Emergent BioSolutions Inc.
Form 10-Q
May 04, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2012

OR

o 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.) |
| 2273 Research Boulevard, Suite 400<br>Rockville, Maryland | 20850 |
| (Address of Principal Executive Offices) | (Zip Code) |

(301) 795-1800
(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. þ Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant 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). þ Yes o 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):

o Large accelerated filer þ Accelerated filer o Non-accelerated filer o 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). o Yes þ No

As of April 30, 2012, the registrant had 36,160,577 shares of common stock outstanding.

Emergent BioSolutions Inc.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q and the documents incorporated by reference herein contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. All statements, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” “wou expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our ability to perform under our contract with the U.S. government related to BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, including the timing of deliveries;
- our plans for future sales of BioThrax, including our ability to obtain funding for our existing procurement contract with the U.S. government;
- our plans to pursue label expansions and other improvements for BioThrax;
- our ability to perform under our development contract with the U.S. government for our product candidate PreviThraxTM (Recombinant Protective Antigen Anthrax Vaccine, Purified);
- our ability to perform under our contract with the U.S. government to develop and obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55, our large-scale vaccine manufacturing facility in Lansing, Michigan;
- our plans to expand our manufacturing facilities and capabilities;
- the rate and degree of market acceptance of our products and product candidates;
- the success of ongoing and planned development programs, preclinical studies and clinical trials of our product candidates and post-approval clinical utility of our products;
- our ability to identify and acquire or in-license products and product candidates that satisfy our selection criteria;
- our ability to successfully integrate and develop the products or product candidates, programs, operations and personnel of any entities or businesses that we acquire;
- the timing of and our ability to obtain and maintain regulatory approvals for our products and product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property portfolio; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this quarterly report, particularly in the “Risk Factors” section in Item 1A of this quarterly report on Form 10-Q, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this quarterly report, including the documents that we have incorporated by reference herein or filed as exhibits hereto, completely and with the understanding that our actual future results may be materially different from what we expect. We disclaim any obligation to update any 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)

| | March 31, 2012 | December 31, 2011 |
|---|---|---|
| ASSETS | (Unaudited) | |
| Current assets: | | |
| Cash and cash equivalents | $150,425 | $143,901 |
| Investments | - | 1,966 |
| Accounts receivable | 43,652 | 74,153 |
| Inventories | 17,319 | 14,661 |
| Deferred tax assets, net | 441 | 1,735 |
| Income tax receivable, net | 19,798 | 9,506 |
| Restricted cash | - | 220 |
| Prepaid expenses and other current assets | 7,907 | 8,276 |
| Total current assets | 239,542 | 254,418 |
| | | |
| Property, plant and equipment, net | 218,749 | 208,973 |
| In-process research and development | 41,800 | 51,400 |
| Goodwill | 5,502 | 5,502 |
| Assets held for sale | - | 11,765 |
| Deferred tax assets, net | 8,349 | 13,999 |
| Other assets | 745 | 807 |
| | | |
| Total assets | $514,687 | $546,864 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $28,316 | $40,530 |
| Accrued expenses and other current liabilities | 1,134 | 1,170 |
| Accrued compensation | 9,982 | 20,884 |
| Contingent value rights, current portion | - | 1,748 |
| Long-term indebtedness, current portion | 3,280 | 5,360 |
| Deferred revenue | 283 | 1,362 |
| Total current liabilities | 42,995 | 71,054 |
| | | |
| Contingent value rights, net of current portion | - | 3,005 |
| Long-term indebtedness, net of current portion | 57,592 | 54,094 |
| Other liabilities | 2,005 | 1,984 |
| Total liabilities | 102,592 | 130,137 |
| | | |
| Commitments and contingencies | | |

| | | |
|---|---|---|
| Stockholders’ equity: | | |
| Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively | - | - |
| Common stock, $0.001 par value; 100,000,000 shares authorized, 36,160,162 and 36,002,698 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively | 36 | 36 |
| Additional paid-in capital | 222,746 | 220,654 |
| Accumulated other comprehensive loss | (3,229) | (3,313) |
| Retained earnings | 190,041 | 196,869 |
| Total Emergent BioSolutions Inc. stockholders' equity | 409,594 | 414,246 |
| Noncontrolling interest in subsidiaries | 2,501 | 2,481 |
| Total stockholders’ equity | 412,095 | 416,727 |
| Total liabilities and stockholders’ equity | $514,687 | $546,864 |

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 March 31, | |
|---|---|---|
| | 2012 | 2011 |
| | (Unaudited) | |
| Revenues: | | |
| Product sales | $34,357 | $5,597 |
| Contracts and grants | 15,954 | 12,936 |
| Total revenues | 50,311 | 18,533 |
| | | |
| Operating expense: | | |
| Cost of product sales | 7,511 | 1,068 |
| Research and development | 26,246 | 34,759 |
| Selling, general and administrative | 19,492 | 18,212 |
| Impairment of in-process research and development | 9,600 | - |
| Loss from operations | (12,538) | (35,506) |
| | | |
| Other income (expense): | | |
| Interest income | 25 | 35 |
| Interest expense | (3) | - |
| Other income (expense), net | 854 | (1) |
| Total other income (expense) | 876 | 34 |
| | | |
| Loss before benefit from income taxes | (11,662) | (35,472) |
| Benefit from income taxes | (3,640) | (12,299) |
| Net loss | (8,022) | (23,173) |
| Net loss attributable to noncontrolling interest | 1,193 | 1,776 |
| Net loss attributable to Emergent BioSolutions Inc. | $(6,829) | $(21,397) |
| | | |
| Loss per share - basic | $(0.19) | $(0.61) |
| Loss per share - diluted | $(0.19) | $(0.61) |
| | | |
| Weighted-average number of shares - basic | 36,045,839 | 35,179,317 |
| Weighted-average number of shares - diluted | 36,045,839 | 35,179,317 |

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 March 31, | |
|---|---|---|
| | 2012 | 2011 |
| | (Unaudited) | |
| Net loss attributable to Emergent BioSolutions Inc. | (6,829) | (21,397) |
| Foreign currency translations | 84 | (693) |
| Comprehensive loss | $(6,745) | $(22,090) |

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

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2012 | 2011 |
| Cash flows from operating activities: | (Unaudited) | |
| Net loss | $(8,022) | $(23,173) |
| Adjustments to reconcile to net cash provided by (used in) operating activities: | | |
| Stock-based compensation expense | 2,712 | 2,441 |
| Depreciation and amortization | 2,373 | 2,235 |
| Deferred income taxes | 6,944 | 2,879 |
| Non-cash development expenses from joint ventures | 1,212 | 2,550 |
| Change in fair value of contingent value rights | (3,005) | 581 |
| Impairment of in-process research and development | 9,600 | - |
| Excess tax benefits from stock-based compensation | 862 | (39) |
| Other | (19) | 13 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 30,501 | 27,350 |
| Inventories | (2,658) | (9,441) |
| Income taxes | (11,154) | (15,238) |
| Prepaid expenses and other assets | 443 | 923 |
| Accounts payable | (1,988) | (736) |
| Accrued expenses and other liabilities | (11) | (33) |
| Accrued compensation | (10,895) | (10,525) |
| Deferred revenue | (1,075) | (2,510) |
| Net cash provided by (used in) operating activities | 15,820 | (22,723) |
| Cash flows from investing activities: | | |
| Purchases of property, plant and equipment | (22,329) | (8,432) |
| Proceeds from sale of assets | 11,765 | - |
| Proceeds from maturity of investments | 1,966 | - |
| Purchase of investments | - | (4,309) |
| Net cash used in investing activities | (8,598) | (12,741) |
| Cash flows from financing activities: | | |
| Proceeds from borrowings on long-term indebtedness | 9,621 | - |
| Issuance of common stock subject to exercise of stock options | 242 | 4,198 |
| Excess tax benefits from stock-based compensation | (862) | 39 |
| Principal payments on long-term indebtedness | (8,203) | (842) |
| Contingent value right payment | (1,748) | - |
| Release of restricted cash deposit | 220 | - |
| Net cash provided by (used in) financing activities | (730) | 3,395 |
| Effect of exchange rate changes on cash and cash equivalents | 32 | (25) |
| Net increase (decrease) in cash and cash equivalents | 6,524 | (32,094) |
| Cash and cash equivalents at beginning of period | 143,901 | 169,019 |

| | | |
|---|---|---|
| Cash and cash equivalents at end of period | $150,425 | $136,925 |

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

EMERGENT BIOSOLUTIONS INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Basis of presentation and consolidation

The accompanying unaudited consolidated financial statements include the accounts of Emergent BioSolutions Inc. (the "Company" or "Emergent") and its wholly-owned and majority-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

The unaudited consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X issued by the Securities and Exchange Commission. 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, 2011, as filed with the Securities and Exchange Commission.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of March 31, 2012 and the results of operations, comprehensive loss and cash flows for the three months ended March 31, 2012 and 2011. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

In June 2011, the Financial Accounting Standard Board ("FASB") issued guidance amending the presentation requirements for comprehensive income. For public entities, this guidance was effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 with early adoption permitted. Subsequently, in December 2011, the FASB deferred the effective date of the portion of the June 2011 accounting standards update requiring separate presentation of reclassifications out of accumulated other comprehensive income. Upon adoption on January 1, 2012, the Company had the option to report total comprehensive income (loss), including components of net income (loss) and components of other comprehensive income (loss), as a single continuous statement or in two separate but consecutive statements. The Company elected to present comprehensive income in two separate but consecutive statements as part of the consolidated financial statements included in this Quarterly Report on Form 10-Q.

2. 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:

| | At March 31, 2012 | | | |
|---|---|---|---|---|
| (in thousands) | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Investment in money market funds (1) | $50,861 | $- | $- | $50,861 |
| Total assets | $50,861 | $- | $- | $50,861 |
| | | | | |
| Liabilities: | | | | |

| | | | | |
|---|---|---|---|---|
| Contingent value rights | $- | $- | $- | $- |
| Total liabilities | $- | $- | $- | $- |

| | At December 31, 2011 | | | |
|---|---|---|---|---|
| (in thousands) | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Investment in money market funds (1) | $73,005 | $- | $- | $73,005 |
| U.S. Treasury securities (2) | - | 1,966 | - | 1,966 |
| Total assets | $73,005 | $1,966 | $- | $74,971 |
| | | | | |
| Liabilities: | | | | |
| Contingent value rights | $- | $- | $4,753 | $4,753 |
| Total liabilities | $- | $- | $4,753 | $4,753 |

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

The fair value of the contingent value right ("CVR") obligations is based on management's assessment of certain development and collaboration milestones, which are inputs that have no observable market (Level 3). The obligation is measured using a discounted cash flow model. For the three months ended March 31, 2012 and 2011, the changes in the fair value of the CVR obligations resulted from an update to the probability and estimated timing of achievement for certain development milestones along with an adjustment to the discount rates. During the three months ended March 31, 2012, the Company recorded a decrease of $3.0 million in the value of the CVRs related to the Pfizer, Inc. ("Pfizer") agreement, and made a CVR payment in the amount of $1.7 million related to the Company's collaboration with Abbott Laboratories ("Abbott"), which was terminated on March 20, 2012. During the three months ended March 31, 2011, the Company recorded a charge to adjust the CVRs to fair value of $581,000. The adjustments to fair value are classified in the Company's statement of operations as research and development expense within the Company's Biosciences segment.

As of March 31, 2012 and 2011, the Company did not have any transfers between Level 1 and Level 2 assets or liabilities.

The following table is a reconciliation of the beginning and ending balance of the liabilities measured at fair value using significant unobservable inputs (Level 3) during the three months ended March 31, 2012 and the year ended December 31, 2011:

| (in thousands) | |
|---|---|
| Balance at January 1, 2011 | $14,532 |
| Expense (income) included in earnings | 221 |
| Expense (income) included in comprehensive income | - |
| Settlements | (10,000) |
| Purchases, sales, issuances and settlements | - |
| Transfers in/(out) of Level 3 | - |
| Balance at December 31, 2011 | $4,753 |
| Expense (income) included in earnings | (3,005) |
| Expense (income) included in comprehensive income | - |
| Settlements | (1,748) |
| Purchases, sales and issuances | - |
| Transfers in/(out) of Level 3 | - |
| Balance at March 31, 2012 | $- |

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. As of March 31, 2012, the Company's SBI-087 in-process research and development ("IPR&D") asset and goodwill were measured at fair value on a nonrecurring basis. As of March 31, 2011 the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis.

Both the carrying value and fair value of long-term indebtedness at March 31, 2012 and December 31, 2011 were $60.9 million and $59.5 million, respectively.

3. Inventories

Inventories consist of the following:

| (in thousands) | March 31, 2012 | December 31, 2011 |
|---|---|---|
| Raw materials and supplies | $2,485 | $ 2,313 |
| Work-in-process | 14,714 | 10,149 |
| Finished goods | 120 | 2,199 |
| Total inventories | $17,319 | $ 14,661 |

4. In-process research and development and goodwill

In mid-March 2012, Pfizer informed the Company of its intent to cease development of one of its two development programs with respect to an SBI-087 product candidate. In April 2012, Pfizer informed the Company of its intent to cease development of the second program, and that it intended to terminate its development and commercialization agreement with the Company. The Company considered this initial communication a potential indicator of an impairment of the related SBI-087 IPR&D asset. As a result of these communications, the Company has assessed the fair value of this asset. As part of this assessment, the Company considered the impact of Pfizer's decision, along with the Company's current intentions not to pursue further development of this asset. As a result of this impairment analysis, the Company recorded an impairment charge of $9.6 million, which represents the entire carrying value of the SBI-087 IPR&D asset as of March 31, 2012. This charge is classified in the Company's statement of operations as impairment of in-process research and development, within the Company's Biosciences segment.

The Company determined the fair value of the SBI-087 IPR&D asset by utilizing an income approach. The Company's cash flow projections include management's estimates related to the costs to develop the acquired technology into commercially viable products, the resulting revenue from the projects, and discounting the net cash flows to present value. The revenue and costs projections were adjusted to reflect the probability of successful new drug development. Additionally, the projections considered the relevant market sizes and growth factors, expected trends in technology, and the nature and expected timing of new product introductions. The rates utilized to discount the net cash flows to their present value were commensurate with the stage of development of the SBI-087 product candidate and uncertainties in the economic estimates used in the projections described above.

As a result of the impairment of the SBI-087 IPR&D asset, the Company also performed an interim impairment analysis of goodwill as of March 31, 2012. Based on the interim impairment assessment, the estimated fair value of the reporting unit was in excess of carrying value, and therefore no impairment of goodwill was recorded.

5. Assets held for sale

In March 2012, the Company completed the sale of two buildings in Frederick, Maryland for $12.2 million. These buildings had been classified as assets held for sale. The Company realized proceeds equal to the carrying value, less cost to sell, of these buildings and there was no gain or loss on the sale.

6. Long-term debt

The components of long-term indebtedness are as follows:

| (in thousands) | March 31, 2012 | December 31, 2011 |
|---|---|---|
| Construction loan dated July 2011; LIBOR plus 3%, due July 2017 | $30,000 | $26,095 |
| Equipment loan dated August 2011; variable, due August 2017 | 7,143 | 1,426 |
| Term loan dated December 2009; three month LIBOR plus 3.25%, due December 2014 | 19,338 | 19,717 |
| Term loan dated November 2009; three month LIBOR plus 3.25%, due November 2014 | 4,391 | 4,478 |
| Loan dated October 2004; 3.0%, repaid in March 2012 | - | 2,500 |
| Term loan dated October 2004; 3.48%, repaid in March 2012 | - | 5,238 |
| Total long-term indebtedness | 60,872 | 59,454 |
| Less current portion of long-term indebtedness | (3,280) | (5,360) |
| Noncurrent portion of long-term indebtedness | $57,592 | $54,094 |

7. Stockholders' equity

Preferred stock

The Company is authorized to issue up to 15,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock"). Any Preferred Stock issued may have dividend rates, voting rights, conversion privileges, redemption characteristics, and sinking fund requirements as approved by the Company's board of directors.

Common stock

The Company currently has one class of $0.001 par value per share common stock ("Common Stock") authorized and outstanding. The Company is authorized to issue up to 100,000,000 shares of the Common Stock. Holders of Common Stock are entitled to one vote for each share of Common Stock held on all matters as may be provided by law.

Stock options and restricted stock units

As of March 31, 2012, the Company had two stock-based employee compensation plans, the Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan") and the Emergent BioSolutions Employee Stock Option Plan (the "2004 Plan") (together, the "Emergent Plans"). The Company has granted options to purchase shares of common stock under the Emergent Plans and has granted restricted stock units under the 2006 Plan. The Emergent Plans have both incentive and non-qualified stock option features. The Company no longer grants equity awards under the 2004 Plan.

As of March 31, 2012, an aggregate of 8,678,826 shares of common stock were authorized for issuance under the 2006 Plan, of which a total of 1,239,071 shares of common stock remain available for future awards to be made to plan participants. Awards of restricted stock units are counted against the maximum aggregate number of shares of common stock available for issuance under the 2006 Plan as one and one-half (1.5) shares of common stock for every one restricted stock unit granted. The maximum number of shares subject to awards that may be granted per year under the 2006 Plan to a single participant is 287,700. The exercise price of each option must be not less than 100% of the fair market value of the shares underlying such option on the date of grant. Awards granted under the 2006 Plan have a contractual life of no more than 10 years. The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Emergent Plans are determined by the compensation committee of the

Company's board of directors, which administers the Emergent Plans. Each equity award granted under the Emergent Plans vests as specified in the relevant agreement and no option can be exercised after ten years from the date of grant.

The following is a summary of option award activity under the Emergent Plans:

| | 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, 2011 | 3,090,909 | $ 17.36 | 53,156 | $ 8.86 | $6,238,427 |
| Granted | 675,581 | 15.83 | - | - | |
| Exercised | (20,739) | 11.68 | - | - | |
| Forfeited | (57,001) | 20.20 | - | - | |
| Outstanding at March 31, 2012 | 3,688,750 | $ 17.07 | 53,156 | $ 8.86 | $5,152,087 |
| Exercisable at March 31, 2012 | 2,157,105 | $ 16.05 | 53,156 | $ 8.86 | $4,858,991 |

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

| | Number of Shares | Weighted-Average Grant Price | Aggregate Intrinsic Value |
|---|---|---|---|
| Outstanding at December 31, 2011 | 635,500 | $ 20.89 | $10,701,820 |
| Granted | 337,797 | 15.83 | |
| Vested | (205,016) | 20.30 | |
| Forfeited | (18,829) | 16.21 | |
| Outstanding at March 31, 2012 | 749,452 | $ 18.79 | $11,991,232 |

8. Variable interest entities

In July 2008, the Company entered into a collaboration with the University of Oxford ("Oxford") and certain Oxford researchers to conduct clinical trials to advance a vaccine product candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium ("OETC"). The Company has a 51% equity interest in OETC and controls the OETC Board of Directors. In addition, the Company has certain funding and service obligations related to its investment. In July 2011, the Company entered into an intercompany loan agreement with OETC, under which the Company agreed to provide OETC with a loan of up to $14.0 million to fund future clinical and development costs for the tuberculosis vaccine product candidate. The loan value can be increased to up to $23.0 million at the sole discretion of the Company. The loan bears interest at the rate of 8% per annum. Principal and interest on the outstanding balance will be due and payable in December 2014 or upon occurrence of either an event of default or the closing of a debt or equity financing by OETC that results in net proceeds equal to or in excess of $30.0 million in a single transaction or a series of related transactions. Under the terms of the loan, OETC is required to comply with certain non-financial covenants. As of March 31, 2012, there have been no draws under this loan. The Company evaluates its variable interests in OETC on a quarterly basis and has determined that it is the primary beneficiary as it has the power to direct the activities of OETC that most significantly impact OETC's economic performance and will absorb the majority of expected losses. Accordingly, the Company consolidates OETC. As of March 31, 2012 and 2011, respectively, assets of $506,000 and $413,000 and liabilities of $1.8 million and $513,000 related to OETC were included within the Company's consolidated balance sheet. During the three months ended March 31, 2012 and 2011, respectively, OETC incurred net losses of $2.4 million and $3.6 million of which $1.2 million and $1.8 million is included in the Company's consolidated statement of operations.

In conjunction with the establishment of OETC, the Company granted a put option to Oxford and certain Oxford researchers whereby the Company may be required to acquire all of the OETC shares held by Oxford and the Oxford

researchers at the fair market value of the underlying shares. This put option is contingent upon the satisfaction of a number of conditions that must exist or occur subsequent to the granting by the European Commission of marketing authorization for the OETC-sponsored vaccine product candidate for tuberculosis. The Company accounts for the put option in accordance with the accounting provisions related to derivatives and distinguishing liabilities from equity. In accordance with these provisions, the Company has determined that the put option had a de minimis fair value as of March 31, 2012.

In July 2010, the Company entered into a collaboration with Temasek Life Sciences Ventures Pte Limited to advance the development of monoclonal products for worldwide prophylaxis or treatment of infection caused by existing or anticipated future pandemic influenza strains via a hemagglutinin-based medical countermeasure, resulting in the formation of EPIC Bio Pte Limited ("EPIC"). The Company has a 60% equity interest in EPIC and controls the EPIC Board of Directors. The Company evaluates its variable interests in EPIC on a quarterly basis and has determined that it is the primary beneficiary as it has the power to direct the activities of EPIC that most significantly impact EPIC's economic performance and will absorb the majority of expected losses. Accordingly, the Company consolidates EPIC. As of March 31, 2012 and 2011, respectively, assets of $546,000 and $1.9 million and liabilities of $214,000 and $423,000 related to EPIC were included within the Company's consolidated balance sheet. During the three months ended March 31, 2012 and 2011, respectively, EPIC incurred net losses of $99,000 and $24,000, of which $59,000 and $14,000 is included in the Company's consolidated statement of operations.

The following is a summary of the stockholders' equity attributable to the Company and the noncontrolling interests:

| (in thousands) | Emergent BioSolutions Inc. | Noncontrolling Interests | Total |
|---|---|---|---|
| Stockholders' equity at December 31, 2011 | $ 414,246 | $ 2,482 | $416,728 |
| Non-cash development expenses from variable interest entities | - | 1,212 | 1,212 |
| Net loss | (6,829) | (1,193) | (8,022) |
| Other | 2,177 | - | 2,177 |
| Stockholders' equity at March 31, 2012 | $ 409,594 | $ 2,501 | $412,095 |

9. Collaboration Agreements

Abbott Laboratories

In August 2009, Trubion Pharmaceuticals, Inc. ("Trubion"), which the Company acquired in October 2010, entered into a collaboration agreement with Facet Biotech Corporation, now a wholly-owned subsidiary of Abbott, for the joint worldwide development and commercialization of TRU-016. The collaboration agreement covered TRU-016 in all indications and all other CD37-directed protein therapeutics. The collaboration agreement terminated on March 20, 2012 and all rights to TRU-016 and other CD37-directed protein therapeutics under the collaboration agreement reverted to the Company.

During the three months ended March 31, 2012 and 2011, the Company recognized revenue of $1.3 million and $2.5 million, respectively, for research and development services pursuant to the Abbott collaboration in the Company's statements of operations as contracts and grants revenue.

Pfizer Inc.

In December 2005, Trubion entered into an agreement (the "Pfizer Agreement") with Wyeth, now a wholly-owned subsidiary of Pfizer, for the development and worldwide commercialization of CD20-directed therapeutics. In May 2011, the Company and Pfizer entered into a third amendment to the Pfizer Agreement (the "Biosimilar Amendment") in which the Company released certain restrictions related to the development and commercialization of biosimilar

CD20 antibodies. Under the terms of this amendment, the Company received a $2.5 million non-refundable payment upon execution of the Biosimilar Amendment, and is entitled to receive royalty payments in the low-single digits on net sales of certain Pfizer biosimilar products directed to CD20, subject to the satisfaction of specified conditions. In April 2012, Pfizer informed the Company of its intent to terminate the Pfizer Agreement. The Company's right to receive these biosimilar royalty payments would survive a termination of the Pfizer Agreement.

For the three months ended March 31, 2012 and 2011, the Company recognized revenue of $365,000 and $551,000, respectively, for research and development services pursuant to the Pfizer Agreement in the Company's financial statements of operations as contracts and grants revenue.

10. Earnings per share

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

| | Three Months Ended March 31, | |
|---|---|---|
| (in thousands, except share and per share data) | 2012 | 2011 |
| Numerator: | | |
| Net loss | $(6,829) | $(21,397) |
| | | |
| Denominator: | | |
| Weighted-average number of shares—basic | 36,045,839 | 35,179,317 |
| Dilutive securities—equity awards | - | - |
| Weighted-average number of shares—diluted | 36,045,839 | 35,179,317 |
| | | |
| Earnings per share-basic | $(0.19) | $(0.61) |
| Earnings per share-diluted | $(0.19) | $(0.61) |

For the three month periods ended March 31, 2012 and 2011, approximately 4.5 million and 4.4 million shares, respectively, pursuant to equity awards were excluded from the calculation of diluted earnings per share because the net loss attributable to Emergent BioSolutions Inc. would make these awards antidilutive.

11. Segment information

For financial reporting purposes, the Company reports financial information for two business segments: Biodefense and Biosciences. The Company's two business segments, or divisions, engage in business activities for which discrete financial information is reviewed by the chief operating decision maker. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies. The Company's reportable segments are business units that offer different products and product candidates and are managed separately because they manufacture and develop distinct products with different development processes.

In the Biodefense division, the Company develops, manufactures and commercializes vaccines and antibody therapies for use against biological agents that are potential weapons of bioterrorism or biowarfare. Revenues in this segment are primarily from sales of the Company's FDA-licensed product, BioThrax® (Anthrax Vaccine Adsorbed), to the U.S. government. The Biosciences division consists of two business units, therapeutics and vaccines. In the Biosciences division, the Company develops vaccines, protein therapeutics and technology platforms for use against infectious diseases, oncology, autoimmune and inflammatory disorders and other medical conditions that have resulted in significant unmet or underserved public health needs. The Biosciences segment comprises development stage product candidates. The "All Other" segment relates to the general operating costs of the Company and includes costs of the centralized services departments, which are not allocated to the other segments, as well as spending on product candidates or activities that are not classified as Biodefense or Biosciences. The assets in this segment consist

primarily of cash.

| | Reportable Segments | | | |
|---|---|---|---|---|
| (in thousands) | Biodefense | Biosciences | All Other | Total |
| Three Months Ended March 31, 2012 | | | | |
| External revenue | $48,636 | $1,675 | $- | $50,311 |
| Net income (loss) | 14,266 | (19,891) | (1,204) | (6,829) |
| Total assets | 247,240 | 123,292 | 144,155 | 514,687 |
| Three Months Ended March 31, 2011 | | | | |
| External revenue | $15,500 | $3,033 | $- | $18,533 |
| Net loss | (6,092) | (15,125) | (180) | (21,397) |
| Total assets | 179,732 | 107,927 | 183,618 | 471,277 |

## 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, include forward-looking statements that involve risks and uncertainties. You should review the "Special Note Regarding Forward-Looking Statements" and the "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

We are a biopharmaceutical company focused on protecting and enhancing life by developing and manufacturing vaccines and therapeutics that are supplied to healthcare providers and purchasers for use in preventing and treating disease. For financial reporting purposes, we operate in two business segments, Biodefense and Biosciences.

Our Biodefense segment is directed to government-sponsored development and supply of countermeasures against potential agents of bioterrorism or biowarfare and targets the infectious disease anthrax. Our programs in this division include a pipeline of investigational product candidates and one marketed product, BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax disease. Operations in this segment include biologics manufacturing, regulatory and quality affairs in support of BioThrax and a product development infrastructure in support of our investigational product candidates.

Our Biosciences segment is directed to commercial opportunities and targets oncology, including the B-cell malignancies chronic lymphocytic leukemia, or CLL, and non-Hodgkin's lymphoma, or NHL; the T-cell malignancies cutaneous T-cell lymphoma, or CTCL, and peripheral T-cell lymphoma, or PTCL; autoimmune and inflammatory disorders, or AIID, and infectious diseases such as tuberculosis and influenza. Our programs in this segment include clinical and preclinical stage investigational product candidates and development programs for our platform technologies. Operations in this segment include product development in support of our investigational product candidates, and manufacturing and related infrastructure initiatives in support of our technology platforms.

Our Biodefense segment has generated net income for each of the last five fiscal years. Over this timeframe, our Biosciences segment has generated revenue through development contracts and collaborative funding, but none of our

Biosciences product candidates have received marketing approval and, therefore, our Biosciences segment has not generated any product sales revenues. As a result, our Biosciences segment has incurred a net loss for each of the last five fiscal years.

Product Sales

We have derived substantially all of our product sales revenues from BioThrax sales to the U.S. government. We are currently a party to a contract with the Centers for Disease Control and Prevention, or CDC, to supply 44.75 million doses of BioThrax for placement into the Strategic National Stockpile, or SNS, over a five year period. We expect for the foreseeable future to continue to derive substantially all of our product sales revenues from our sales of BioThrax to the U.S. government. Our total revenues from BioThrax sales were $34.4 million and $5.6 million for the three months ended March 31, 2012 and 2011, respectively. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers domestically and internationally and pursuing label expansions and improvements for BioThrax.

Contracts and Grants

We seek to advance development of our product candidates through external funding arrangements. We may slow down development programs or place them on hold during periods that are not covered by external funding. We have received funding from the U.S. government for the following development programs:

- BioThrax as a post-exposure prophylaxis, or PEP;
- NuThrax TM (Anthrax Vaccine Adsorbed containing CPG 7909 Adjuvant);
- Large-scale manufacturing for BioThrax;
- PreviThrax TM (Recombinant Protective Antigen Anthrax Vaccine, Purified);
- Thravixa TM (Fully Human Anthrax Monoclonal Antibody);
- Double mutant recombinant protective antigen anthrax vaccine;
- Recombinant botulinum vaccine; and
- Tuberculosis vaccine

Additionally, our tuberculosis vaccine product candidate is indirectly supported by grant funding provided to the University of Oxford by the Wellcome Trust and Aeras Global Tuberculosis Vaccine Foundation and the European and Developing Countries Clinical Trial Partnership.

We continue to actively pursue additional government sponsored development contracts and grants and commercial collaborative relationships. We also encourage both governmental and non-governmental agencies and philanthropic organizations to provide development funding or to conduct clinical studies of our product candidates.

Manufacturing Infrastructure

We conduct our primary vaccine manufacturing operations at a multi-building campus on approximately 12.5 acres in Lansing, Michigan. To augment our existing manufacturing capabilities, we have constructed Building 55, a 50,000 square foot large-scale manufacturing facility on our Lansing campus. In July 2010, we entered into an agreement with the Biomedical Advanced Research and Development Authority, or BARDA, to finalize development of and obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55. This agreement provides for funding from BARDA of up to approximately $107 million over a five-year contract term, including a two-year base period of performance valued at approximately $55 million.

In November 2009, we purchased a building in Baltimore, Maryland for product development and manufacturing purposes, and are in the process of completing renovation, improvement and equipment acquisitions at this facility. We have entered into two loan agreements with PNC Bank totaling up to $42.0 million to fund these renovations,

improvements and equipment acquisitions. Our specific plans for this facility will be contingent on the progress of our existing development programs and the outcome of our efforts to acquire new product candidates.

Critical Accounting Policies and Estimates

There have been no significant changes to our Critical Accounting Policies and Estimates during the three months ended March 31, 2012. Refer to the Critical Accounting Policies and Estimates section in our Annual Report on Form 10-K for the year ended December 31, 2011 filed with the Securities and Exchange Commission, or SEC.

Financial Operations Overview

Revenues

On September 30, 2011, we received a contract award from the CDC, and on March 8, 2012, entered into the related contract with the CDC to supply up to 44.75 million doses of BioThrax to the CDC over a five-year period. The maximum amount that could be paid to us under the contract is up to $1.25 billion, subject to availability of funding. The period of performance under the award is from September 30, 2011 through September 29, 2016. We began delivery of doses under the contract in December 2011. Through March 31, 2012, we have delivered and recognized revenue on approximately 2.0 million doses under this contract.

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

| Development Programs | Funding Source | Award Date | Performance Period |
|---|---|---|---|
| Recombinant botulinum vaccine | NIAID | 6/2008 | 6/2008 — 5/2012 |
| NuThrax | NIAID | 7/2008 | 7/2008 — 6/2013 |
| Thravixa | NIAID/BARDA | 9/2008 | 9/2008 — 8/2012 |
| NuThrax | NIAID/BARDA | 9/2008 | 9/2008 — 7/2012 |
| Double mutant recombinant protective antigen anthrax vaccine | NIAID | 9/2009 | 9/2009 — 8/2012 |
| Large-scale manufacturing for BioThrax | BARDA | 7/2010 | 7/2010 — 7/2015 |
| NuThrax | NIAID | 7/2010 | 8/2010 — 8/2014 |
| PreviThrax | BARDA | 9/2010 | 9/2010 — 9/2015 |
| Tuberculosis vaccine | NIAID | 3/2012 | 3/2012 — 2/2017 |

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 delivery of doses of BioThrax to our customers and work done under new and existing contracts and grants, including collaborative relationships.

Cost of Product Sales

The primary expense that we incur to deliver BioThrax to our customers is manufacturing cost, which consists primarily of fixed costs. These fixed manufacturing costs consist of facilities, utilities and personnel-related expenses for indirect manufacturing support staff. Variable manufacturing costs for BioThrax consist primarily of costs for materials, direct labor and contract filling operations.

We determine the cost of product sales for doses sold during a reporting period based on the average manufacturing cost per dose in the period those doses were manufactured. We calculate the average manufacturing cost per dose in the period of manufacture by dividing the actual costs of manufacturing in such period by the number of units produced in that period. In addition to the fixed and variable manufacturing costs described above, the average

manufacturing cost per dose depends on the efficiency of the manufacturing process, utilization of available manufacturing capacity and the production yield for the period of production.

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, preclinical and analytical testing, independent monitoring or other administration of our clinical trials and acquiring and evaluating data from our clinical trials and non-clinical studies;
- costs of contract manufacturing services for clinical trial material;
- costs of materials used in clinical trials and research and development;
- depreciation of capital assets used to develop our products; and
- operating costs, such as the operating costs of facilities and the legal costs of pursuing patent protection of our intellectual property.

We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to be in a position to realize the potential of our product candidates. We expect that spending for our product pipeline will increase as our product development activities continue based on ongoing advancement of our product candidates, and as we prepare for regulatory submissions and other regulatory activities. We expect that the magnitude of any increase in our research and development spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, participation of current or potential future third-party collaborators, number of product candidates under development, the size, structure and duration of any follow-on clinical programs that we may initiate, 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 salaries and other related costs for personnel serving the executive, sales and marketing, business development, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales or research and development expense and professional fees for legal and accounting services. We currently market and sell BioThrax directly to the U.S. government with a small, targeted marketing and sales group. As we seek to broaden the market for BioThrax, and if we receive marketing approval for additional products, we expect that we will increase our spending for marketing and sales activities.

In-process Research and Development and Goodwill

In mid-March 2012, Pfizer Inc., or Pfizer, informed us of its intent to cease development of one of its two development programs with respect to an SBI-087 product candidate. In April 2012, Pfizer informed us of its intent to cease development of the second program, and that it intended to terminate its development and commercialization agreement with us. We considered these communications a potential indicator of impairment of the related SBI-087 IPR&D asset, and as a result we have assessed the fair value of this asset. As part of this assessment, we considered the impact of Pfizer's decision, along with our current intentions not to pursue further development of this asset. As a result of this impairment analysis, we recorded an impairment charge of $9.6 million, which represents the entire carrying value of the SBI-087 IPR&D asset as of March 31, 2012.

As a result of the impairment of the SBI-087 IPR&D asset, we also performed an interim impairment analysis of goodwill as of March 31, 2012. Based on the interim impairment assessment, the estimated fair value of the reporting

unit was in excess of carrying value, and therefore no impairment of goodwill was recorded.

Results of Operations

Quarter Ended March 31, 2012 Compared to Quarter Ended March 31, 2011

Revenues

Product sales revenues increased by $28.8 million to $34.4 million for the three months ended March 31, 2012 from $5.6 million for the three months ended March 31, 2011. This increase in product sales revenues was due to a 636% increase in the number of doses of BioThrax delivered. This increase in the number of doses delivered was due to the use of production lots in the qualification of a second fill-finish contract manufacturer and the redeployment of our potency testing capacity from BioThrax release testing to qualification of replacement reference standards and other development testing during the first quarter of 2011. Product sales revenues during the three months ended March 31, 2012 consisted of BioThrax sales to the CDC of $34.3 million and aggregate international and other sales of $89,000. Product sales revenues for the three months ended March 31, 2011 consisted of BioThrax sales to the CDC of $5.0 million and aggregate international and other sales of $565,000.

Contracts and grants revenues increased by $3.0 million, or 23%, to $16.0 million for the three months ended March 31, 2012 from $12.9 million for the three months ended March 31, 2011. The increase in contracts and grants revenues was primarily due to increased activity and associated revenue from our development contracts with BARDA for large-scale manufacturing of BioThrax and PreviThrax. Contracts and grants revenues during the three months ended March 31, 2012 consisted of $14.3 million in development contract and grant revenue from BARDA and NIAID and $1.7 million from Abbott and Pfizer. Contracts and grants revenues for the three months ended March 31, 2011 consisted of $9.9 million in development contract and grant revenue from BARDA and NIAID and $3.0 million from Abbott and Pfizer.

Cost of Product Sales

Cost of product sales increased by $6.4 million to $7.5 million for the three months ended March 31, 2012 from $1.1 million for the three months ended March 31, 2011. This increase was substantially attributable to the 636% increase in the number of BioThrax doses sold.

Research and Development Expenses

Research and development expenses decreased by $8.5 million, or 24%, to $26.2 million for the three months ended March 31, 2012 from $34.8 million for the three months ended March 31, 2011. This decrease primarily reflects lower contract service expenses, and includes decreased expenses of $9.6 million for product candidates and technology platform development activities that are categorized in the Biosciences segment, increased expenses of $474,000 for product candidates that are categorized in the Biodefense segment, and increased expenses of $595,000 in other research and development, which are in support of central research and development activities. During the three months ended March 31, 2012 and 2011, we incurred research and development expenses net of development contract and grant revenues along with the net loss attributable to noncontrolling interests of $9.1 million and $20.0 million, respectively.

The increase in spending on Biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials. The decrease in spending for NuThrax was primarily due to the timing of clinical trial activities. The increase in spending for our large-scale manufacturing for BioThrax program was primarily due to non-clinical studies and preparation for the manufacturing of consistency lots. The spending for BioThrax related programs was related to clinical and non-clinical studies to support applications for marketing approval of these programs. The increase in

spending for PreviThrax was primarily due to optimization and stability studies. The decrease in spending for Anthrivig was primarily due to the substantial completion of clinical trial activities. The decrease in spending for Thravixa was primarily due to timing of clinical trial activities. The decrease in spending for our other biodefense activities was primarily due to decreased spending associated with our double mutant recombinant protective antigen anthrax vaccine in light of reduced funding by the U.S. government for this product candidate. As such, we expect that spending for our double mutant recombinant protective antigen anthrax vaccine will be minimal in the future.

The decrease in spending on Biosciences product candidates, detailed in the table below, was primarily attributable to the timing of development efforts and the acquisition of certain Biosciences product candidates. The decrease in spending for our tuberculosis vaccine product candidate is related to the timing of costs incurred for the continued conduct of a Phase IIb clinical trial along with process development and manufacturing activities. The decrease in spending for our TRU-016 product candidate is primarily due to the timing of clinical manufacturing and clinical trial activities. The decrease in spending for our ES301 product candidate is primarily due to the timing of non-clinical activities. The spending for our zanolimumab product candidate was primarily for process and clinical development related to our May 2011 acquisition of certain assets of TenX BioPharma, Inc. The decrease in spending for our influenza vaccine product candidate is primarily due to the timing of process and analytical development. The decrease in spending for our X1 product candidate is primarily related to reduced non-clinical activities. We have significantly reduced ongoing spending with regard to X1 and we expect that future spending will be further reduced. The decrease in spending for Typhella was primarily due to the substantial completion of manufacturing and clinical studies. The decrease in spending for our other Biosciences activities was primarily due to a reduction of the contingent value right obligations associated with our agreement with Pfizer, partially offset by increased spending associated with development of platform technologies along with preclinical product candidates as a result of our acquisition of Trubion Pharmaceuticals, Inc., or Trubion.

The spending for other research and development activities was primarily due to central research and development activities not attributable to product candidates.

Our principal research and development expenses for the three months ended March 31, 2012 and 2011 are shown in the following table:

| | Three Months ended March 31, | |
|---|---|---|
| (in thousands) | 2012 | 2011 |
| Biodefense: | | |
| NuThrax | $2,606 | $3,699 |
| Large-scale manufacturing for BioThrax | 4,697 | 3,246 |
| BioThrax related programs | 2,464 | 1,710 |
| PreviThrax | 4,503 | 3,115 |
| Anthrivig | 103 | 635 |
| Thravixa | 533 | 1,308 |
| Other Biodefense | 261 | 980 |
| Total Biodefense | 15,167 | 14,693 |
| Biosciences: | | |
| Tuberculosis vaccine | 3,231 | 5,904 |

| | | |
|---|---|---|
| TRU-016 | 2,782 | 5,025 |
| ES301 (formerly DRACO) | 1,053 | 1,961 |
| Zanolimumab | 592 | - |
| X1 | 65 | 907 |
| Influenza vaccine | 101 | 824 |
| Typhella | 133 | 840 |
| Other Biosciences | 1,269 | 3,347 |
| Total Biosciences | 9,226 | 18,808 |
| Other | 1,853 | 1,258 |
| Total | $26,246 | $34,759 |

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $1.3 million, or 7%, to $19.5 million for the three months ended March 31, 2012 from $18.2 million for the three months ended March 31, 2011. This increase is primarily due to legal and other professional services to support business initiatives. The majority of the expense is attributable to the Biodefense segment, in which selling, general and administrative expenses increased by $453,000, or 3%, to $14.5 million for the three months ended March 31, 2012 from $14.0 million for the three months ended March 31, 2011. Selling, general and administrative expenses related to our Biosciences segment increased by $827,000, or 20%, to $5.0 million for the three months ended March 31, 2012 from $4.2 million during the three months ended March 31, 2011.

Impairment of in-process research and development

Impairment of in-process research and development was $9.6 million for the three months ended March 31, 2012. There was no impairment for the three months ended March 31, 2011. The impairment charge resulted from the full impairment of our SBI-087 in-process research and development asset.

Total Other Income (Expense)

Total net other income increased by $842,000 to $876,000 for the three months ended March 31, 2012 from $34,000 for the three months ended March 31, 2011. The net increase was due primarily to a business interruption insurance recovery related to a power outage at our Lansing, Michigan facility.

Income Taxes

Benefit from income taxes decreased by $8.7 million, or 70%, to $3.6 million for the three months ended March 31, 2012 from $12.3 million for the three months ended March 31, 2011. The decrease in the benefit from income taxes is due to the $23.2 million decrease in our loss before benefit from income taxes and the loss attributable to noncontrolling interests.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest decreased by $583,000, or 33%, to $1.2 million for the three months ended March 31, 2012 from $1.8 million for the three months ended March 31, 2011. The decrease resulted primarily from the timing of clinical and development activities and related expenses incurred by our joint ventures. These

amounts represent the portion of the losses incurred by the joint ventures for the three months ended March 31, 2012 and 2011, respectively, that is attributable to our joint venture partners.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our cash requirements from inception through March 31, 2012 principally with a combination of revenues from BioThrax product sales, debt financings and facilities leases, development funding from government entities and non-government and philanthropic organizations and collaborative partners, the net proceeds from our initial public offering and from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the five years ended December 31, 2011.

As of March 31, 2012, we had cash and cash equivalents of $150.4 million. Additionally, at March 31, 2012, our accounts receivable balance was $43.7 million.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2012 and 2011:

| | Three Months ended March 31, | |
|---|---|---|
| (in thousands) | 2012 | 2011 |
| Net cash provided by (used in): | | |
| Operating activities(1) | $15,852 | $(22,748) |
| Investing activities | (8,598) | (12,741) |
| Financing activities | (730) | 3,395 |
| Total net cash provided by (used in) | $6,524 | $(32,094) |

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

Net cash provided by operating activities of $15.9 million for the three months ended March 31, 2012 was principally due to a decrease in accounts receivable of $30.5 million due to the timing of collection of amounts billed to the CDC, non-cash charges of $9.6 million for the impairment of in-process research and development, $2.7 million for stock-based compensation, $2.4 million for depreciation and amortization, and $1.2 million for development expenses primarily from our joint ventures, partially offset by our net loss of $6.8 million, a decrease in accrued compensation of $10.9 million associated with the payment of 2011 bonuses, a net decrease of income taxes of $4.2 million related to timing differences and a $3.0 million decrease in the fair value of contingent value right, or CVR, obligations related to our agreement with Pfizer.

Net cash used in operating activities of $22.7 million for the three months ended March 31, 2011 was principally due to our net loss of $21.4 million, a $9.4 million increase in inventory related to the timing of BioThrax shipments, a net decrease in income taxes of $12.4 million related to timing differences, a decrease in accrued compensation of $10.3 million primarily due to the payment of 2010 bonuses, partially offset by a decrease in accounts receivable of $27.4 million due to the timing of collection of amounts billed primarily to HHS, and non-cash charges of $2.4 million for stock-based compensation, $2.2 million for depreciation and amortization, and $2.6 million for development expenses primarily from our joint venture with the University of Oxford.

Net cash used in investing activities for the three months ended March 31, 2012 was $8.6 million, primarily due to capital expenditures of $22.3 million related to the construction and related costs of our facility in Baltimore,

Maryland, and infrastructure investments and other equipment, partially offset by net proceeds from the sale of our two Frederick, MD buildings of $11.8 million and the maturity of U.S. Treasury securities of $2.0 million.

Net cash used in investing activities for the three months ended March 31, 2011 was $12.7 million, primarily due to capital expenditures of $8.4 million related to the construction and related costs for our facility in Baltimore, Maryland, and infrastructure investments and other equipment, along with the purchase of U.S. Treasury securities of $4.3 million.

Net cash used in financing activities of $730,000 for the three months ended March 31, 2012 resulted primarily from $8.2 million in principal payments on indebtedness, including $7.7 million in repayment of debts related to our Frederick, MD buildings, a $1.7 million CVR payment to former Trubion stockholders and option holders and $862,000 related to excess tax benefits from the exercise of stock options, partially offset by $9.6 million in advances under our construction and equipment loans with PNC Bank related to the renovation, improvement and equipment purchases at our Baltimore facility.

Net cash provided by financing activities of $3.4 million for the three months ended March 31, 2011 resulted primarily from $4.2 million in proceeds from stock option exercises and $39,000 related to excess tax benefits from the exercise of stock options, partially offset by $842,000 in principal payments on indebtedness.

Debt Financing

As of March 31, 2012, we had $60.9 million principal amount of debt outstanding, comprised primarily of the following:

§ $19.3 million outstanding under a term loan from HSBC Realty Credit Corporation used to finance a portion of the costs of our facility expansion in Lansing, Michigan;
§ $4.4 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance a portion of the purchase price of our facility in Gaithersburg, Maryland;
§ $30.0 million outstanding under a construction loan from PNC Bank used to fund the ongoing renovation of our Baltimore, Maryland facility; and
§ $7.2 million outstanding under an equipment loan from PNC Bank used to fund equipment purchases at our Baltimore, Maryland facility.

In March 2012, in conjunction with the sale of our Frederick, Maryland buildings, we repaid the remaining $5.2 million and $2.5 million due under the loans from PNC Bank and the Department of Business and Economic Development of the State of Maryland that was used to finance a portion of the purchase price for our first facility at the Frederick site.

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures and debt service requirements from existing cash and cash equivalents, revenues from BioThrax product sales, collaboration funding, development contract and grant funding, and any lines of credit we may establish from time to time. There are numerous risks and uncertainties associated with BioThrax 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:

§ the level and timing of BioThrax product sales and cost of product sales;
§ our ability to obtain funding from government entities and non-government and philanthropic organizations for our development programs;
§ the acquisition of and capital improvements to new facilities;

- the timing of, and the costs involved in, completion of qualification and validation activities related to Building 55, our large-scale manufacturing facility in Lansing, Michigan, the build out of our facility in Baltimore, Maryland, and any capital improvements to other existing facilities;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the costs, timing and outcome of regulatory review and regulatory compliance of our product candidates;
- the number of, and development requirements for, other product candidates that we may pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the market acceptance and sales growth of any of our products and product candidates upon regulatory approval;
- the extent to which our growth generates increased administrative costs;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- the extent to which we acquire or invest in companies, businesses, products or technologies; and
- the effect of technological and market developments.

We may require additional sources of funds for future acquisitions that we may make or, depending on the size of the obligation, to meet balloon payments upon maturity of our current borrowings. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Current economic conditions may make it difficult to obtain financing on attractive terms or at all. Lenders may be able to impose covenants on us that could be difficult to satisfy, which could put us at increased risk of defaulting on debt. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

Our ability to borrow amounts under any line of credit we may establish will likely be subject to our satisfaction of specified conditions. Additional equity or debt financing, grants, or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional 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.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is currently confined to our cash and cash equivalents that have maturities of less than three months and our long-term indebtedness. 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 cash and cash equivalents, but any increase in market rates would likely increase the interest expense associated with our debt.

## ITEM 4. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2012. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or 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 March 31, 2012, 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

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the quarter ended March 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Not applicable.

ITEM 1A. RISK FACTORS

Risks Related to Our Dependence on U.S. Government Contracts

We have derived substantially all of our revenue from sales of BioThrax under contracts with the U.S. government. If the U.S. government's demand for BioThrax is reduced, our business, financial condition and operating results could be materially harmed.

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales to the U.S. government of BioThrax, our FDA-approved anthrax vaccine and only marketed product. We are currently party to a contract with the Centers for Disease Control, or CDC, for the supply of 44.75 doses of BioThrax for placement into the SNS over a five year period. If the SNS priorities change, our revenues could be substantially reduced.

The procurement of doses of BioThrax by the CDC is subject to availability of funding. Our existing contract with the CDC and prior contracts with Health and Human Services, or HHS, and the Department of Defense, or DoD, do not necessarily increase the likelihood that funding for the procurement of doses will be available. If funding to procure doses of BioThrax is not available, our business, financial condition and operating results would be materially harmed. The success of our business and our operating results for the foreseeable future are substantially dependent on the terms of our BioThrax sales to the U.S. government, including price per dose, the number of doses and the timing of deliveries.

Our business may be harmed as a result of the government contracting process, which may be a competitive bidding process that involves risks and requirements not present in commercial contracting.

We expect that a significant portion of our near-term business will be under government contracts or subcontracts awarded through competitive bidding. Competitive bidding for government contracts presents a number of risks or

requirements, some of which are not typically present in the commercial contracting process, 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
- if our competitors protest or challenge contract 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 termination, reduction or modification of the awarded contract.

The U.S. government may choose not to award us future contracts for the development and supply of anthrax vaccines and other biodefense product candidates that we are developing, and may instead award such contracts to our competitors. If we are unable to win particular contracts, we may not be able to operate in the market for products that are provided under those contracts for a number of years. 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 and resources that will be required to secure and, if applicable, perform such contract awards, our growth strategy and our business, financial condition and operating results could be materially and adversely affected.

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

Our principal customer for BioThrax is the U.S. government. We anticipate that the U.S. government will also be the principal customer for any other biodefense products that we successfully develop. Over its lifetime, a U.S. government program may be implemented through the award of many different individual contracts and subcontracts. The funding for government programs is subject to Congressional appropriations, often made on a fiscal year basis, even for programs designed to continue for several years. These appropriations can be subject to political considerations and stringent budgetary constraints. For example, sales of BioThrax supplied under our multi-year procurement contract with the CDC will be subject to available funding, mostly from annual appropriations. 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 development contract we were awarded in September 2010 for development of PreviThrax consists of a two-year base period of performance valued at approximately $51 million, three successive one-year option periods valued at approximately $126 million and funding for optional non-clinical studies valued at approximately $9 million. 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 with it, our business, revenues and operating results may suffer.

The success of our business with the U.S. government depends on our compliance with regulations and obligations under our U.S. government contracts and various federal statutes and regulations.

Our business with the U.S. government is subject to specific procurement regulations and a variety of other legal compliance obligations. These laws and rules include those related to:

- procurement integrity;
- export control;
- government security;

- § employment practices;
- § protection of the environment;
- § accuracy of records and the recording of costs; and
- § foreign corrupt practices.

In addition, before awarding us any future contracts, the U.S. government could require that we respond satisfactorily to a request to substantiate our commercial viability and industrial capabilities. Compliance with these obligations increases our costs. Failure to comply with these regulations and requirements could lead to suspension or debarment, from government contracting or subcontracting for a period of time. The termination of a government contract or relationship as a result of our failure to satisfy any of these obligations would have a negative impact on our operations and harm our reputation and ability to procure other government contracts in the future.

The pricing under our fixed price government contracts is based on estimates of the time, resources and expenses required to perform those contracts. If our estimates are not accurate, we may not be able to earn an adequate return or may incur a loss under these contracts.

Our prior contracts for the supply of BioThrax with HHS and the DoD, as well as our current contract for the procurement of 44.75 million doses of BioThrax by the CDC, are fixed price contracts. We expect that our potential future contracts with the U.S. government for BioThrax, as well as contracts for biodefense product candidates that we successfully develop, if any, 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 and to absorb any costs in excess of the fixed price. 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 a fixed price contract or cause a loss, which could in turn harm our operating results.

Unfavorable provisions in government contracts, some of which may be customary, may harm our business, financial condition and operating results.

Government contracts customarily contain provisions that give the U.S. government substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the U.S. government to:

- § terminate existing contracts, in whole or in part, for any reason or no reason;
- § unilaterally reduce or modify contracts or subcontracts, including by imposing equitable price adjustments;
- § cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- § decline to exercise an option to renew a contract;
- § exercise an option to purchase only the minimum amount, if any, specified in a contract;
- § decline to exercise an option to purchase the maximum amount, if any, specified in a contract;
- § claim rights to products, including intellectual property, developed under the contract;
- § 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 criminal or civil remedies under the False Claims Act and False Statements Act; and
- § control or prohibit the export of products.

Generally, government contracts, including our CDC contract for BioThrax, 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 other party to that contract 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 defaulting company 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. One or more of our government contracts could be terminated under these circumstances. Some U.S. government contracts grant the U.S. government the right to use, for or on behalf of the U.S. government, any technologies developed by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the U.S. government.

Additional Risks Related to Sales of Biodefense Products to the U.S. Government

Our business is subject to audit by the U.S. government and a negative audit could adversely affect our business.

U.S. government agencies such as the Defense Contract Audit Agency, or the DCAA, routinely audit and investigate government contractors. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The DCAA also reviews the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

§ termination of contracts;
§ forfeiture of profits;
§ suspension of payments;
§ fines; and
§ suspension or prohibition from conducting business with the U.S. government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us.

Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business.

We must comply with numerous laws and regulations, including those relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under these contracts. These laws and regulations affect how we conduct business with federal, state and local government agencies. Among the most significant government contracting regulations that affect our business are:

§ the Federal Acquisition Regulations, and agency-specific regulations supplemental to the Federal Acquisition Regulations, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
§ the 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 and the Foreign Corrupt Practices Act, or FCPA;
§ export and import control laws and 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.

In addition, qui tam lawsuits have been brought against us in which the plaintiffs argued that we defrauded the U.S. government by distributing non-compliant doses of BioThrax. Although we ultimately prevailed in this litigation, we spent significant time and money defending the litigation. U.S. states, many municipalities and foreign governments

typically also have laws and regulations governing contracts with their respective agencies. These domestic and foreign laws and regulations affect how we and our customers conduct business and, in some instances, impose additional costs on our business. Any changes in applicable laws and regulations could restrict our ability to maintain our existing contracts and obtain new contracts, which could limit our ability to conduct our business and materially and adversely affect our revenues and results of operations.

Risks Related to Our Financial Position and Need for Additional Financing

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 quarter of 2012. Our profitability is substantially dependent on BioThrax product sales. BioThrax product sales have fluctuated significantly in recent quarters, and we expect that they will continue to fluctuate significantly from quarter to quarter based on several factors, including the timing of our fulfillment of orders from the U.S. government. Additionally, our profitability may be adversely affected as we progress through various stages of ongoing or planned clinical trials for our product candidates. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

Our indebtedness may limit cash flow available to invest in the ongoing needs of our business.

As of March 31, 2012, we had $60.9 million principal amount of debt outstanding. We may seek to raise substantial external debt financing to provide additional financial flexibility. The assumption of debt could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of any cash flow from operations to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- increasing the amount of interest that we have to pay on debt with variable interest rates if market rates of interest increase;
- increasing our vulnerability to general adverse economic and industry conditions;
- obligating us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. In addition, a failure to comply with the covenants under our existing debt instruments could result in an event of default under those instruments. In the event of an acceleration of amounts due under our debt instruments as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness. In addition, the covenants under our existing debt instruments and the pledge of our existing assets as collateral limit our ability to obtain additional debt financing.

We may require additional funding and may be unable to raise capital when needed, which would harm our business, financial condition and operating results.

We expect our development expenses to increase in connection with our ongoing activities, particularly as we conduct additional and later stage clinical trials for our product candidates. We also expect our commercialization expenses to increase in the future as we seek to broaden the market for BioThrax and if we receive marketing approval for

additional products. We also may undertake additional facility projects in the future. In the event that our ability to sell BioThrax to the U.S. government is interrupted for an extended period of time, we will utilize our cash balances to help fund our ongoing operations.

As of March 31, 2012, we had $194.1 million of cash, cash equivalents and accounts receivable. Our future capital requirements will depend on many factors, including:

§ the level and timing of BioThrax product sales and cost of product sales;
§ our ability to obtain funding from government entities and non-government and philanthropic organizations for our development programs;
§ the acquisition of new facilities and capital improvements to new or existing facilities;
§ the timing of, and the costs involved in, completion of qualification and validation activities related to Building 55, our large-scale manufacturing facility in Lansing, Michigan, the build out of our facility in Baltimore, Maryland, and any other new facilities;
§ the scope, progress, results and costs of our preclinical and clinical development activities;
§ the costs, timing and outcome of regulatory review of our product candidates;
§ the number of, and development requirements for, other product candidates that we may pursue;
§ the costs of commercialization activities, including product marketing, sales and distribution;
§ the market acceptance and sales growth of any of our products or product candidates upon regulatory approval;
§ the extent to which our growth generates increased administrative costs;
§ the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
§ the extent to which we acquire or invest in companies, businesses, products or technologies; and
§ the effect of competing technological and market developments.

We may require additional sources of funds for future acquisitions that we may make or, depending on the size of the obligation, to meet balloon payments upon maturity of our current borrowings. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Current economic conditions may make it difficult to obtain financing on attractive terms or at all. Lenders may be able to impose covenants on us that could be difficult to satisfy, which could put us at increased risk of defaulting on debt. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

Our ability to borrow additional amounts under any line of credit we may establish will likely be subject to our satisfaction of specified conditions. Additional equity or debt financing, development contracts and grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional 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.

Risks Related to Manufacturing and Manufacturing Facilities

We are in the process of expanding our manufacturing facilities. Delays in completing facilities, or delays or failures in obtaining regulatory approvals for new manufacturing facility projects or new contract manufacturing partners, could limit our potential revenues and growth.

We continually evaluate alternatives for the manufacture of BioThrax and our various product candidates. We may seek to acquire one or more additional facilities or sign agreements with contract manufacturing organizations. We have constructed Building 55, a large-scale manufacturing facility on our Lansing, Michigan campus for which we received an award from the Biomedical Advanced Research and Development Authority, or BARDA, in July 2010 for scale-up, qualification and validation to manufacture BioThrax. Additionally, in 2009, we acquired a facility in Baltimore, Maryland which we expect to utilize for certain product development or manufacturing projects.

Constructing, preparing and maintaining a facility for manufacturing purposes is a significant project. For example, the process for qualifying and validating Building 55 for FDA approval of the large-scale manufacture of BioThrax has been costly and time consuming, may result in unanticipated delays and may cost more than expected due to a number of factors, including regulatory requirements. The costs and time required to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements for sales of our products outside the U.S. may be significant. We may also need to hire and train significant numbers of employees to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. If our qualification, validation and licensure activities are delayed, we may limit our opportunities for growth and may be in breach of the obligations included in our government funded development contracts. Costs associated with constructing, qualifying, validating and licensing manufacturing facilities could require us to raise additional funds from external sources, and we may not be able to do so on favorable terms or at all.

BioThrax and our product candidates are complex to manufacture and ship, which could cause us to experience delays in revenues or shortages of products.

BioThrax and all our product candidates 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. Accordingly, it is essential to be able to validate and control the manufacturing process to assure that it is reproducible. Slight deviations anywhere in the manufacturing process, including maintaining master seed or cell banks and preventing drift, obtaining materials, seed or cell growth, fermentation, filtration, filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures or manufacturing shut-down, delays in the release of lots, product recalls, spoilage or regulatory action. Success rates can 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 or cause the FDA to cease releasing product until the deviations are explained and corrected, any of which could be costly to us and negatively impact our business.

FDA approval is required for the release of each lot of BioThrax. We will not be able to sell any lots that fail to satisfy the release testing specifications. We must provide the FDA with the results of potency testing before lots are released for sale. We have one mechanism for conducting this potency testing that is reliant on a unique animal strain for which we currently have no alternative. In developing alternatives, we may face significant regulatory hurdles. In the event of a problem with this strain, if we have not developed alternatives, we would not be able to provide the FDA with required potency testing data and not be able to release product.

Additionally, potency testing of each lot of BioThrax is performed against a qualified reference lot that we maintain. We continually monitor the status of our reference lot and periodically produce and qualify a new reference lot to replace the existing reference lot. For example, we prepared and qualified a new reference lot during 2011 to replace our prior, qualified reference lot. If we are not able to 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 such 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.

Under our current contract with the CDC, we have the option to perform shipping services at no cost to the U.S. government. If we perform these shipping services, we are contractually required to ship BioThrax at a prescribed temperature range, and variations from that temperature range could result in loss product and could adversely affect our profitability. 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 our clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

Disruption at, damage to or destruction of our facilities could impede our ability to manufacture BioThrax, develop our product candidates, or perform our contractual obligations, any of which would harm our business, financial condition and operating results.

We currently rely on our manufacturing facilities at a single location in Lansing, Michigan for the production of BioThrax. Any interruption in manufacturing operations at this location could result in our inability to satisfy the product demands of our customers. A number of factors could cause interruptions, including:

§ equipment malfunctions or failures;
§ technology malfunctions;
§ cyberattacks;
§ work stoppages or slow-downs;
§ protests, including by animal rights activists;
§ damage to or destruction of the facility;
§ natural disasters;
§ regional power shortages; or
§ product tampering.

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.

In addition, providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. For example, the U.S. government has designated our Lansing facility as a facility requiring additional security to protect against potential terrorist threats to the facility. Any disruption that impedes our ability to manufacture and ship BioThrax in a timely manner could reduce our revenues and materially harm our business, financial condition and operating results.

The factors listed above including but not limited to, equipment malfunctions or failures, technology malfunctions, cyber attacks, protests and natural disasters could also cause disruption of, damage to or destruction of our other locations, including our research and product development facilities and our additional manufacturing facility currently under development in Baltimore, Maryland. Any such disruption, damage, or destruction could result in losses and delays, including delay in performance of our contractual obligations or delay in our clinical trials, any of which could be costly to us and otherwise harm our business.

Our business may be harmed if we do not adequately forecast customer demand.

The timing and amount of customer demand is difficult to predict. We may not be able to scale-up our production quickly enough to fill any new customer orders on a timely basis. This could cause us to lose new business and possibly existing business. For example, we, or third party manufacturers with whom we may contract, may not be able to scale-up manufacturing processes for our product candidates to allow production of commercial quantities at a reasonable cost or at all. Furthermore, if we overestimate customer demand, or choose to commercialize products for

which the market is smaller than we anticipate, we could incur significant unrecoverable costs from creating excess capacity. In addition, if we do not successfully develop and commercialize any of our product candidates, we may never utilize the production capacity that we expect to have available.

If we are unable to obtain supplies for our manufacture of BioThrax or our product candidates in sufficient quantities and at an acceptable cost, our ability to manufacture BioThrax or to develop and commercialize our 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 materials and services necessary for the manufacture of BioThrax and our product candidates. 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 BioThrax or our 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.

If third parties do not manufacture our product candidates in sufficient quantities and at an acceptable cost or in compliance with regulatory requirements and specifications, the development and commercialization of our product candidates could be delayed, prevented or impaired.

We currently rely, or plan to rely, on third parties to manufacture some or all of our vaccine and therapeutic product candidates that we require for preclinical and clinical development. Any significant delay in obtaining adequate supplies of our product candidates could adversely affect our ability to develop or commercialize these product candidates. For example, in 2008, the initial manufacturer of Thravixa informed us it was discontinuing contract manufacturing operations and we were forced to secure alternative manufacturing resources to continue development of this product candidate.

We also expect that we will rely on third parties for some or all of the manufacturing services necessary to produce commercial supplies of product candidates that we successfully develop. The manufacture and delivery of sufficient quantities of pharmaceutical products is a time-consuming and complex process. If our contract manufacturers are unable to scale-up production to generate enough materials for commercial launch, if manufacturing is of insufficient quality or not compliant with applicable rules and regulations, or if the costs of manufacturing are prohibitively high, the success of those products may be jeopardized. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our ability to develop product candidates and commercialize any products that receive regulatory approval on a timely and competitive basis.

Reliance on contract manufacturers, other vendors and collaborators limits our control regarding many aspects of the manufacturing and delivery process and therefore exposes us to a variety of significant risks, including:

§ limitations on our ability to schedule production with contract suppliers when needed to supply clinical trials;
§ reliance on contract suppliers for legal and regulatory compliance and quality assurance;
§ potential rejection by a contract supplier of a purchase order;
§ contract supplier’s insistence on exclusivity, minimum or maximum levels of supply and related restrictions on our ability to increase or decrease supply, including provisions whereby we pay a penalty if we fail to order a minimum amount;
§ breach of agreements by contract suppliers; and
§ termination, price increases, or non-renewal of agreements by contract suppliers, based on other business priorities, at times that are costly or inconvenient for us.

We operate under short-term supply agreements with a number of third party manufacturers that are not obligated to accept any purchase orders we may submit. Third party manufacturers may also be unable or unwilling to accommodate our production scheduling requests, or may insist on exclusivity or minimum or maximum levels of supply, or may raise prices or decline to renew contracts. If any third party terminates or declines to renew its agreement with us, or otherwise fails to fulfill our purchase orders on terms acceptable to us, we would need to rely on alternative sources or develop our own manufacturing capabilities to satisfy our requirements.

If alternative suppliers are not available or are delayed in fulfilling our requirements, or if we are unsuccessful in developing our own manufacturing capabilities, we may not be able to obtain adequate supplies of our product candidates on a timely basis. A change of manufacturers would require review and approval by the FDA and the applicable foreign regulatory agencies. This review and approval may be costly and time consuming. There are a limited number of manufacturers that operate under cGMP requirements and that are both capable of manufacturing for us and willing to do so. We may not be able to reach agreement on reasonable terms, if at all, with these manufacturers.

We currently rely on third parties for regulatory compliance and quality assurance with respect to the supplies of our product candidates that they produce for us. We also may rely for these purposes on any third party that we use for production of commercial supplies of product candidates that we successfully develop. Manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP regulations and other governmental regulations and corresponding foreign standards.

We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the U.S. We do not control compliance by manufacturers with these regulations and standards. If we or these third parties fail to comply with applicable regulations, sanctions could be imposed on us, which could significantly and adversely affect supplies of our product candidates. The sanctions that might be imposed include:

§ fines, injunctions and civil penalties;
§ refusal by regulatory authorities to grant marketing approval of our product candidates;
§ delays, suspension or withdrawal of regulatory approvals, including license revocation;
§ seizures or recalls of product candidates or products;
§ temporary or permanent shut-down of manufacturing facilities;
§ operating restrictions; and
§ criminal prosecutions.

If we or third parties are unable to manufacture our product candidates in compliance with regulatory requirements, in sufficient quantities, at an acceptable cost and according to applicable timelines, our clinical trials could be delayed, production costs could be significantly increased and the development prospects and commercial viability of our product candidates could be harmed.

Our use of hazardous materials, chemicals, bacteria and viruses requires us to comply with regulatory requirements and exposes us to significant potential liabilities.

Our research and development and manufacturing processes may involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we, the third parties that conduct clinical trials on our behalf and the third parties that manufacture our product candidates are subject to federal, state, local and foreign laws and regulations governing the use, manufacture, distribution, storage, handling, disposal and recordkeeping with respect to these materials. The Public Health Security and Bioterrorism Preparedness and Response Act and the Agricultural Protection Act require us to register with the CDC and the Animal and Plant Health Inspection Service, our possession, use or transfer of 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 laws in Michigan, including those regarding underground storage tanks. One such tank on our Lansing, Michigan campus has leaked in the past. The State of Michigan removed the tank, continues to monitor the situation and has agreed to indemnify us for any resulting liabilities. In the event that the State of Michigan does not indemnify us, or if our insurance does not cover the exposure of any remediation that may be necessary, we may be required to spend significant amounts on remediation efforts. 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.

We also are subject to export control regulations governing the export of BioThrax and technology and materials used to develop and manufacture BioThrax and our product candidates. These laws and regulations may limit the countries in which we may conduct development and manufacturing activities.

If we fail to comply with environmental, occupational health and safety, biosafety and export control laws, we could be held liable for fines, penalties and damages that may result from such non-compliance, and any such liability could exceed our assets and resources. In addition, we could be required to cease immediately all use of a select agent or toxin, and we could be prohibited from exporting our products, technology and materials or we could be suspended from the right to do business with the U.S. government. In addition, we cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of hazardous materials. In the event of injury or a future contamination event, we could be held liable for resulting damages, and any such liability could significantly impact our financial position.

Our insurance policies may not adequately compensate us for all liabilities that we may incur in the event of unanticipated costs, which may expose us to potential expense and reduced profitability.

We hold a number of insurance policies in an effort to protect ourselves against extraordinary or unanticipated costs. Our general liability and excess insurance policies provide for coverage up to annual aggregate limits of $12 million, with coverage of $1 million per occurrence and $2 million in the aggregate for general liability and $10 million per occurrence and in the aggregate for excess liability. Both policies exclude coverage for liabilities relating to the release of pollutants. We do not currently hold insurance policies expressly providing for coverage relating to our use of hazardous materials other than storage tank liability insurance for our Lansing facility with coverage of $1 million per occurrence and $2 million annual aggregate limit and a $25,000 per claim deductible. We hold product liability and clinical trial liability insurance policies for our commercial products and each clinical trial we are conducting in amounts we deem appropriate.

These policies are subject to deductibles, exclusions and coverage limitations. We may be unable to maintain existing insurance or obtain new coverage or increase limits in the future on reasonable terms or at all. Circumstances may arise where we face liabilities that are not covered by our insurance policies, or where our coverage is not adequate, which may expose us to significant liabilities and significantly and adversely affect our business or financial position.

Risks Related to Product Development

Our business depends significantly on our success in completing development and commercialization of our product candidates at acceptable costs. If we are unable to commercialize these product candidates, or experience significant delays or unanticipated costs in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of our vaccines and therapeutic product candidates and the acquisition of additional product candidates. In addition to BioThrax sales, our

ability to generate near term revenue is dependent on the success of our development programs and collaboration programs, on the U.S. government's interest in providing development funding for or procuring certain of our product candidates, on the interest of non-governmental organizations in providing grant funding for development of certain of our product candidates and on the commercial viability of our 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 biological manufacturing that meets FDA requirements;
- successful development of animal models;
- successful completion of non-clinical development, including toxicology studies and studies in approved animal models;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- successful completion of clinical trials;
- receipt of marketing approvals from the FDA and equivalent foreign regulatory authorities;
- procurement of our biodefense product candidates prior to FDA approval;
- establishing commercial manufacturing processes of our own or arrangements with contract manufacturers;
- manufacturing stable commercial supplies of product candidates, including materials based on recombinant technology;
- launching commercial sales of the product candidate, whether alone or in collaboration with others; and
- acceptance of the product candidate by potential government customers, physicians, patients, healthcare payors and others in the medical community.

If we are prevented from developing and commercializing a product candidate in an economically acceptable manner, that product program may be adversely affected and the commercial success of the product candidate may be harmed.

We will not be able to commercialize our product candidates if our preclinical development efforts are not successful, our clinical trials do not demonstrate safety or our clinical trials or animal studies do not demonstrate efficacy.

Before obtaining regulatory approval for the sale of our product candidates, we and our collaborative partners must conduct extensive preclinical studies and clinical trials to establish proof of concept, 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 the outcome of such trials is uncertain. 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.

We expect to rely on FDA regulations known as the "animal rule" to obtain approval for certain of our product candidates. 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. These regulations are relatively new, and 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 vaccine and therapeutic product candidates in humans. If we are not successful in completing the development and commercialization of our vaccine and therapeutic product candidates, or if we are significantly delayed in doing so, our business will be materially harmed.

A failure of one or more of our clinical trials or animal efficacy studies can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial or animal efficacy study process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

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regulators or institutional review boards may not authorize us, or our collaborators, to commence a clinical trial or conduct a clinical trial at a prospective trial site;

§ we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;

§ we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;

§ regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;

§ regulators may determine that service providers we use in the conduct of a clinical trial are precluded from providing such services;

§ we or our collaborative partners may experience delay in beginning the clinical trial;

§ we may experience competition in recruiting clinical investigators;

§ the cost of our clinical trials could escalate and become cost prohibitive;

§ any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;

§ regulatory requirements, policy and guidelines could change;

§ we may experience limitations in our ability to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials;

§ we or our collaborators may fail to adequately manage the increasing number, size and complexity of our clinical trials;

§ any or all of our collaborators, the FDA and foreign regulatory agencies may interpret data differently;

§ third parties conducting and overseeing the operations of our clinical trials may fail to perform their contractual or regulatory obligations in a timely fashion;

§ we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials or may experience delays in patient enrollment and variability in the number and types of patients available for clinical trials; and

§ the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

In addition, because some of our current and future vaccine product candidates contain live attenuated viruses, our testing of these vaccine product candidates is subject to additional risk. For example, there have been reports of serious adverse events following administration of live vaccine products in clinical trials conducted by other vaccine developers. Also, for some of our current and future vaccine product candidates, we expect to conduct clinical trials in chronic carriers of the disease that our product candidate seeks to prevent. There have been reports of disease flares in chronic carriers following administration of live vaccine products.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if our clinical trials are not well designed, if we are unable to successfully complete our clinical trials or other testing, or if the results of these trials or tests are not positive, we may:

§ be delayed in obtaining marketing approval for our product candidates;

§ obtain approval for indications that are not as broad as intended; or

§ not be able to obtain marketing approval.

Our product development costs will also increase if we experience delays in testing, are required to conduct additional testing, or experience delays in product approval. Significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

Under the Project BioShield Act of 2004, or Project BioShield, the Secretary of HHS, or the Secretary, can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances.

Project BioShield also allows the Secretary to authorize the emergency use of medical products that have not yet been approved by the FDA. However, our biodefense product candidates might not be selected by the Secretary under this authority. Moreover, this authority could result in increased competition for our products and product candidates.

If our drug discovery and development programs do not progress as anticipated, our revenue and stock price could be negatively impacted.

We estimate the timing of a variety of preclinical, clinical, regulatory and other milestones for planning purposes, including when a drug candidate is expected to enter clinical trials, when a clinical trial will be completed, when and if additional clinical trials will commence, or when an application for regulatory approval will be filed. We base our estimates on facts that are currently known to us and on a variety of assumptions that may prove not to be correct for a variety of reasons, many of which are beyond our control. For example, delays in the development of drugs by us or our collaborators may be caused by many factors, including regulatory or patent issues, negative or inconclusive interim or final results of ongoing clinical trials, scheduling conflicts with participating clinics and the rate of patient enrollment in clinical trials and the development priorities of our collaborators. In addition, in preparing these estimates we rely on the timeliness and accuracy of information and estimates reported or provided to us by our collaborators concerning the timing, progress and results of clinical trials or other development activities they conduct under our collaborations with them. If we or our collaborators do not achieve milestones when anticipated, we may not achieve our planned revenue or we may be forced to record an impairment charge to our intangible assets and our stock price could decline. In addition, any delays in obtaining approvals to market and sell drugs may result in the loss of competitive advantages in being on the market sooner than, or in advance of, competing products, which may reduce the value of these products and the potential revenue we receive from the eventual sale of these products, either directly or under agreements with our partners.

Our product development efforts could also result in large and immediate write-offs, significant milestone payments, incurrence of debt and contingent liabilities or amortization of expense related to intangible assets, any of which could negatively impact our financial results. Additionally, if we were unable to develop any of our product candidates into viable commercial products, we will be reliant solely on sales of our currently approved product BioThrax for our revenues, thus limiting our growth opportunities and diversification.

Risks Related to Commercialization

If we fail to achieve significant sales of BioThrax to customers in addition to the U.S. government, our opportunities for growth could be harmed.

An element of our business strategy is to establish a market for sales of BioThrax to customers in addition to the U.S. government. These potential customers include foreign governments and state and local governments, which we anticipate may be interested in BioThrax to protect emergency responders such as police, fire and emergency medical personnel, multinational companies, non-governmental organizations and hospitals.

The market for sales of BioThrax to customers other than the U.S. government is undeveloped, and we may not be successful in generating meaningful sales of BioThrax to these potential customers. To date, we have supplied only small amounts of BioThrax directly to foreign governments and our sales of BioThrax to customers other than the U.S. government has represented a small portion of our revenue. If we fail to significantly increase our sales of BioThrax to these customers, our business and opportunities for growth could be materially harmed.

Government regulations may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, many foreign governments require licensure of BioThrax in their jurisdictions before they will consider procuring doses. Additionally, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of BioThrax and related technology, the U.S. government may decide, particularly in the current environment of elevated concerns about

global terrorism, to increase the scope of export prohibitions. These prohibitions could limit our sales of BioThrax to foreign governments and other foreign customers. In addition, U.S. government demand for an anthrax vaccine may limit supplies of BioThrax available for sale to non-U.S. government customers. For example, our efforts to develop domestic commercial and international sales may be impeded by the DoD's right under the Defense Production Act to require us to deliver more doses than we currently anticipate. Furthermore, the DoD's sale of BioThrax to foreign governments under the Foreign Military Sales program has had and may continue to have an adverse effect on our ability to sell BioThrax internationally.

Our ability to meet any future potential increased demand for sales of BioThrax to customers other than the U.S. government also depends on our available production capacity. We use substantially all of our current production capacity at our FDA-approved manufacturing facility in Lansing, Michigan to manufacture BioThrax for current sales to the U.S. government. Although, we have constructed Building 55, a large-scale manufacturing facility at our Lansing campus that is available for large-scale production of BioThrax, use of Building 55 for large-scale production remains subject to final qualification and validation activities.

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

We must comply with numerous laws and regulations relating to international business operations. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

For example, the FCPA prohibits any U.S. individual or business from paying, offering or authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of a foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed on the United States securities exchanges to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

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

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

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC may also

suspend or bar issuers from listing their securities on United States securities exchanges for violations of the FCPA's accounting provisions.

The commercial success of BioThrax and any additional products that we may develop will depend upon the degree of market acceptance by the government, physicians, patients, healthcare payors and others in the medical community.

Any products that we bring to the market may not gain or maintain market acceptance by potential government customers, physicians, patients, healthcare payors and others in the medical community.

In particular, our biodefense product and product candidates are subject to the product criteria that may be specified by potential U.S. government customers. The product specifications in any government procurement request may prohibit or preclude us from participating in the government program if our products or product candidates do not satisfy the stated criteria.

The U.S. government could conduct clinical trials involving BioThrax in populations or in a manner that may attract negative public attention or otherwise have a detrimental effect on the market's acceptance of BioThrax.

The use of vaccines carries a risk of adverse health effects. The adverse reactions that have been associated with the administration of BioThrax include local reactions, such as redness, swelling, injection site cellulitus and temporary limitation of motion in the inoculated arm, and systemic reactions, such as headache, fever, chills, nausea and general body aches. In addition, some serious adverse events have been reported to the vaccine adverse event reporting system database maintained by the CDC and the FDA with respect to BioThrax, including diabetes, heart attacks, autoimmune disorders, including Guillain-Barre syndrome, lupus, multiple sclerosis, lymphoma and death. None of these events have been causally linked to the administration of BioThrax. The report of any adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event.

The commercial success of many of our product candidates, including our oncology and autoimmune therapeutic product candidates, will depend upon, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments.

If any products that we develop do not achieve an adequate level of acceptance, we may not generate material revenues from sales of these products. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- availability, relative cost and relative efficacy of alternative and competing treatments;
- the ability to offer our product candidates for sale at competitive prices;
- the relative convenience and ease of administration;
- the willingness of the target patient population to try new products and of physicians to prescribe these products;
- the strength of marketing and distribution support;
- publicity concerning our products or competing products and treatments; and
- the sufficiency of coverage or reimbursement by third parties.

If our products and product candidates do not become widely accepted by potential government customers, physicians, patients, third-party payors and other members of the medical community, our business, financial condition and operating results could be materially and adversely affected.

Political or social factors, including litigation, may delay or impair our ability to market BioThrax and our biodefense product candidates and may require us to spend time and money to address these issues.

Products developed to treat diseases caused by or to combat the threat of bioterrorism are subject to changing political and social environments. The political and social responses to bioterrorism may vary over time. We do not believe that the recent changes in the leadership of prominent terrorist networks are likely to reduce the risk of bioterrorism, but they could result in a public perception that risk is reduced. Political or social pressures or changes in the perception of the risk that military personnel or civilians could be exposed to biological agents as weapons of bioterrorism may delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, which would harm our business.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Furthermore, lawsuits brought against us by third parties or activists, even if not successful, require us to spend time and money defending the related litigation. The need to address political and social issues may divert our management's time and attention from other business concerns. For example, between 2001 and 2006, members of the military and various activist groups who oppose mandatory inoculation with BioThrax petitioned the FDA and the federal courts to revoke the license for BioThrax and to terminate the DoD program for the mandatory administration of BioThrax to military personnel. Although the DoD has prevailed in those challenges to date, the actions of these groups have created negative publicity about BioThrax. Additional lawsuits, publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of, and thereby limit the demand for, BioThrax and our biodefense product candidates. In such event, our ability to market and sell such products may be hindered and the commercial success of BioThrax and other products we develop will be harmed, thereby reducing our revenues.

We have a small sales and marketing group. If we are unable to expand our internal capabilities or enter into agreements with third parties, we may be unable to generate revenue from product sales to customers other than the U.S. government.

To achieve commercial success for any approved product, we must either develop our own sales and marketing capabilities, enter into collaborations with third parties able to perform these services or outsource these functions to third parties. We currently market and sell BioThrax through a small, targeted sales and marketing group. We plan to continue to do so and expect that we will use a similar approach for sales to the U.S. government of any other biodefense product candidates that we successfully develop. This small sales group would not be capable of supporting sales efforts for our biosciences product candidates. If we do not enter into collaborative agreements with respect to our Biosciences product candidates with third parties with appropriate commercialization capabilities, we may need to further expand our sales, marketing and distribution infrastructure to effectively commercialize these product candidates.

Our efforts to develop our sales, marketing and distribution infrastructure are subject to the following risks:

§ potential difficulties in recruiting, training and retaining adequate numbers of effective sales and marketing personnel;
§ the potential that the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities could be delayed, resulting in us incurring related expenses too early relative to the product launch and causing personnel retention issues;
§ our limited experience in the commercialization of pharmaceutical products other than BioThrax;
§ difficulties in establishing an effective distribution network, including entering into marketing and distribution agreements with third parties on acceptable terms;
§ the inability of sales personnel to obtain access to or persuade adequate numbers of potential government customers to purchase our products and physicians to prescribe our products;
§ the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
§ unforeseen costs and expenses associated with creating and maintaining a sales and marketing organization.

If we are not successful in our efforts to expand our sales and marketing capability, our ability to market and sell BioThrax and any other product candidates that we successfully develop will be impaired, which could negatively impact our business, financial condition and operating results.

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 BioThrax, our current product candidates and any products we may seek to develop or commercialize in the future from pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include biodefense companies, academic institutions, government agencies and other public and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than any products that we may develop or market. Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours. They may also devote greater resources to market or sell their products, adapt more quickly to new technologies and scientific advances, initiate or withstand substantial price competition more successfully than we can, more effectively negotiate third-party licensing and collaborative arrangements and take advantage of acquisition or other opportunities more readily than we can. Any therapeutic product candidate that we successfully develop and commercialize is likely to compete with currently marketed products and with other product candidates currently in development for the same indications. In many cases, the currently marketed products have well-known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. In particular, any new product candidate that competes with a generic market-leading product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome severe price competition and be commercially successful.

Although BioThrax is the only anthrax vaccine approved by the FDA for the prevention of anthrax infection, the U.S. government is funding the development of new products that could compete with BioThrax and could eventually procure those new products in addition to, or instead of, BioThrax, potentially reducing our BioThrax revenues. For example, HHS awarded a development and SNS procurement contract to a competitor for an anthrax immune globulin therapeutic and has assisted this company in its production efforts by providing it with BioThrax doses that we delivered for placement into the SNS so that the competitor could immunize donors and obtain plasma for the competitor’s product candidate. HHS awarded another development and SNS procurement contract to another competitor for an anthrax monoclonal antibody as a post-exposure therapeutic for anthrax infection.

We believe that our most significant competitors in the area of biodefense and commercial vaccines are a number of pharmaceutical companies that have vaccine programs, including Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Pfizer and Novartis, as well as smaller more focused companies engaged in vaccine and immune therapeutics development, such as Human Genome Sciences, Soligenix, Dynport Vaccine Company, Elusys, Bavarian Nordic and PharmAthene. With respect to our tuberculosis vaccine product candidate specifically, the Aeras Global Tuberculosis Vaccine Foundation is developing or supporting the development of five tuberculosis vaccine product candidates in addition to ours, any of which could present competitive risks.

With respect to protein therapeutics developed to target oncology and AIID indications, our competitors include Amgen, Pfizer, Takeda, Centocor Ortho Biotech, Merck, Mitsubishi Tanabe, Abbott, Eisai, Celgene, Bristol-Myers Squibb, UCB, Otsuka, Roche, Chugai, Genentech, Biogen Idec, Spectrum Pharmaceuticals, Inc., Bayer Schering AG, GSK, Genzyme, Cephalon Oncology, Genmab, Allos Therapeutics, AstraZeneca, Boehringer Ingleheim and ImmunoGen, Inc.

If approved for the treatment of chronic lymphocytic leukemia, or CLL, non-hodgkins lymphoma, or NHL, or other B-cell malignancies, we anticipate that our product candidates would compete with other B-cell depleting therapies and related therapeutics. Non-CD37-directed therapeutics marketed for the treatment of NHL or CLL, or both, include Rituxan ® (Genentech), Zevalin ® (Spectrum Pharmaceuticals, Inc. and Bayer Schering AG), Bexxar ® (GlaxoSmithKline), Campath ® (Genzyme and Bayer Schering AG), Treanda ® (Cephalon Oncology) and Arzerra ® (GlaxoSmithKline and Genmab). In addition, Boehringer Ingelheim and ImmunoGen, Inc. are both developing antibody therapies directed to CD37.

If approved for the treatment of cutaneous T-cell lymphoma, or CTCL, peripheral T-cell lymphoma, or PTCL, or other T-cell lymphomas, we anticipate that our product candidates would compete with other T-cell therapies and related therapeutics. Therapeutics marketed for the treatment of CTCL or PTCL include Ontak and Targretin (Eisai), Istodax ® (Celgene), Zolinza ® (Merck), Folotyn ® (Allos Therapeutics) and Campath® (Bayer Schering AG). In addition, GlaxoSmithKline, Roche, Bristol-Myers Squibb, AstraZeneca and Spectrum Pharmaceuticals are developing therapies directed to CTCL or PTCL.

If we are not able to compete effectively against our current and future competitors, our business may not grow or it may decline, and our financial condition and operating results may suffer.

Legislation and contractual provisions limiting or restricting liability of manufacturers or providing for indemnification may not be adequate to protect us from all liabilities associated with the manufacture, sale and use of our products.

Provisions of federal legislation enacted to protect manufacturers of biodefense and anti-terrorism countermeasures may limit our potential liability related to the manufacture, sale and use of BioThrax and our biodefense product candidates. However, this legislation may not fully protect us from all related liabilities.

The Public Readiness and Emergency Preparedness Act, or PREP Act, which was signed into law in December 2005, 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 state or federal law for loss arising out of the administration or use of a covered countermeasure. In October 2008, the Secretary of HHS issued a PREP Act declaration identifying BioThrax and Anthrivig as covered countermeasures. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct. Upon a declaration by the Secretary of HHS, a compensation fund is created to provide “timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure.” The “covered injuries” to which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer only after they have exhausted their remedies under the compensation program. Therefore, a willful misconduct action could be brought against us if any individuals exhaust their remedies under the compensation program and thereby expose us to liability.

Our prior contracts with the DoD and HHS provided that the U.S. government would indemnify us for any damages resulting from product liability claims. However, our current contracts with HHS do not contain such indemnification, and we may not be able to negotiate similar indemnification provisions in future contracts.

Product liability lawsuits could cause us to incur substantial liabilities and require us to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the sale of BioThrax and any other products that we successfully develop and the testing of our product candidates in clinical trials. For example, we have been a defendant in lawsuits filed on behalf of military personnel who alleged that they were vaccinated with BioThrax by the DoD and claimed damages resulting from personal injuries allegedly suffered because of the vaccinations. The plaintiffs in these lawsuits claimed different injuries and sought varying amounts of damages. Although we

successfully defended these lawsuits, we cannot ensure that we will be able to do so in the future.

If we cannot successfully defend ourselves against future claims that our product or product candidates caused injuries and if we are not entitled to indemnity by the U.S. government, or if the U.S. government does not honor its indemnification obligations, we may incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- withdrawal of a product from the market;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently have product liability insurance for coverage up to a $30 million annual aggregate limit with a deductible of $75,000 per claim up to $375,000 in aggregate. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. 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 any liability that may arise. For example, from 2002 through February 2006, we were unable to obtain product liability insurance for sales of BioThrax on commercially reasonable terms. We do not believe that the amount of insurance we have been able to obtain for BioThrax is sufficient to manage the risk associated with the potential large scale deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on statutory protections in addition to insurance to help mitigate our liability exposure for BioThrax.

A successful product liability claim or series of claims brought against us could cause our stock price to fall and could decrease our financial resources and materially and adversely affect our business.

If we are unable to obtain adequate reimbursement from governments or third party payors for any products that we may develop or to obtain acceptable prices for those products, our revenues will suffer.

Our revenues and profits from any products that we successfully develop, other than with respect to sales of our biodefense products under government contracts, will depend heavily upon the availability of adequate reimbursement for the use of such products from governmental and other third party payors, both in the U.S. and in other markets. Reimbursement by a third party payor may depend upon a number of factors, including the third party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining a determination that a product is covered is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to gain coverage.

Even when a payor determines that a product is covered, the payor may impose limitations that preclude payment for some uses that are approved by the FDA or comparable authorities but are determined by the payor to not be medically reasonable and necessary. Moreover, eligibility for coverage does not imply that any product will be

covered in all cases or that reimbursement will be available at a rate that permits the health care provider to cover its costs of using the product.

We expect that the success of some of our Biosciences vaccine product candidates for which we obtain marketing approval will depend on inclusion of those product candidates in government immunization programs. Most non-pediatric commercial vaccines are purchased and paid for, or reimbursed by, managed care organizations, other private health plans or public insurers or paid for directly by patients. In the U.S., pediatric vaccines are funded by a variety of federal entitlements and grants, as well as state appropriations. Foreign governments also commonly fund pediatric vaccination programs through national health programs. In addition, with respect to some diseases affecting the public health generally, particularly in developing countries, public health authorities or non-governmental, charitable or philanthropic organizations fund the cost of vaccines.

Medicare Part B reimburses for physician-administered drugs and biologics based on the product's "average sales price." This reimbursement methodology went into effect in 2005 and has generally led to lower Medicare reimbursement levels than under the reimbursement methodology in effect prior to that time. The Medicare Part D outpatient prescription drug benefit went into effect in January 2006. Coverage under Medicare Part D is provided primarily through private entities, which act as plan sponsors and negotiate price concessions from pharmaceutical manufacturers.

Our future revenues and profitability will be adversely affected if third party payors do not sufficiently cover and reimburse the cost of future drug products we may market. If these entities do not provide coverage and reimbursement for our products, or if they provide an insufficient level of coverage and reimbursement, our products may be too costly for use, and physicians may not prescribe them or may prescribe them less frequently. In this manner, levels of reimbursement for drug products by government authorities, private health insurers and other organizations, such as Health Maintenance Organizations, may have a material adverse effect on our business, financial condition, cash flows and results of operations.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably and increase competition.

In both the U.S. and in foreign jurisdictions, legislative and regulatory actions may reduce the revenues that we derive from our future products. In particular, in March 2010, Congress enacted sweeping legislation to reform the U.S. health care system. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, contains a number of cost-containment measures that could adversely affect our operating results and our overall financial condition. For example, the legislation imposes an annual fee on branded prescription drug manufacturers, including biologics manufacturers, which will be allocated based on market share in the aggregate for certain government programs. In addition, the legislation creates a licensure pathway for biological products shown to be biosimilar to previously licensed biological reference products and will permit litigation of patent infringement cases between patent owners and biosimilar manufacturers prior to biosimilar market entry. The legislation also establishes a program to phase out the coverage gap under Medicare Part D by 2020 through a combination of manufacturer discounts and federal subsidies, increases the minimum Medicaid drug rebates for pharmaceutical companies and creates an Independent Payment Advisory Board to recommend changes in Medicare payment rates.

We expect the reforms imposed by the new law to have a significant impact on our business and the entire life sciences industry. Until many of the provisions are implemented, however, the full impact of the legislation cannot be known. Our results of operations could be adversely affected by current and potential future healthcare reforms.

Certain products we may develop may be eligible for reimbursement under Medicaid. If the state-specific Medicaid programs do not provide adequate coverage and reimbursement for any products we may develop, it may have a negative impact on our operations.

The scope of coverage and payment policies varies among third party private payors, including indemnity insurers, employer group health insurance programs and managed care plans. These third party carriers may base their coverage and reimbursement on the coverage and reimbursement rate paid by carriers for Medicaid beneficiaries. Furthermore, many such payors are investigating or implementing methods for reducing health care costs, such as the establishment of prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by health care providers. If third party payors do not provide adequate coverage or reimbursement for any products we may develop, it could have a negative effect on our revenues and results of operations.

Foreign governments tend to impose strict price controls, which may adversely affect our revenues.

In some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could force us to lower the prices at which we sell any approved products and impair our ability to derive revenue from these products.

Legislation has been introduced into Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the U.S., which may include re-importation from foreign countries where the drugs are sold at lower prices than in the U.S. Such legislation, or similar regulatory changes, could decrease the price we receive for any approved products which, in turn, could adversely affect our operating results and our overall financial condition.

If we fail to attract and retain senior management and key scientific and technical personnel, we may be unable to sustain or expand our BioThrax operations or develop or commercialize our product candidates.

Our success depends on our continued ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel. We consider Fuad El-Hibri, executive chairman of our Board of Directors and our former chief executive officer, and Daniel J. Abdun-Nabi, a member of our Board of Directors and our president and chief executive officer, to be key to our BioThrax operations and our efforts to develop and commercialize our product candidates. Mr. Abdun-Nabi succeeded Mr. El-Hibri as our chief executive officer on April 1, 2012. Mr. El-Hibri continues to serve as executive chairman of the Board of Directors. Both of these key employees are at will employees and can terminate their employment at any time. We do not maintain “key person” insurance on any of our employees.

In addition, our growth will require us to retain and hire a significant number of qualified technical and commercial and management personnel, including scientific, clinical development, manufacturing and process development, regulatory, marketing and sales executives and field sales personnel, as well as administrative personnel. Our ability to achieve our business strategies, including advancing drug candidates through later stage development or commercialization, depends on our ability to hire and retain high caliber scientists and other qualified personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

Risks Related to Our Acquisition Strategy

If we fail to successfully manage any acquisition, our ability to develop our product candidates and expand our product candidate pipeline may be harmed.

As part of our business strategy, we have obtained development stage product candidates and intend to continue to seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties. The failure to adequately address the financial, operational or legal risks of these transactions could harm our business. Financial aspects of these transactions that could alter our financial position, reported operating results or stock price include:

§ use of cash resources;
§ higher than anticipated acquisition costs and expenses;
§ potentially dilutive issuances of equity securities;
§ the incurrence of debt and contingent liabilities, impairment losses or restructuring charges; and
§ amortization expenses related to intangible assets.

We also may face significant challenges in effectively integrating entities and businesses that we acquire, and we may not realize the benefits anticipated from such acquisitions or realize them in the predicted timeframe. Achieving the anticipated benefits of any acquired entities or businesses will depend in part upon whether we can integrate them in an efficient and effective manner. Operational risks that could harm our existing operations or prevent realization of anticipated benefits from these transactions include:

§ challenges associated with managing an increasingly diversified business;
§ prioritization of product portfolios and related changes in resources available to each product portfolio;
§ disruption of our pre-acquisition business;
§ greater administrative burdens and operating costs;
§ difficulty and expense in assimilating and integrating the operations, products, technology, information systems, culture or personnel of the acquired entities or businesses;
§ potential loss of key collaborators;
§ difficulty in entering markets in which we have limited or no direct experience;
§ diversion of management's time and attention from other business concerns;
§ difficulty in implementing uniform standards, controls, procedures and policies;
§ the assumption of known and unknown liabilities of the acquired entities or businesses;
§ increased exposure to uncertainties inherent in developing and commercializing new products;
§ impairment of acquired intangible assets as a result of technological advances or worse-than-expected clinical results or performance of the acquired company or the partnered assets;
§ challenges and costs associated with reductions in work force; and
§ potential loss of key personnel.

If we are unable to integrate acquired entities and businesses successfully, our ability to develop new products and continue to expand our product pipeline may be limited and we may experience material adverse consequences to our business, financial condition or results of operations.

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

Since our inception we have pursued a strategy of growing our business through licensing and acquisition. We commenced operations in September 1998 through an acquisition of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how, all from the Michigan Biologic Products Institute. We acquired vaccine and therapeutic product candidates through our acquisition of Microscience Limited in 2005, our acquisition of substantially all of the

assets of ViVacs GmbH in 2006, our acquisition of Trubion Pharmaceuticals, Inc. in October 2010 and our acquisition of certain assets of Vaxgen, Inc. in 2008, Avanir Pharmaceuticals, Inc. in 2008 and TenX BioPharma, Inc. in May 2011. We have been unsuccessful in our efforts to develop and commercialize many of the product candidates acquired by these acquisitions.

In the future, we may be unable to license or acquire suitable products or product candidates from third parties for a number of reasons. A number of more established companies are also pursuing strategies to license or acquire products in the vaccine and therapeutic field and these established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, we expect competition for acquisition candidates in the vaccine and therapeutic field to increase, which may result in fewer suitable acquisition opportunities for us, as well as higher acquisition prices. Other factors that may prevent us from licensing or otherwise acquiring suitable products and product candidates include the following:

§ we may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return on the investment;
§ companies that perceive us to be their competitor may be unwilling to assign or license their product rights to us; or
§ we may be unable to identify suitable products or product candidates within our areas of expertise.

Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote resources to potential acquisitions that are never completed. If we are unable to successfully obtain rights to suitable products and product candidates and manage the risks and costs of pursuing an acquisition strategy, our business, financial condition and prospects for growth could suffer.

We may fail to manage our growth and increased breadth of our activities effectively.

We have expanded the scope of our business in recent years. We have acquired several drug candidates and have been advancing pre-clinical and multiple clinical stage product candidates. We plan to continue adding products and product candidates through internal development, in-licensing and acquisition over the next several years and to continue developing our existing product candidates that demonstrate the requisite efficacy and safety to advance into and through clinical trials. To manage the existing and planned future growth and the increasing breadth and complexity of our activities, we have grown our employee base substantially and will need to continue building our organization and making additional investments in personnel, infrastructure, information management systems and resources. Our ability to develop and advance the commercialization of our products and product candidates, achieve our research and development objectives, add and integrate new products, and satisfy our commitments under our collaboration and acquisition agreements depends on our ability to respond effectively to these demands and expand our internal organization and infrastructure to accommodate our growth and additional anticipated growth. If we are unable to manage and advance these activities effectively, our ability to operate our business successfully and maximize the value of our product or our product candidates could suffer, which could materially and adversely affect our business, financial condition and prospects for future growth.

Risks Related to Regulatory Approvals

If we and our collaborative partners are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us

and our collaborators 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.

Securing FDA approval requires the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to establish the product candidate's safety and efficacy. Our future products may not be effective, may be only moderately effective or may prove to have significant side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

In the United States, BioThrax and our product candidates are regulated by the FDA as biologics. To obtain approval from the FDA to market our product candidates, 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 effectiveness 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. For example, this will be the case with respect to any BLA that we may file in the future with respect to our oncology and auto-immune disease product candidates. However, our biodefense product candidates require slightly different treatment. Specifically, because humans are rarely exposed to anthrax toxins under natural conditions, and cannot be intentionally exposed, statistically significant effectiveness of our biodefense product candidates cannot be demonstrated in humans, but instead may be demonstrated, in part, by utilizing animal models before they can be approved for marketing. This is known as the FDA's "animal rule".

We intend to use the animal rule in pursuit of FDA approval of Anthrivig, PreviThrax, Thravixa, NuThrax and BioThrax as a post-exposure prophylaxis, or PEP. We cannot guarantee that the FDA will permit us to proceed with licensure of any of our BioThrax related programs or our other 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 for approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products.

The process of obtaining 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 candidates involved. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review for a submitted product application, 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 for 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.

Our products could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any vaccine and therapeutic product 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. As an approved product, BioThrax is subject to these requirements and ongoing review.

These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents and recordkeeping. The FDA enforces its cGMP and other requirements through periodic

unannounced inspections of manufacturing facilities. The FDA is authorized to inspect manufacturing facilities without a warrant or prior notice at reasonable times and in a reasonable manner.

The FDA conducted six routine, biannual inspections of our Lansing facilities with the most recent being in August 2011. Following each of these inspections, the FDA issued inspectional observations on Form FDA 483, some of which were significant. We responded to the FDA regarding the inspectional observations relating to each inspection and, where necessary, implemented corrective action. All observations from inspections prior to 2011 have been successfully closed out. We have implemented corrective action where necessary in response to the FDA observations during the August 2011 inspection and we anticipate that all observations from the 2011 inspection will also be successfully closed out. If in connection with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, or if the FDA is not satisfied with the corrective actions we take in connection with any such inspection, the FDA may undertake enforcement action against us.

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. Later discovery of previously unknown problems with our products or manufacturing processes, or failure to comply with regulatory requirements, may result in:

§ restrictions on the marketing or manufacturing of a product;
§ warning letters;
§ withdrawal of the product from the market;
§ refusal to approve pending applications or supplements to approved applications;
§ voluntary or mandatory product recall;
§ fines or disgorgement of profits or revenue;
§ suspension or withdrawal of regulatory approvals, including license revocation;
§ shut down, or substantial limitations of the operations in, manufacturing facilities;
§ refusal to permit the import or export of products;
§ product seizure; and
§ injunctions or the imposition of civil or criminal penalties.

If we experience any of these post-approval events, our business, financial condition and operating results could be materially and adversely affected.

If our competitors are able to obtain orphan drug exclusivity for any products that are competitive with our products or if we fail to maintain orphan drug status for our product candidates we may be precluded from selling or obtaining approval of our competing products by the applicable regulatory authorities for a significant period of time.

If one of our competitors obtains orphan drug exclusivity for an indication for a product that competes with one of the indications for one of our product candidates before we obtain orphan drug designation, and if the competitor’s product is the same drug as ours, the FDA would be prohibited from approving our product candidate for the same orphan indication unless we demonstrate that our product is clinically superior or the FDA determines that the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the drug. We have obtained orphan drug status from the FDA for Anthrivig, Thravixa, TRU-016 (CLL indication), and zanolimumab (CTCL indication), and in the European Union for Anthrivig, Thravixa and our tuberculosis vaccine product candidate. None of our other products or product candidates have been designated as an orphan drug and there is no guarantee that the FDA will grant such designation in the future. Even if we obtain orphan drug exclusivity for one or more indications for one of our product candidates, we may not be able to maintain it. For example, if a competitive product that is the same drug or biologic as our product is shown to be clinically superior to our product, any orphan drug exclusivity we may have obtained will not block the approval of that competitive product.

The Fast Track designation for our product candidates may not actually lead to a faster development, regulatory review or approval.

We have obtained a Fast Track designation from the FDA for BioThrax as a PEP against anthrax infection and for Anthrivig, Thravixa and zanolimumab for CTCL. However, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw a Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical development program. Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the FDA's expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

Failure to obtain regulatory approval in international jurisdictions could prevent us from marketing our products abroad.

We intend to have some or all of our products marketed outside the United States. To market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. With respect to some of our product candidates, we expect that a future collaborator may have responsibility to obtain regulatory approvals outside the United States, and in that case, we would depend on our collaborator to obtain these approvals. The approval procedure varies among countries and can involve additional testing and data review. The time required to obtain approval may differ from that required to obtain FDA approval.

The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval, or may include different or additional risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in another jurisdiction, including approval by the FDA. For example, a provision of the European Pharmacopoeia may prevent use of our preferred cell line for the manufacture of our Tuberculosis vaccine product candidate in the European Union unless such provision can be interpreted in a manner consistent with our product candidate's manufacturing process, despite the fact that the FDA had provided recent guidance to the contrary. We are continuing to work with the United Kingdom Medicines and Healthcare products Regulatory Agency and outside advisors to clarify the provision but we cannot be certain that our efforts will be successful, which could preclude our ability to commercialize this product candidate in the European Union. We and our collaborators may not be able to obtain regulatory approvals to commercialize our products in any market. The failure to obtain regulatory approval in foreign jurisdictions could materially harm our business.

Risks Related to Our Dependence on Third Parties

We may not be successful in maintaining and establishing collaborations, which could adversely affect our ability to develop and commercialize our product candidates domestically and internationally.

For each of our product candidates, we plan to evaluate the merits of retaining commercialization rights or entering into collaboration arrangements with leading pharmaceutical or biotechnology companies or non-governmental organizations. We expect that we will selectively pursue collaboration arrangements in situations in which the collaborator has particular expertise or resources for the development or commercialization of our products and product candidates or for accessing particular markets.

If we are unable to reach agreements with suitable collaborators, we may fail to meet our business objectives for the affected product or program. We face, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and

implement. We may not be successful in our efforts to establish, implement and maintain collaborations or other alternative arrangements, or the arrangements that we establish may not turn out to be productive or beneficial for us. The terms of any collaboration or other arrangements that we establish may not be favorable to us.

Any collaboration that we enter into may not be successful and the success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. It is likely that our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations.

The risks that we are subject to in our current collaborations, and anticipate being subject to in future collaborations, include the following:

- we may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of product candidates;
- our collaborators may delay clinical trials, design clinical trials in a manner with which we do not agree, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new version of a product candidate for clinical testing;
- our collaboration agreements are likely to be for fixed terms and may be subject to termination by our collaborators;
- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not do so, our ability to maintain and defend our intellectual property rights may be compromised by our collaborators' acts or omissions;
- our collaborators may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;
- our collaborators may decide not to pursue further development and commercialization of products and product candidates resulting from the collaboration, or may elect to discontinue research and development programs, which could delay development and increase the cost of developing our product candidates;
- our collaborators may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;
- we may experience difficulties in the day-to-day activities required by collaboration including close and frequent communications between several different teams, technology transfer and a collaborative sharing of responsibilities;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- our collaborators may experience financial difficulties;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations; and
- our collaborators could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

Any of these potential outcomes could harm our business reputation and adversely affect us financially including by resulting in lower than expected revenues or increased development costs, delaying development, leading to a loss of market opportunities or impairing the value of the related product candidate.

If third parties on whom we rely for clinical or non-clinical trials 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 or non-clinical trials required to obtain regulatory approval for our products. 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. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as current Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. We 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. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult. If we must replace any contract research organization, our trials may have to be suspended until we find another contract research organization that offers comparable services. The time that it takes us to find alternative organizations may cause delay in the commercialization of our product candidates or may cause us to incur significant expenses to replicate data that may be lost. Although we do not believe that the contract research organizations on which we rely offer services that are not available elsewhere, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost. Any delay in or inability to complete our clinical trials could significantly compromise our ability to secure regulatory approval of the relevant product candidate and preclude our ability to commercialize the product, thereby limiting our ability to generate revenue from the sales of product candidates, which may result in a decrease in our stock price. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates.

In addition, in certain cases, we encourage government entities and non-government organizations to conduct studies of, and pursue other development efforts for, our product candidates. For example, we expect to rely on data from clinical trials conducted by third parties seeking marketing approval for certain of our product candidates, including our BLA supplement for a label expansion of BioThrax for a regimen of fewer doses, which is based on the results of a clinical trial conducted by the CDC. 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. In addition, government entities depend on annual Congressional appropriations to fund these development efforts.

We face potential liability related to the privacy of health information we obtain from research institutions.

Most health care providers, including research institutions from which we or our collaborators obtain patient information, are subject to privacy regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA. Our clinical research efforts are not directly regulated by HIPAA. However, conduct by a person that may not be prosecuted directly under HIPAA's criminal provisions could potentially be prosecuted under aiding and abetting or conspiracy laws. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we receive individually identifiable health information from a health care provider or research institution that has not satisfied HIPAA's disclosure standards. In addition, international data protection laws including the European Union Data Protection Directive and member state implementing legislation may apply to some or all of the clinical data obtained outside of the U.S. Furthermore, certain privacy laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our use and dissemination of individuals' health information.

Moreover, patients about whom we or our collaborators obtain information, as well as the providers who share this information with us, may have contractual rights that limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Risks Related to Our Intellectual Property

Protection of our intellectual property rights could be costly, and if we fail to protect them, our business could be harmed.

Our success, particularly with respect to the Biosciences portion of our business, will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property covering or incorporated into our technology, products and product candidates, including those which are the subject of collaborations. Obtaining and maintaining this protection is very costly. The patentability of technology in the field of vaccine and therapeutic development and other pharmaceuticals 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 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. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, or result in costly defense measures.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, we know that other entities have filed patent applications in various jurisdictions that relate to several areas in which we are developing products. Some of these patent applications have already resulted in patents and some are still pending. If use of technology incorporated into or used to produce our product candidates is challenged, or if our processes or product candidates conflict with patent rights of others, third parties could bring legal actions against us in Europe, the U.S. and elsewhere claiming damages and seeking to enjoin manufacturing and marketing of the affected products. Further, patents generally expire, regardless of their date of issue, 20 years from the earliest claimed non-provisional filing date. As a result, the time required to obtain regulatory approval for a product candidate may consume part or all of the patent term. We are not able to accurately predict the remaining length of the applicable patent term following regulatory approval of any of our product candidates.

Should third parties file patent applications or obtain patents claiming technology also claimed by us in pending applications, we may be required to participate in deviation proceedings in the U.S. Patent and Trademark Office to determine inventorship, which could result in substantial costs to us and an adverse decision as to the inventorship, and therefore ownership, of our inventions. An unfavorable outcome in a deviation proceeding could require us to cease using the technology or to license rights from prevailing third parties. We cannot assure you that any prevailing party would offer us a license or that we could acquire any license made available to us on commercially acceptable terms.

The cost of litigation to uphold the validity of patents to prevent infringement or to otherwise protect our proprietary rights could be substantial. Some of our competitors may be better able to sustain the costs of complex patent litigation because they may have substantially greater resources. Intellectual property lawsuits are expensive and unpredictable and would consume time 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. 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 our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not do so, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties. For example, we license an oligonucleotide adjuvant, CPG 7909, for use in NuThrax from Pfizer. One of the licensed U.S. patents has been revoked by the U.S. Patent and Trademark Office, as a result of a patent interference between Pfizer and a third party.

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.

If we are unable to in-license any intellectual property necessary to develop, manufacture or sell any of our product candidates, we will not be successful in developing or commercializing such product candidate.

We expect that we may need to in-license various components or technologies, including, for example, adjuvants and novel delivery systems, for some of our current or future product candidates. We may be unable to obtain the necessary licenses on acceptable terms, or at all. If we are unable to obtain such licenses, we could be prevented or delayed from continuing further development or from commercially launching the applicable product candidate. If we or our collaborators must obtain licenses from third parties, fees must be paid for such licenses, which would reduce the revenues and royalties we may receive on commercialized products.

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. For example, we consider our license from the Oxford-Emergent Tuberculosis Consortium for our tuberculosis vaccine product candidate to be material to our business. 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, in which event we might not be able to market any product that is covered by the licensed patents.

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 BioThrax or the label expansions and improvements that we are pursuing for BioThrax, our only intellectual property protection for BioThrax, other than the BioThrax trademark, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and biological 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.

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 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.

If we infringe or are alleged to infringe intellectual property rights of third parties, we may be limited in our ability to commercialize our products.

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 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 U.S. and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses 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 or our collaborators, we or they could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement or other similar claims, or to avoid potential claims, we or our collaborators 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 or our collaborators 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 or our collaborators are unable to enter into licenses on acceptable terms or if an injunction is granted against us, which could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology and pharmaceutical industries. For example, modified vaccinia Ankara, or MVA,-based vaccines have been the subject of significant intellectual property litigation. Specifically, Bavarian Nordic sued Acambis for patent infringement and other claims arising out of Acambis' importation of an MVA-based smallpox vaccine for biodefense use by the U.S. government. Bavarian Nordic claimed that its patents broadly covered the manufacture of MVA-based biological products and that Bavarian Nordic had rights in the biological materials used by Acambis. That litigation was terminated in July 2007 by a settlement and consent order. Bavarian Nordic subsequently sued Oxford BioMedica PLC, Oxford BioMedica Ltd. and Biomedica Inc., collectively Oxford BioMedica, alleging that Oxford BioMedica has infringed certain Bavarian Nordic U.S. patents by making, using and importing and inducing others to use Oxford BioMedica's experimental drug TroVax®, which is an MVA-based therapeutic cancer vaccine. The lawsuit was settled in January 2010 by agreement between the parties. We are also involved in several patent oppositions filed in the European Patent Office against certain of Bavarian Nordic's patents covering certain aspects of MVA technology. In each of the opposition proceedings, the subject patents have also been opposed by one or more additional parties, including Sanofi Pasteur, Transgene, Baxter, Virbac and Innogenetics. These oppositions have resulted in the European Patent Office narrowing the claims in each of the contested Bavarian Nordic patents, and each is now subject to appeal proceedings before the Technical Board of Appeal of the European Patent Office.

The strain of MVA that we use in our platform technology is a distinct lineage from the strains used by Acambis and Oxford BioMedica; however, we cannot be certain that we will not become the target of an infringement action. We also cannot be certain that the oppositions pending in the European Patent Office will be resolved in our favor. If we are sued for infringement, we could incur expensive legal costs, development delays or other costs and delays that could harm our business.

Risks Related to Information Technology

Disruptions of information technology systems or breaches of data security could adversely affect our business.

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 employees or others—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.

Such disruptions and breaches of security could have a material and adverse effect on our business, prospects, operating results, and financial condition.

Risks Related to Our Common Stock

Fuad El-Hibri, executive chairman of our Board of Directors, has significant influence over us, including through his ability to control the election of the members of our Board of Directors, and could delay or prevent a change of control.

Mr. El-Hibri has the ability to control the election of the members of our Board of Directors through his ownership interests in our significant stockholders. As of April 30, 2012, Mr. El-Hibri was the beneficial owner of approximately 28% of our outstanding common stock. Because Mr. El-Hibri has significant influence over the election of the members of our board, and because of his substantial control of our capital stock, Mr. El-Hibri will likely have the ability to delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial control 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 and may result in conflicts of interest that could cause our stock price to decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us.

Provisions of 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 for election 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 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 publicly-held Delaware 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 our 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 a rights agreement that establishes 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. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through April 30, 2012, our common stock has traded as high as $27.00 per share and as low as $4.40 per share. The stock market in general and the market for biotechnology companies in particular have 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:

§ the success of competitive products or technologies;
§ results of clinical trials of our product candidates or those of our competitors and success in our research and development programs;
§ decisions and procurement policies by the U.S. government affecting BioThrax and our biodefense product candidates;
§ regulatory developments in the U.S. and foreign countries;
§ public concern as to the safety of drugs developed by us or others;
§ announcements of issuances of common stock or acquisitions by us;
§ the announcement and timing of new product introductions by us or others;
§ termination or delay of development program(s) by our collaborative partners, or delay in achievement of collaboration milestones;
§ announcements of technological innovations or new therapeutic products or methods by us or others;
§ acts or omissions of our licensees, collaborators and suppliers;
§ developments or disputes concerning patents or other proprietary rights;
§ the recruitment or departure of key personnel;

- § variations in our financial results or those of companies that are perceived to be similar to us;
- § market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- § general economic, industry and market conditions or other external factors, such as disaster or crisis; and
- § the other factors described in this "Risk Factors" section.

In the past, securities class action litigation often has been instituted following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in potential liabilities, substantial costs and the diversion of management's attention and resources, regardless of whether we win or lose.

We do not anticipate paying any cash dividends in the foreseeable future.

We currently intend to retain our future earnings, if any, to fund the development and growth of our business. Our current 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, even if our business is doing well.

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 8.8 million shares of our common stock outstanding as of April 30, 2012 have the right to require us to register these shares of common stock under specified circumstances.

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

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

Not applicable.

Purchases of Equity Securities

Not applicable.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## ITEM 5. OTHER INFORMATION

Amendment to Consulting Agreement with Robert Kramer

On May 3, 2012, we entered into an amendment, or Amendment, to a consulting agreement, or Consulting Agreement, that we entered into on September 6, 2011 with Robert G. Kramer. Under the Consulting Agreement, Mr. Kramer has provided us with services as interim executive vice president, corporate services division since January 1, 2012, and as interim executive vice president and president, biosciences division from September 2011 to December 2011. Under the terms of the Consulting Agreement, we agreed to pay Mr. Kramer $37,500 per month for his services, to reimburse Mr. Kramer for reasonable out-of-pocket expenses, and to consider Mr. Kramer for a grant of up to 20,000 restricted stock units after approximately one year of service, to be granted in the sole discretion of the compensation committee of our Board of Directors. The Consulting Agreement expires on December 5, 2012. The Amendment, which is dated effective January 1, 2012, sets forth specific goals to be met by Mr. Kramer in 2012 and does not modify or amend any other provisions of the Consulting Agreement.

The foregoing is only a brief description of the terms of the Consulting Agreement and Amendment, does not purport to be complete and is qualified in its entirety by reference to the Consulting Agreement and Amendment filed as Exhibit 10.5 and Exhibit 10.6 to this quarterly report on Form 10-Q.

Pfizer Agreement

Although we have not yet received a notice of termination, Pfizer has notified us of its intent to terminate its license agreement with us for the development and commercialization of therapeutics that bind to CD20, including SBI-087. In a recently completed Phase 2 study in rheumatoid arthritis, SBI-087 met the primary endpoint for efficacy and was generally well-tolerated. However, Pfizer has informed us that SBI-087 did not meet other criteria for advancement defined by Pfizer.

Under the Pfizer agreement, Pfizer holds an exclusive license to develop and commercialize SMIP therapeutics that bind to CD20. Pfizer's financial obligations to us include milestone payments of up to $250.5 million and royalty payments on net sales. These provisions would terminate when the Pfizer agreement terminates. The Pfizer agreement also provides for us to receive low single digit royalty payments from Pfizer on net sales of certain Pfizer biosimilar products directed to CD20, subject to satisfaction of specified conditions. This provision would remain in effect following the Pfizer agreement's effective date of termination.

If the agreement is terminated as we anticipate, the licensed technology would revert to us. However, this technology may be insufficient to enable full commercialization of SBI-087. We do not currently plan to pursue further development of SBI-087 on our own or with a partner and no longer consider the Pfizer agreement to be material to our business.

The foregoing is only a brief description of the terms of the Pfizer agreement, does not purport to be complete and is qualified in its entirety by reference to the agreement that was filed as Exhibit 10.11 to the Form S-1 filed by us with the SEC on October 5, 2006, and the amendments dated November 30, 2006, April 14, 2010 and May 26, 2011, filed as Exhibit 10.12 to the Form 10-K filed by us for the year ended December 31, 2006, Exhibit 10.1 to the Form 10-Q filed by us for the quarter ended June 30, 2010 and Exhibit 10.2 to the Form 10-Q filed by us for the quarter ended June 30, 2011, respectively.

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 Abdun-Nabi
Daniel Abdun-Nabi
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 4, 2012

By: /s/ R. Don Elsey
R. Don Elsey
Sr. Vice President Finance, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Date: May 4, 2012

EXHIBIT INDEX

| Exhibit Number | Description |
|---|---|
| 10.1 | Employment Agreement, effective January 1, 2012, between Emergent Product Development UK Ltd and Dr. Steven Chatfield (incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011 filed with the SEC on March 9, 2012) |
| 10.2 | Modification No. 14 to Contract No. HHS0100200700037C, effective January 3, 2012, between Emergent BioDefense Operations Lansing LLC, formerly known as Emergent BioDefense Operations Lansing Inc., and the Department of Health and Human Services (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011 filed with the SEC on March 9, 2012) |
| 10.3 | Third Amendment to Lease Agreement, dated effective February 27, 2012, between Brandywine Research LLC and the Registrant (incorporated by reference to Exhibit 10.47 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011 filed with the SEC on March 9, 2012) |
| 10.4#† | Solicitation, Offer and Award, dated effective September 30, 2011, from the Centers for Disease Control and Prevention to Emergent BioDefense Operations Lansing LLC |
| 10.5#† | Consulting Agreement, dated effective September 6, 2011, between Emergent BioSolutions Inc. and Robert Kramer |
| 10.6#† | Amendment to Consulting Agreement, dated effective January 1, 2012, between Emergent BioSolutions Inc. and Robert Kramer |
| 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 Linkbase Document |
| 101.DEF | XBRL Taxonomy Definition Linksbase Document |
| 101.LAB | XBRL Taxonomy Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Presentation Linkbase Document |

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language):

(i) Condensed Consolidated Statements of Income for the three months ended March 31, 2012 and March 31, 2011, (ii) Condensed Consolidated Statements of Comprehensive Income for the three months ended March 31, 2012 and 2011 (iii) Condensed Consolidated Balance Sheets at March 31, 2012 and December 31, 2011, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2012 and 2011 and (v) Notes to Consolidated Financial Statements.

In Accordance with Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this Quarterly Report on Form 10-Q is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, is deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

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