality control, international sales and marketing, and domestic government affairs in support of our marketed products, as well as product development and manufacturing infrastructure in support of our investigational stage product candidates.

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 nine months ended September 30, 2016 and 2015. See Note 2. "Discontinued Operations" for further details regarding the spin-off. Unless otherwise stated, financial results herein reflect continuing operations.

Our portfolio consists of the following marketed products and investigational stage product candidates.

Our marketed products 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;
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 for the treatment of botulinum disease;
VIGIV (Vaccinia Immune Globulin Intravenous (Human)), the only therapeutic licensed by the FDA to address adverse events from smallpox vaccination; and
RSDL® (Reactive Skin Decontamination Lotion Kit), the only device cleared by the FDA for the removal or neutralization of chemical agents, T-2 toxin and many pesticide-related chemicals from the skin.

Our investigational stage product 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;

VAX161C, a recombinant pandemic influenza vaccine candidate being developed by VaxInnate, Inc. and for which we have an exclusive license agreement to manufacture and sell in the event of a surge order from the Biomedical Advanced Research and Development Authority, or BARDA; and
Other product candidates that are focused on public health threats and emerging infectious diseases.

A unique attribute of our investigational stage product portfolio is that most of our candidates are under an active development contract with significant funding from the U.S. government. This allows our development pipeline, along with our marketed products, to be aligned with the strategic priorities of our U.S. and allied foreign government customers.

We also have programs that leverage our proven manufacturing infrastructure and expertise. We have responded to specific Task Order Requests issued by 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, including pandemic influenza and Ebola. On June 27, 2016, we received a task order from BARDA to develop and manufacture three cGMP lots of Zika vaccine for use in a Phase 1 clinical trial. Using a base vaccine candidate provided by BARDA, we will conduct technology transfer of process materials and information, process and analytical method development, execute small-scale production runs, and perform cGMP cell banking leading to cGMP manufacture of bulk drug substance and final drug product. The task order consists of a 30-month base period valued at $17.9 million and includes options that, if executed, will bring the total value to up to $21.9 million.

We also have multiple platform technologies, including the MVAtor™ (modified vaccinia virus Ankara vector) platform technology and Emergard™, a military-grade auto-injector device designed for intramuscular self-injection of antidotes and other emergency response medical treatments that can address exposure to certain chemical agents and other similar emerging threats and our hyperimmune specialty plasma product manufacturing platform. In February 2016, we announced that Emergard was selected by the U.S. Department of Defense, or DoD, and Battelle Memorial Institute to be tested against and developed to U.S. military specifications as a platform for nerve agent antidote delivery. Initial development and testing of Emergard is expected to be completed in 2016 and, if successful, could lead to Emergard's future procurement for U.S. military and emergency responder use. The testing and development of Emergard will be performed under a subcontract with Battelle, which in turn has a prime contract with the DoD.

In addition, we provide contract manufacturing services to third-party customers. The majority of these services are performed at our 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. We manufacture both vial and pre-filled syringe formats for a wide variety of drug products - small molecule and biological - in all stages of development and commercialization, including 20 licensed products, which are currently sold in more than 40 countries. 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 manufacturing facility under the regulatory regimes in the United States, Canada, Japan, Brazil, the Middle East and several countries in the European Union.

We have derived the majority of our historical product sales revenues from BioThrax sales to the U.S. government. We are focused on increasing the sales of our products to U.S. government customers and expanding the market for our product portfolio to other customers domestically and internationally. We are currently a party to a contract with the Centers for Disease Control and Prevention, or the CDC, an operating division of the U.S. Department of Health and Human Services, or HHS, to supply up to 44.75 million doses of BioThrax for the placement into the Strategic National Stockpile, or SNS, over a five-year period, which was scheduled to expire on September 30, 2016. On September 21, 2016, the CDC exercised an option to procure all remaining BioThrax doses under this contract, thereby committing to take delivery of the full 44.75 million doses and granted a no-cost extension to enable delivery of the remaining doses. We completed the delivery of doses under this no-cost extension in October 2016.

On June 21, 2016, HHS issued a Sole Source Notification indicating its intention to award Emergent a follow-on contract for the purchase of 29.4 million doses of BioThrax with a period of performance of five years. The solicitation does not state the number of doses expected to be procured per year, but represents a smaller annual procurement on average over the five-year period of the anticipated follow-on contract than under our current contract. The terms of the anticipated contract, including the price per dose and the timing of deliveries, remain subject to contract negotiation. In addition, the procurement of doses of BioThrax by the CDC remains subject to the availability of funding.

On August 10, 2016, the CDC exercised a contract option valued at $11.6 million over 12 months for the supply of Vaccinia Immune Globulin, or VIGIV, into the SNS. VIGIV is a therapeutic licensed by the FDA, for the treatment of complications arising from smallpox vaccinations. The contract option will require us to conduct manufacturing runs and additional activities in support of maintaining FDA licensure of VIGIV.

On September 30, 2016, we were awarded a multi-year contract with BARDA for the advanced development and delivery of NuThrax. The contract, valued at up to approximately $1.6 billion, consists of a five-year base period of performance valued at approximately $200 million to develop NuThrax for post-exposure prophylaxis of anthrax disease and to deliver to the SNS an initial two million doses following Emergency Use Authorization, or EUA, pre-approval by the FDA. We anticipate that the FDA could authorize NuThrax for emergency use as early as 2018, triggering deliveries of NuThrax to the SNS in 2019. The contract also includes procurement options for the delivery of an additional 7.5 million to 50 million doses of NuThrax to the SNS, valued from approximately $255 million to up to $1.4 billion, respectively, and options for an additional clinical study and post-marketing commitments valued at $48 million, which if both were to be exercised in full, would increase the total contract value to up to $1.6 billion.

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 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 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.

Financial Operations Overview

Revenues

Effective September 30, 2011, we entered into a contract with the CDC to supply up to 44.75 million doses of BioThrax to the CDC over a five-year period from September 30, 2011 through September 30, 2016. On September 21, 2016, the CDC exercised an option to procure all remaining BioThrax doses, thereby committing to take delivery of the full 44.75 million doses under this contract and granted a no-cost extension to enable delivery of the remaining doses to be completed by November 30, 2016. Through September 30, 2016, we have approximately 1.0 million doses remaining to deliver under this contract, which were delivered in October 2016.

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

| Development Programs | Funding Source | Award Date | Performance Period |
|---|---|---|---|
| Anthrasil | BARDA | Sep-05 | 9/2005 — 4/2021 |
| | BARDA | Sep-13 | 9/2013 — 9/2018 |
| BAT | BARDA | May-06 | 5/2006 — 5/2026 |
| CIADM | BARDA | Jun-12 | 6/2012 — 6/2037 |
| GC-072 | DTRA | Aug-14 | 8/2014 — 8/2017 |
| Large-scale manufacturing for BioThrax | BARDA | Jul-10 | 7/2010 — 7/2016 |
| NuThrax | NIAID | Aug-14 | 8/2014 — 10/2019 |
| | BARDA | Mar-15 | 3/2015 — 8/2017 |
| | BARDA | Sep-16 | 9/2016 — 9/2021 |
| VIGIV | CDC | Aug-12 | 8/2012 — 8/2017 |
| Zika | BARDA | Jun-16 | 6/2016 — 12/2018 |

Our revenue, operating results and profitability have varied, and we expect that they will continue to vary on a quarterly basis, primarily due to the timing of sales of our products and timing of work completed under existing and new grants, development contracts and collaborative relationships.

Cost of Product Sales and Contract Manufacturing

The primary expense that we incur to deliver to our customers our marketed vaccines and therapeutics and to perform for our customers our contract manufacturing operations is manufacturing costs consisting of fixed and variable costs. Variable manufacturing costs consist primarily of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff, contract manufacturing and filling operations, and sales-based royalties. Fixed manufacturing costs include facilities, utilities and amortization of intangible assets. We determine the cost of product sales for products sold during a reporting period based on the average manufacturing cost per unit in the period those units were manufactured. In addition to the fixed and variable manufacturing costs described above, the cost of product sales depends on utilization of available manufacturing capacity.

The primary expense that we incur to deliver our medical devices to our customers is the cost per unit of production from our third-party contract manufacturers. Other associated expenses include sales-based royalties, amortization of intangible assets, shipping, logistics and the cost of support functions.

Research and Development Expenses

We expense research and development costs as incurred. Our research and development expenses consist primarily of:

personnel-related expenses;
fees to professional service providers for, among other things, analytical testing, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies;
costs of contract manufacturing services for clinical trial material; and
costs of materials used in clinical trials and research and development.

We intend to focus our product development efforts on promising late-stage candidates that we believe satisfy well-defined criteria and seek to utilize collaborations or non-dilutive funding. We plan to seek funding for development activities from external sources and third parties, such as governments and non-governmental organizations, or through collaborative partnerships. We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development spending, the number of product candidates under development, the size, structure and duration of any clinical programs that we may initiate, the costs associated with manufacturing our product candidates on a large-scale basis for later stage clinical trials, and our ability to use or rely on data generated by government agencies, such as studies involving BioThrax conducted by the CDC.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel-related costs and professional fees in support of our executive, sales and marketing, business development, government affairs, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales and contract manufacturing or research and development expense.

Critical Accounting Policies and Estimates

There have been no significant changes to our Critical Accounting Policies and Estimates during the nine months ended September 30, 2016,. Refer to the Critical Accounting Policies and Estimates section in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission.

Results of Operations

Three Months Ended September 30, 2016 Compared to Three Months Ended September 30, 2015

Revenues

| | Three Months Ended September 30, | | | |
|---|---|---|---|---|
| (in thousands) | 2016 | 2015 | Change | % Change |
| Product sales: | | | | |
| BioThrax | $94,116 | $109,785 | $(15,669) | (14 %) |
| Other | 2,582 | 7,727 | (5,145 ) | (67 %) |
| Total product sales | 96,698 | 117,512 | (20,814) | (18 %) |
| Contract manufacturing | 14,712 | 11,341 | 3,371 | 30 % |
| Contracts and grants | 31,504 | 29,525 | 1,979 | 7 % |
| Total revenues | $142,914 | $158,378 | $(15,464) | (10 %) |

Product Sales:

The decrease in BioThrax sales was primarily due to the timing of deliveries to the SNS. The decrease in other product sales was primarily due to the timing of BAT sales to the SNS.

Contract Manufacturing:

The increase in Contract manufacturing is primarily due to the timing of fill/finish services provided to third parties.

Contracts and grants:

The increase in Contracts and grants was primarily due to:

- increased development funding of $6.9 million related to our CIADM program, including $3.2 million from new CIADM task orders;
- increased development funding of $3.8 million for NuThrax related to non-clinical studies and manufacturing activities; and
- increased development funding of $3.3 million for VIGIV related to plasma collection.

These increases were partially offset by:

- decreased development funding of $5.7 million for Anthrasil related to the timing of plasma collection; and
- decreased development funding of $5.2 million for large scale manufacturing of BioThrax due to our Building 55 facility receiving FDA approval in August 2016.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $4.4 million, or 13%, to $39.6 million for the three months ended September 30, 2016 from $35.2 million for the three months ended September 30, 2015. The increase was attributable to an increase in BioThrax sales to the SNS along with an increase in the BioThrax cost per dose sold associated with lower production yield in the period in which the doses sold were produced, partially offset by a decrease in BioThrax sales to the SNS. In addition, the increase is due to an increase in costs associated with underutilized manufacturing capacity at our Winnipeg site.

Research and Development Expenses

Research and development expenses decreased by $7.0 million, or 20%, to $27.2 million for the three months ended September 30, 2016 from $34.2 million for the three months ended September 30, 2015. This decrease primarily reflects lower contract service costs. Net of contracts and grants revenues, our research and development expenses were fully funded during the three months ended September 30, 2016. Net of contracts and grants revenues, we incurred net research and development expenses of $4.7 million during the three months ended September 30, 2015.

Our principal research and development expenses for the three months ended September 30, 2016 and 2015 are shown in the following table:

| | Three Months Ended September 30, | | | |
|---|---|---|---|---|
| (in thousands) | 2016 | 2015 | Change | % Change |
| Biodefense: | | | | |
| Large-scale manufacturing for BioThrax | $1,491 | $3,577 | $(2,086) | (58 %) |
| BioThrax related programs | 1,012 | 1,449 | (437) | (30 %) |
| PreviThrax | 294 | 1,972 | (1,678) | (85 %) |
| NuThrax | 6,182 | 3,764 | 2,418 | 64 % |
| Pandemic influenza | 201 | 5,243 | (5,042) | (96 %) |
| Anthrasil | 178 | 3,923 | (3,745) | (95 %) |
| BAT | 814 | 578 | 236 | 41 % |
| EV-035 series of molecules | 1,331 | 4,357 | (3,026) | (69 %) |
| CIADM task orders | 2,600 | 375 | 2,225 | 593 % |
| VIGIV | 1,475 | (828) | 2,303 | 278 % |
| Emergard | 2,475 | 1,207 | 1,268 | 105 % |
| Other | 9,135 | 8,562 | 573 | 7 % |
| Total | $27,188 | $34,179 | $(6,991) | (20 %) |

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 expense for BioThrax related programs was primarily related to the timing of clinical studies to support applications for label expansion for BioThrax. The decrease in expense for PreviThrax was primarily due to the timing of non-clinical

studies. In light of reduced funding by the U.S. government for this product candidate, we determined to cease further development work on our PreviThrax vaccine and expect the spending for PreviThrax will be minimal in the future. The increase in expense for NuThrax was primarily due to the timing of non-clinical animal studies and manufacturing activities. The decrease in spending for Pandemic influenza was primarily for a $5.0 million milestone payment to VaxInnate Corporation in the third quarter of 2015. The decrease in expense for our Anthrasil program was primarily due to the timing of plasma collection services. The spending for our BAT program was primarily related to stability testing and plasma collection. The decrease in expense for our EV-035 series of molecules was primarily due to pharmacologic and formulation activities and a third quarter 2015 non-cash impairment charge of $9.8 million due to toxicity related issues, partially offset by a third quarter 2015 $6.7 million reduction of contingent consideration associated with the estimated timing and probability of achievement for certain development and regulatory milestones. The increase in expense for CIADM task orders was primarily for manufacturing development for Ebola monoclonal antibodies. The increase in expense for VIGIV was primarily due to the timing of plasma collection partially offset by a reduction in 2015 of a liability to BARDA associated with 2013 manufacturing activities. The increase in expense for Emergard was primarily for formulation development. The spending for our Other activities was primarily for our funded pre-clinical product candidates and manufacturing development activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $14.9 million, or 58%, to $40.7 million for the three months ended September 30, 2016 from $25.8 million for the three months ended September 30, 2015. The increase includes costs associated with the Aptevo spin-off, restructuring activities at our Lansing, Michigan site, along with increased professional services to support our strategic growth initiatives, and increased information technology investments. In addition, during the third quarter of 2015, we recorded a $3.3 million reduction in contingent consideration related to the estimated timing and probability of potential future sales of EV-035.

Provision for Income Taxes

Provision for income taxes decreased by $6.9 million, or 34%, to $13.1 million for the three months ended September 30, 2016 from $20.1 million for the three months ended September 30, 2015. The decrease was primarily due to a $28.5 million decrease in income before provision for income taxes, partially offset by an increase in the effective tax rate related to one-time, non-cash charges to complete the Aptevo spin-off.

Nine Months Ended September 30, 2016 Compared to Nine Months Ended September 30, 2015

Revenues

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| (in thousands) | 2016 | 2015 | Change | % Change |
| Product sales: | | | | |
| BioThrax | $193,255 | $182,026 | $11,229 | 6 % |
| Other | 15,530 | 22,537 | (7,007 ) | (31 %) |
| Total product sales | 208,785 | 204,563 | 4,222 | 2 % |
| Contract manufacturing | 32,455 | 32,443 | 12 | 0 % |
| Contracts and grants | 95,879 | 92,541 | 3,338 | 4 % |
| Total revenues | $337,119 | $329,547 | $7,572 | 2 % |

Product Sales:

The increase in BioThrax sales was primarily due to the timing of deliveries to the SNS. The decrease in Other product sales was primarily due to the timing of a $6.7 million decrease in BAT sales to the SNS and a one-time payment of $7.0 million for Anthrasil associated with FDA approval in the first quarter of 2015.

Contracts and grants:

The increase in Contracts and grants was primarily due to:

- increased development funding of $25.5 million related to our CIADM program, including $13.0 million from new CIADM task orders;
- increased development funding of $7.2 million for NuThrax related to non-clinical animal studies and manufacturing activities;and
- increased development funding of $18.8 million for VIGIV related to plasma collection.

These increases were partially offset by:

- decreased development funding of $36.9 million for Anthrasil related to the timing of plasma collection; and
- decreased development funding of $8.5 million for large scale manufacturing of BioThrax due to our Building 55 facility receiving FDA approval in August 2016.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $19.9 million, or 27%, to $93.0 million for the nine months ended September 30, 2016 from $73.1 million for the nine months ended September 30, 2015. The increase was attributable to an increase in BioThrax sales to the SNS along with an increase in the BioThrax cost per dose sold associated with lower production yield in the period in which the doses sold were produced. In addition, the increase is due to an increase in costs associated with underutilized manufacturing capacity at our Winnipeg site.

Research and Development Expenses

Research and development expenses decreased by $12.6 million, or 13%, to $81.2 million for the nine months ended September 30, 2016 from $93.8 million for the nine months ended September 30, 2015. This decrease primarily reflects lower contract service costs. Net of contracts and grants revenues, our research and development expenses were fully funded during the nine months ended September 30, 2016. Net of contracts and grants revenues, we incurred net research and development expenses of $1.3 million during the nine months ended September 30, 2015.

Our principal research and development expenses for the nine months ended September 30, 2016 and 2015 are shown in the following table:

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| (in thousands) | 2016 | 2015 | Change | % Change |
| Biodefense: | | | | |
| Large-scale manufacturing for BioThrax | $4,870 | $8,526 | $(3,656) | (43%) |
| BioThrax related programs | 2,701 | 2,732 | (31) | (1%) |
| PreviThrax | 1,369 | 5,772 | (4,403) | (76%) |
| NuThrax | 15,847 | 9,098 | 6,749 | 0% |
| Pandemic influenza | 1,260 | 6,469 | (5,209) | (81%) |

| | | | | | |
|---|---|---|---|---|---|
| Anthrasil | 626 | 25,533 | (24,907) | (98 | %) |
| BAT | 2,964 | 4,277 | (1,313 ) | (31 | %) |
| EV-035 series of molecules | 2,973 | 6,076 | (3,103 ) | (51 | %) |
| CIADM task orders | 7,899 | 375 | 7,524 | 2,006 | % |
| VIGIV | 7,428 | (106 ) | 7,534 | 7,108 | % |
| Emergard | 7,645 | 2,405 | 5,240 | 218 | % |
| Other | 25,591 | 22,676 | 2,915 | 13 | % |
| Total | $81,173 | $93,833 | $(12,660) | (13 | %) |

The decrease in expense for large-scale manufacturing of BioThrax was primarily due to the timing of manufacturing development activities due to the licensure of the large-scale manufacturing facility in August 2016. The spending for BioThrax related programs was primarily related to the timing of clinical studies to support applications for label expansion for BioThrax. The decrease in expense for PreviThrax was primarily due to the timing of non-clinical studies, and in light of reduced funding by the U.S. government for this product candidate, we determined to cease further development work on our PreviThrax vaccine and expect the spending for PreviThrax will be minimal in the future. The increase in expense for NuThrax was primarily due to the timing of non-clinical animal studies and manufacturing activities. The decrease in spending for Pandemic influenza was primarily for a $5.0 million milestone payment to VaxInnate Corporation in the third quarter of 2015. The decrease in expense for our Anthrasil program was primarily due to the timing of plasma collection services. The decrease in expense for our BAT program was primarily related to stability testing and plasma collection. The decrease in expense for EV-035 series of molecules was primarily due to pharmacologic and formulation activities and a third quarter 2015 non-cash impairment charge of $9.8 million due to toxicity related issues, partially offset by a third quarter 2015 $6.7 million reduction of contingent consideration associated with the estimated timing and probability of achievement for certain development and regulatory milestones. The increase in expense for CIADM task orders awarded was primarily for manufacturing development of Ebola monoclonal antibodies. The increase in expense for VIGIV was primarily due to the timing of plasma collection partially offset by a reduction in 2015 of a liability to BARDA associated with 2013 manufacturing activities. The increase in expense for Emergard was primarily for formulation development. The increase in spending for our Other activities was primarily for manufacturing development activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $22.0 million, or 25%, to $108.3 million for the three months ended September 30, 2016 from $86.3 million for the nine months ended September 30, 2015. The increase includes costs associated with the Aptevo spin-off, restructuring activities at our Lansing, Michigan site, along with increased professional services to support our strategic growth initiatives, and increased information technology investments. In addition, during the third quarter of 2015 we recorded a $3.3 million reduction in contingent consideration related to the estimated timing and probability of potential future sales of EV-035.

Provision for Income Taxes

Provision for income taxes decreased by $3.7 million, or 16%, to $19.9 million for the nine months ended September 30, 2016 from $23.6 million for the nine months ended September 30, 2015. The decrease was primarily due to a $22.2 million decrease in income before provision for income taxes, partially offset by an increase in the effective tax rate related to one-time, non-cash charges to complete the Aptevo spin-off.

Liquidity and Capital Resources

Sources of Liquidity

From inception through September 30, 2016, we have funded our cash requirements principally with a combination of revenues from sales of BioThrax, debt financing, development funding from government entities, non-government

and philanthropic organizations, and collaborative partners, 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 five years ended December 31, 2015. As of September 30, 2016, we had cash and cash equivalents of $298.9 million.

At the closing of the spin-off of Aptevo from Emergent,we provided to Aptevo cash of $45 million from our cash reserves, along with a commitment in the form of a promissory note to provide another $20 million due within six to 12 months after the separation.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2016 and 2015:

| | Nine Months Ended September 30, | |
|---|---|---|
| (in thousands) | 2016 | 2015 |
| Net cash provided by (used in): | | |
| Operating activities(i) | $62,800 | $41,373 |
| Investing activities | (56,243) | (33,631) |
| Financing activities | (20,420) | 20,477 |
| Net increase in cash and cash equivalents | $(13,863) | $28,219 |

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

Net cash provided by operating activities of $62.8 million for the nine months ended September 30, 2016 was primarily due to our net income of $14.4 million, a $45.0 million decrease in accounts receivable related to the timing of collection of amounts billed primarily to the CDC along with non-cash charges of $28.2 million for depreciation and amortization and a $14.5 million increase in stock-based compensation expense, partially offset by an increase in inventories of $16.2 million, primarily due to the timing of deliveries of BioThrax to the CDC.

Net cash provided by operating activities of $41.4 million for the nine months ended September 30, 2015 was primarily due to our net income of $29.5 million and non-cash charges of $25.9 million for depreciation and amortization along with a $9.8 million impairment charge for EV-035, partially offset by an increase in inventories of $14.4 million primarily due to the timing of deliveries of BioThrax to the CDC and a $10.9 million decrease in contingent consideration to Evolva for regulatory, development and sales-based royalty contingencies.

Net cash used in investing activities of $56.2 million for the nine months ended September 30, 2016 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 $33.6 million for the nine months ended September 30, 2015 was due to infrastructure and equipment investments.

Net cash used in financing activities of $20.4 million for the nine months ended September 30, 2016 was primarily due to $15.0 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 that is partially offset by $45.0 million in cash provided to Aptevo on date of distribution, August 1, 2016.

Net cash provided by financing activities of $20.5 million for the nine months ended September 30, 2015 was primarily due to $15.9 million in proceeds from the issuance of common stock pursuant to employee equity plans, $8.0 million in excess tax benefits from the exercise of stock options and $2.0 million in proceeds from long-term

indebtedness, partially offset by $5.4 million in contingent obligation payments.

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 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 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.

Share Repurchase Program

On July 14, 2016, our board of directors authorized our management to repurchase, from time to time, up to an aggregate of $50 million of our common stock under a board-approved share repurchase program. The timing, amount, and price of any repurchases will be made pursuant to one or more 10b5-1 plans. The term of the board

authorization of the repurchase program is until December 31, 2017. The plan will permit shares to be repurchased when we might otherwise be precluded from doing so based upon insider trading laws. The repurchase program may be suspended or discontinued at any time. Any repurchased shares will be available for use in connection with our stock plans and for other corporate purposes. As of September 30, 2016, we have neither implemented a repurchase plan nor repurchased any shares under this program.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2016, 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

During 2016, we completed the implementation of an enterprise resource planning ("ERP") system. In connection with the implementation, we updated the processes that constitute our internal control over financial reporting, as necessary, to accommodate related changes to our business processes and accounting procedures.

Although the processes that constitute our internal control over financial reporting have been materially affected by the implementation of this system and will require testing for effectiveness as the implementation progresses, we do not believe that the implementation has had or will have a material adverse effect on our internal control over financial reporting.

Except as otherwise described above, there have been no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the nine months ended September 30, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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.

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, among other matters, 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 flow. 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 flow.

THE SPIN-OFF OF OUR BIOSCIENCES BUSINESS

We may not realize some or all of the anticipated benefits of the spin-off of Aptevo due to a number of factors.

On August 1, 2016, we completed the spin-off of Aptevo Therapeutics Inc. Aptevo is now an independent public company trading under the symbol "APVO" on the NASDAQ Global Select Market. We may not realize some or all of the anticipated strategic, financial or other benefits from the spin-off. We are now smaller, less diversified with a narrower business focus and may be more vulnerable to changing market conditions, which could materially and adversely affect our business, financial condition and results of operations. Further, the combined value of the common stock of the two publicly-traded companies may not be equal to or greater than what the value of our common stock would have been had the spin-off not occurred.

If our distribution on August 1, 2016 of all of the outstanding shares of Aptevo 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 is intended 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 transaction 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.

GOVERNMENT CONTRACTING RISKS

We currently derive the majority of our revenue from sales of BioThrax to our principal customer, the U.S. government. If we are unable to secure a new procurement contract for BioThrax on favorable terms, or the U.S. government's demand for and funding for procurement of BioThrax is substantially reduced, our business, financial condition, operating results and cash flow could be materially harmed.

We have derived and currently expect 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. We are currently party to a contract with the Centers for Disease Control and Prevention, or the CDC, for the supply of up to 44.75 million doses of BioThrax for placement into the Strategic National Stockpile, or the SNS, over a five-year period, which was scheduled to expire on September 30, 2016. On September 21, 2016, the CDC exercised an option to procure all remaining BioThrax doses, thereby committing to take delivery of the full 44.75 million doses and granted a no-cost extension to enable delivery of the remaining doses under this contract to be completed by November 30, 2016.

On June 21, 2016, the U.S. Department of Health and Human Services, or HHS, issued a Sole Source Notification indicating its intention to award Emergent a follow-on contract for the purchase of 29.4 million doses of BioThrax with a period of performance of five years. The solicitation does not state the number of doses expected to be procured per year, but represents a smaller annual procurement on average over the five-year period of the anticipated contract than under our current contract. As of the date hereof, we remain in active negotiations with respect to this anticipated contract. The terms of the anticipated contract, including the price per dose and the timing of deliveries, remain subject to contract negotiation, and there can be no assurance that we will reach agreement on the terms of a follow-on BioThrax procurement contract.

In addition, the procurement of doses of BioThrax by the CDC remains subject to the availability of funding. Our existing contract with the CDC for BioThrax does not, and any follow-on procurement contract for BioThrax will not, guarantee that funding for the procurement of doses will be made available. 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 could be materially harmed. The success of our business and our operating results for the foreseeable future are significantly dependent on the level of 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. If we are unable to secure a new contract for procurement of BioThrax on acceptable terms, or if the U.S. government's demand for and level of funding for procurement of BioThrax is reduced, our business, financial condition, operating results and cash flows could be materially harmed.

Our submission of NuThrax for Emergency Use Authorization 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.

On September 30, 2016, we entered into a contract with HHS, through the Biomedical Advanced Research and Development Authority, or BARDA, for the advanced development and delivery of NuThrax, our next generation anthrax vaccine candidate. The contract, valued at up to approximately $1.6 billion, consists of a five-year base period of performance valued at approximately $200 million to develop NuThrax for post-exposure prophylaxis of anthrax disease and to deliver to the SNS an initial two million doses, following receipt of Emergency Use Authorization, or EUA, pre-approval by the FDA. 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 in 2019. The contract also includes procurement options for the delivery of an additional 7.5 million to 50 million doses

of NuThrax to the SNS, valued from approximately $255 million to up to $1.4 billion, respectively, and options for an additional clinical study and post-marketing commitments valued at approximately $48 million, which if both were to be exercised in full, would increase the potential total contract value to up to approximately $1.6 billion.

We currently intend to submit an application in 2017 with the FDA for EUA pre-approval, so that NuThrax may be delivered 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 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.

Our principal customer for BioThrax, BAT, Anthrasil, VIGIV and RSDL products and our primary source of funds for the development of our NuThrax product candidate is the U.S. government. We anticipate that the U.S. government will also be a principal customer for other Biodefense products that we successfully acquire or develop. 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 supplied under our current procurement contract with the CDC as well as sales of BioThrax to be supplied under our expected follow-on procurement contract with the CDC and any future sales of NuThrax that may be supplied under our contract with BARDA for the development and delivery of NuThrax to the SNS are subject to the availability of funding, mostly from annual appropriations. These appropriations can be subject to political considerations and stringent budgetary constraints. For example, in April 2016, we were notified by BARDA that, after prioritization of its development funding, BARDA would not be exercising the clinical trial option for our PreviThrax rPA vaccine development program. As a consequence of this decision, we determined to cease further development work on our PreviThrax vaccine product candidate. 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 contract with BARDA we were awarded in September 2016 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 to develop NuThrax to deliver to the SNS an initial two million doses, following receipt of EUA pre-approval by the FDA, includes procurement options for the delivery of an additional 7.5 million to 50 million doses of NuThrax to the SNS, valued from approximately $255 million to up to $1.4 billion, respectively, and options for an additional clinical study and post-marketing commitments valued at $48 million, which if both were to be exercised in full, would increase the total contract value to up to $1.6 billion. If levels of government expenditures and authorizations for biodefense 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 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 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 possibility that we may be ineligible to respond to a request for proposal issued by the government;
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 would 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 the development of our Biodefense product candidates or for the procurement of our Biodefense products, 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.

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 the business of our Biodefense division 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 ITAR (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 was 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 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 contracts with HHS and the DoD for the procurement of our Biodefense products are fixed price contracts. We expect that our potential future contracts with the U.S. government for our Biodefense products also may 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 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, including our contract for procurement of BioThrax and our contract for the development and delivery of NuThrax, 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. Our CDC contract for the procurement of BioThrax and our contract with BARDA for the development and delivery of NuThrax to the SNS are, and our expected follow-on contract for the procurement of BioThrax and our future U.S. government procurement and development contracts are likely to be, terminable at the U.S. government's convenience with these potential consequences.

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.

COMMERCIALIZATION 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 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 from other companies and governments, universities and other non-profit research organizations. 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 biodefense products or product candidates competing with us for both U.S. government procurement and development resources. For example, in terms of additional procurement of anthrax countermeasures, HHS awarded an SNS procurement contract to GlaxoSmithKline plc for ABThrax™ (raxibacumab), an FDA-approved anthrax monoclonal antibody therapeutic, and recently awarded an SNS procurement contract to Elusys Therapeutics, Inc. for Anthim (obiltoxaximab), an FDA-approved anthrax monoclonal antibody therapeutic.

Any reduction in demand for our products as a result of a competing product could lead to reduced revenues, reduced margins, reduced levels of profitability and loss of market share for our products. These competitive pressures could adversely affect our business and operating results.

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

Competition for BioThrax, BAT, Anthrasil, and VIGIV or 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 pathway, 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 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 treat diseases caused by or to combat Chemical, Biological, Radiological, Nuclear and Explosives, or CBRNE, threats are subject to changing political and social environments. The political responses and social awareness of the risks of biowarfare and bioterrorism attacks on military personnel or civilians may vary over time. If the threat of terrorism were to decline, then the public perception of the risk of bioterrorism may be reduced. This perception, as well as political or social pressures, could delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, any of which could negatively affect our revenues.

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 Biodefense products and thereby limit the demand for our Biodefense products, which would adversely affect our revenues.

REGULATORY AND COMPLIANCE RISKS

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 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 sponsor to support a BLA with substantial evidence of the product'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 Biodefense product candidates, for example, is subject to a different regulatory approval pathway. Specifically, because humans are rarely exposed to anthrax toxins under natural conditions, and cannot be intentionally exposed, statistically significant efficacy for these product candidates cannot be demonstrated in humans. Instead, efficacy must be demonstrated, in part, by utilizing animal models instead of 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 Biodefense product 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, current good manufacturing practices, or 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 world 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 January 2015 and Health Canada in March 2015, and our Baltimore (Camden) facility was most recently inspected by Health Canada in October 2016 and the FDA in August 2015. Following each of these inspections, both the FDA and Health Canada have issued inspectional observations, some of which were significant, but all of which are being, or have been, addressed through corrective actions. If, in connection with any future inspection, the FDA or Health Canada find that we are not in substantial compliance with cGMP 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.

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 currently sell and intend to sell certain of our products outside the United States that are currently sold only in 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. 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.

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 outside the United States are found to be in violation of the FCPA or similar foreign laws, 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, which would harm our business, financial condition and operating results.

We have completed the transition to moving BioThrax manufacturing from our Building 12 manufacturing facility on our Lansing, Michigan campus to Building 55, our large-scale manufacturing facility on our Lansing, Michigan campus. Any interruption in manufacturing operations at Building 55 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 flow. 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 or the imposition of civil or criminal penalties.
- damage to or destruction of the facility; or
- product contamination or tampering.

Providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. The U.S. government has designated both our Lansing, Michigan and our Biodefense Baltimore facility 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 Building 55, which could impact our future revenues and materially harm our business, financial condition, operating results and cash flows.
On August 15, 2016, we received FDA approval for the manufacture of BioThrax in Building 55, our large-scale manufacturing facility on our Lansing, Michigan campus and have moved BioThrax manufacturing to Building 55, which significantly increases our BioThrax manufacturing capacity compared to the capacity of our Building 12 licensed facility. Although we recently secured FDA approval for the manufacture of BioThrax in Building 55 and have begun to utilize Building 55, we may not secure procurement contracts for BioThrax or other products or product candidates sufficient to utilize its full manufacturing capacity. For example, on June 21, 2016, HHS issued a Sole Source Notification indicating its intention to award Emergent a contract for the purchase of 29.4 million doses of BioThrax with a period of performance of five years. As of the date hereof, we remain in active negotiations with respect to this solicitation. Although the notification does not state the number of doses expected to be procured per year, the 29.4 million doses represents a smaller annual procurement on average over the five-year period of the anticipated contract than under our current contract. An inability to utilize the full manufacturing capacity of Building 55 could impact our future revenues and materially harm our business, financial condition, operating results and cash flows.

Our biologic products and product candidates are complex to manufacture and ship, which could cause us to experience delays in product manufacturing or development and resulting 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 may arise during manufacturing 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.

For example, FDA approval is required for the release of each lot of BioThrax. A "lot" is approximately 186,000 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 control lot and periodically produce and qualify a new control lot to replace the existing control lot. If we are not able to produce and qualify a new control 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 significantly impact our revenues, require us to utilize our cash balances to help fund our ongoing operations and otherwise harm 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 impact our revenues. 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.

If we are unable to obtain supplies for the manufacture of BioThrax or our other products and product candidates in sufficient quantities and at an acceptable cost, our ability to manufacture BioThrax or to develop and commercialize our other products and product candidates could be impaired, which could harm our revenues, lead to a termination of one or more of our contracts, lead to delays in clinical trials or otherwise 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 and the specialty plasma in our hyperimmune specialty plasma products. A disruption in the availability of such materials or services from these 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 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. 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 RISKS

Our business 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 efforts 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 Biodefense 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 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 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.

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 Biodefense product candidates, 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 Biodefense 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 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.

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 business 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. For example, in April 2016, we were notified by BARDA that, after prioritization of its development funding, BARDA would not be exercising the clinical trial option for our PreviThrax rPA vaccine program. As a consequence of this decision, we determined to cease further development work on our PreviThrax vaccine product candidate. As a result of changes in our strategy or in government development funding decisions, we may change or refocus our existing product development, commercialization and manufacturing activities. 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. 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 could be 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 and operating results 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 and operating results, 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 affect our business.

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 under 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 harm our business significantly.

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 may be subject to damages.

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 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. 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 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 future acquisitions with our existing businesses, or operate any acquired business profitably, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect the growth of our business.

FINANCIAL RISKS

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

As of September 30, 2016, our total consolidated indebtedness was $253 million, including $250 million of obligations under our senior convertible notes. 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, results of operations and financial condition.

We may require significant additional funding to grow our business, including 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 September 30, 2016, we had approximately $298.9 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 government entities for our development programs; 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 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.

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.

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 first and second quarters 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.

OTHER BUSINESS RISKS

Pending litigation and legal proceedings and the impact of any finding of liability or damages could adversely impact the company and its 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 results adverse to us.

For example, as more fully described under Part II, "ITEM 1 – LEGAL PROCEEDINGS," on July 19, 2016, 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 alleges, among other things, that we made 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.

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, possibly materially.

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 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, 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.

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 adversely affect our business, financial condition and operating results.

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

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

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

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

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his substantial beneficial ownership of our common stock. As of October 31, 2016, Mr. El-Hibri was the beneficial owner of approximately 14% of our outstanding common stock. As a result, Mr. El-Hibri could delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial influence over all corporate actions requiring board or stockholder approval, including 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;
limitations on the removal and appointment of the chairman of our Board of Directors;
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, Section 203 of the General Corporation Law of Delaware prohibits a 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 stockholder rights plan 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.

Under our stockholder rights plan, we issue to each of our stockholders one preferred stock purchase right for each outstanding share of our common stock. Each right, when exercisable, will entitle 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 is 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. The rights plan may have anti-takeover effects. The rights plan will cause substantial dilution to a person or group that attempts to acquire us on terms that our Board of Directors does not believe are in our best interests or those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

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

Our stock price has been, and is likely to continue to be, volatile. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this "Risk Factors" section, or for reasons unrelated to our operations, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as industry conditions and general financial, economic and political instability. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through October 31, 2016, 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 biodefense 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 and any future debt agreements that we enter into may limit our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 6 million shares of our common stock outstanding as of October 28, 2016, 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: November 8, 2016

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

Date: November 8, 2016

EXHIBIT INDEX

| Exhibit Number | Description |
|---|---|
| 2.1 | Contribution Agreement, dated July 29, 2016, by and among Emergent BioSolutions Inc., Aptevo Therapeutics Inc., Aptevo Research and Development LLC and Aptevo BioTherapeutics LLC (incorporated by reference to Exhibit 2.1 to the Company's Quarterly Report on Form 10-Q, filed on August 5, 2016). |
| 2.2 | Separation and Distribution Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc. (incorporated by reference to Exhibit 2.2 to the Company's Quarterly Report on Form 10-Q, filed on August 5, 2016). |
| 10.1 | Promissory Note, dated July 29, 2016, made by Emergent BioSolutions Inc. in favor of Aptevo Therapeutics Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed on August 5, 2016). |
| 10.2#†† | Award/Contract, effective September 30, 2016, from the BioMedical Advanced Research and Development Authority to Emergent Product Development Gaithersburg Inc. |
| 10.3#†† | Modification No. 16 to the Solicitation, Offer and Award, effective September 30, 2011, from the Centers for Disease Control and Prevention to Emergent Biodefense Operations Lansing LLC (the "CDC BioThrax Procurement Contract"), effective March 22, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention. |
| 10.4# | Modification No. 17 to the CDC BioThrax Procurement Contract, effective April 19, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention. |
| 10.5#†† | Modification No. 18 to the CDC BioThrax Procurement Contract, effective May 6, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention. |
| 10.6#†† | Modification No. 19 to the CDC BioThrax Procurement Contract, effective August 11, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention. |
| 10.7#†† | Modification No. 20 to the CDC BioThrax Procurement Contract, effective September 7, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention. |
| 10.8#†† | Modification No. 21 to the CDC BioThrax Procurement Contract, effective September 8, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention. |
| 10.9# | Modification No. 22 to the CDC BioThrax Procurement Contract, effective September 20, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention. |
| 12# | Ratio of Earnings to Fixed Charges. |
| 31.1# | Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a). |
| 31.2# | Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a). |
| 32.1# | Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2# | Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101. INS | XBRL Instance Document. |
| 101.SCH | XBRL Taxonomy Extension Schema Document. |
| 101.CAL | XBRL Taxonomy Calculation Linksbase Document. |
| 101.DEF | XBRL Taxonomy Definition Linksbase Document. |
| 101.LAB | XBRL Taxonomy Label Linksbase Document. |
| 101.PRE | XBRL Taxonomy Presentation Linksbase Document. |

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language):
(i) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2016 and 2015;

(ii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended September 30, 2016 and 2015;
(iii) Condensed Consolidated Balance Sheets at September 30, 2016 and December 31, 2015;
(iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015; and
(v) Notes to Consolidated Financial Statements.

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