Emergent BioSolutions Inc.
Form 10-Q
May 03, 2013

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, 2013

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 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, 2013, the registrant had 36,121,353 shares of common stock outstanding.

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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," "would" and similar 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 contracts 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 existing procurement contracts with the U.S. government;
- our ability to successfully execute our growth strategy and achieve our financial and operational goals;
- our plans to pursue label expansions and other improvements for BioThrax;
- our ability to perform under our development contracts with the U.S. government including for our product candidate PreviThrax™ (Recombinant Protective Antigen Anthrax Vaccine, Purified) and BioThrax in Building 55, our large-scale vaccine manufacturing facility in Lansing, Michigan;
- our ability to obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55;
- 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;
- our ability to selectively enter into new collaborative arrangements;
- 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; 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 this special note and elsewhere 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, 2013 (Unaudited)	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 130,238	$ 141,666
Accounts receivable	62,964	96,043
Inventories	22,148	15,161
Deferred tax assets, net	1,264	1,264
Income tax receivable, net	10,762	-
Prepaid expenses and other current assets	9,703	9,213
Total current assets	237,079	263,347
Property, plant and equipment, net	242,344	241,764
In-process research and development	41,800	41,800
Goodwill	5,502	5,502
Deferred tax assets, net	11,087	11,087
Other assets	573	730
Total assets	$ 538,385	$ 564,230
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 23,871	$ 31,297
Accrued expenses and other current liabilities	1,517	1,603
Accrued compensation	11,675	22,726
Long-term indebtedness, current portion	4,470	4,470
Deferred revenue	2,008	1,811
Total current liabilities	43,541	61,907
Long-term indebtedness, net of current portion	57,187	58,304
Other liabilities	1,852	1,891
Total liabilities	102,580	122,102
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 36,521,011 shares issued and 36,117,853 shares outstanding at March 31, 2013; 36,272,550 shares issued and 35,869,392 shares outstanding at December 31, 2012	36	36
Treasury stock, at cost, 403,158 common shares at March 31, 2013 and December 31, 2012	(5,906)	(5,906)
Additional paid-in capital	232,887	230,964
Accumulated other comprehensive loss	(3,759)	(4,129)

Retained earnings	212,330	220,393
Total Emergent BioSolutions Inc. stockholders' equity	435,588	441,358
Noncontrolling interest in subsidiaries	217	770
Total stockholders' equity	435,805	442,128
Total liabilities and stockholders' equity	$ 538,385	$ 564,230

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,	
	2013 (Unaudited)	2012
Revenues:		
Product sales	$30,359	$34,357
Contracts and grants	12,741	15,954
Total revenues	43,100	50,311
Operating expense:		
Cost of product sales	5,698	7,511
Research and development	30,724	26,246
Selling, general and administrative	20,028	19,492
Impairment of in-process research and development	-	9,600
Loss from operations	(13,350)	(12,538)
Other income (expense):		
Interest income	23	25
Interest expense	(11)	(3)
Other income (expense), net	17	854
Total other income (expense)	29	876
Loss before benefit from income taxes	(13,321)	(11,662)
Benefit from income taxes	(4,516)	(3,640)
Net loss	(8,805)	(8,022)
Net loss attributable to noncontrolling interest	743	1,193
Net loss attributable to Emergent BioSolutions Inc.	$(8,062)	$(6,829)
Loss per share - basic	$(0.22)	$(0.19)
Loss per share - diluted	$(0.22)	$(0.19)
Weighted-average number of shares - basic	35,968,064	36,045,839
Weighted-average number of shares - diluted	35,968,064	36,045,839

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

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

	Three Months Ended March 31,	
	2013	2012
	(Unaudited)	
Net loss attributable to Emergent BioSolutions Inc.	$(8,062)	$(6,829)
Foreign currency translations, net of tax	370	84
Comprehensive loss	$(7,692)	$(6,745)

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,	
	2013	2012
Cash flows from operating activities:	(Unaudited)	
Net loss	$ (8,805)	$ (8,022)
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	2,976	2,712
Depreciation and amortization	4,163	2,373
Current and deferred income taxes	(4,516)	6,944
Non-cash development expenses from joint venture	190	1,212
Change in fair value of contingent value rights	-	(3,005)
Impairment of in-process research and development	-	9,600
Excess tax benefits from stock-based compensation	(1,608)	(1,118)
Other	6	(19)
Changes in operating assets and liabilities:		
Accounts receivable	33,079	30,501
Inventories	(6,987)	(2,658)
Income taxes	(7,918)	(11,154)
Prepaid expenses and other assets	(246)	443
Accounts payable	(4,196)	(1,988)
Accrued expenses and other liabilities	21	(11)
Accrued compensation	(10,982)	(10,895)
Deferred revenue	197	(1,075)
Net cash provided by (used in) operating activities	(4,626)	13,840

Cash flows from investing activities:		
Purchases of property, plant and equipment	(7,679)	(22,329)
Proceeds from sale of assets	-	11,765
Proceeds from maturity of investments	-	1,966
Net cash used in investing activities	(7,679)	(8,598)
Cash flows from financing activities:		
Proceeds from borrowings on long-term indebtedness	-	9,621
Issuance of common stock subject to exercise of stock options	504	242
Excess tax benefits from stock-based compensation	1,608	1,118
Principal payments on long-term indebtedness	(1,117)	(8,203)
Contingent value right payment	-	(1,748)
Restricted cash	-	220
Net cash provided by financing activities	995	1,250
Effect of exchange rate changes on cash and cash equivalents	(118)	32
Net increase (decrease) in cash and cash equivalents	(11,428)	6,524
Cash and cash equivalents at beginning of period	141,666	143,901
Cash and cash equivalents at end of period	$ 130,238	$ 150,425

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, 2012, 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, 2013 and the results of operations, comprehensive loss and cash flows for the three months ended March 31, 2013 and 2012. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

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, 2013			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Investment in money market funds (1)	$31,562	$ -	$ -	$31,562
Total assets	$31,562	$ -	$ -	$31,562

	At December 31, 2012			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Investment in money market funds (1)	$42,720	$ -	$ -	$42,720
Total assets	$42,720	$ -	$ -	$42,720

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

As of March 31, 2013 and December 31, 2012, the Company did not have any transfers between Level 1 and Level 2 assets or liabilities.

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, the Company recorded a decrease in the CVR obligations of $3.0 million due to Pfizer ceasing development of programs related to the CVR milestones and made a $1.7 million CVR payment under the Company's agreement with Abbott. 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, 2013 and December 31, 2012, the Company had no assets or liabilities measured at fair value using significant unobservable inputs (Level 3).

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. For the three months ended March 31, 2013, no assets or liabilities were measured at fair value on a nonrecurring basis. For the year ended December 31, 2012, the Company's SBI-087 in-process research and development ("IPR&D") asset, which was categorized as a level 3 fair value measurement, was the only asset or liability measured at fair value on a nonrecurring basis (see Note 4).

3. Inventories

Inventories consist of the following:

(in thousands)	March 31, 2013	December 31, 2012
Raw materials and supplies	$2,565	$ 2,733
Work-in-process	17,080	9,813
Finished goods	2,503	2,615
Total inventories	$22,148	$ 15,161

4. In-process research and development and goodwill

During the three months ended March 31, 2012, Pfizer terminated its development programs with respect to the Company's SBI-087 product candidate. The Company considered this termination a potential indicator of impairment of the related SBI-087 IPR&D asset, and assessed the fair value of this asset. As part of the assessment, the Company considered the impact of Pfizer's decision, along with the Company's decision to no longer pursue further development of this asset due to reduced overall probability of success and increased development costs for the product candidate. As a result, the Company recorded an impairment charge of $9.6 million during the three months ended March 31, 2012, which represented the entire carrying value of the SBI-087 IPR&D asset. 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.

As a result of the impairment of the SBI-087 IPR&D asset, the Company also performed an analysis of the Biosciences therapeutic reporting unit, which contains all goodwill reported on the Company's consolidated balance sheets for the period ended March 31, 2012. Based on the analysis, the Company concluded that goodwill was not more likely than not impaired and therefore an interim impairment analysis was deemed unnecessary.

5. Equity awards

The following is a summary of stock option award activity under the Second Amended and Restated Emergent BioSolutions Inc., 2006 Stock Incentive Plan (the "2006 Plan") and the Emergent BioSolutions Employee Stock Option Plan (the "2004 Plan"):

	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, 2012	3,550,842	$ 17.07	53,156	$ 8.86	$4,801,378
Granted	812,910	14.67	-	-	
Exercised	(56,499)	8.91	-	-	
Forfeited	(127,786)	18.55	-	-	
Outstanding at March 31, 2013	4,179,467	$ 16.67	53,156	$ 8.86	$2,848,569
Exercisable at March 31, 2013	2,575,695	$ 16.86	53,156	$ 8.86	$2,848,569

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, 2012	715,609	$ 18.41	$11,478,368

Granted	406,454	14.67	
Vested	(291,619)	14.77	
Forfeited	(15,848)	17.16	
Outstanding at March 31, 2013	814,596	$ 16.46	$5,737,280

During the three months ended March 31, 2013, the Company corrected an immaterial prior period error for the three months ended March 31, 2012 of approximately $2.0 million. This immaterial error related to the cash flow presentation of the excess tax benefit attributed to the exercise of non-qualified stock options and restricted stock units. The immaterial error had no impact on the Company's consolidated cash flows, consolidated statements of operations and comprehensive loss or the consolidated balance sheets. The correction of the error is reflected as a reduction of originally reported operating cash flow from operating activities and an increase in originally reported cash flow from financing activities.

6. Variable interest entities

In July 2008, the Company entered into a collaboration with the University of Oxford ("Oxford") and certain Oxford researchers 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 had certain funding and service obligations related to its investment. In February 2013, the Company published clinical trial data which showed its tuberculosis vaccine product candidate did not confer statistically significant protection for the tuberculosis disease or infection in infants from those vaccinated at birth with the Baccile Calmette-Guerin vaccine. As a result of this clinical trial data, the Company is ceasing development work on this product candidate and expects future funding of OETC to be minimal.

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, 2013 and 2012, respectively, assets of $1.3 million and $506,000 and liabilities of $950,000 and $1.8 million related to OETC were included within the Company's consolidated balance sheets. During the three months ended March 31, 2013, OETC incurred net losses of $1.5 million of which $771,000 is included in the Company's consolidated statement of operations. During the three months ended March 31, 2012, OETC incurred net losses of $2.4 million, of which $1.2 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 tuberculosis vaccine product candidate. 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 no value as of December 31, 2012 and March 31, 2013.

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, 2012	$ 441,358	$ 770	$442,128
Non-cash development expenses from variable interest entities	-	190	190
Net loss	(8,062)	(743)	(8,805)
Other	2,292	-	-
Stockholders' equity at March 31, 2013	$ 435,588	$ 217	$435,805

7. 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 Laboratories ("Abbott"), for the joint worldwide development and commercialization of TRU-016. The collaboration agreement was terminated on March 20, 2012 and all rights to TRU-016 and other CD37-directed protein therapeutics under the collaboration agreement reverted back to the Company.

During the three months ended March 31, 2012, the Company recorded revenue of $1.4 million for collaborative research and development services pursuant to the Abbott agreement, which is included in the Company's financial statements of operations as contracts and grants revenue within the Company's Biosciences segment.

Pfizer Inc.

In December 2005, Trubion entered into an agreement (the "Pfizer Agreement") with Wyeth Pharmaceuticals, now a wholly-owned subsidiary of Pfizer, for the development and worldwide commercialization of CD20-directed therapeutics. In September 2012, the Pfizer Agreement was terminated. 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 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. The Company's right to receive royalty payments under the Biosimilar Amendment survives termination of the Pfizer Agreement.

During the three months ended March 31, 2012, the Company recorded revenue of $365,000 for research and development services pursuant to the Pfizer agreement, which is included in the Company's financial statements of operations as contracts and grants revenue within the Company's Biosciences segment.

8. Restructuring

In February 2013, the Company adopted a plan to restructure the operations of Emergent Product Development UK Limited ("EPDU") and OETC. The key driver for this restructuring was the reprioritization of the Company's product development portfolio.

The Company has made estimates and judgments regarding the amount and timing of this restructuring expense and liability, including current and future period termination benefits and other exit costs to be incurred when related actions take place. Severance and other related costs and asset-related charges are reflected within the Company's consolidated statement of income as a component of selling, general and administrative expense. Actual results may differ from these estimates.

The restructuring plan includes a headcount reduction of 14 employees at EPDU, the termination of a facility lease, and the impairment of leasehold improvements and equipment. The Company expects to complete this restructuring in 2013, and estimates that the total cost of the restructuring will be approximately $2.8 million. These estimated costs are detailed below:

(in thousands)	Incurred as of March 31, 2013	Total Expected to be Incurred
Termination benefits	$ 1,840	$ 1,904

Contract termination costs	-	500
Other costs	181	381
Total	$ 2,021	$ 2,785

The Company incurred $2.0 million in restructuring charges during the three months ended March 31, 2013, which is included in selling, general and administrative expense in its statement of operations and is included within the Biosciences segment.

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

(in thousands)	Termination Benefits	Lease Termination Costs	Total
Balance at December 31, 2012	$ -	$ -	$ -
Expenses incurred	1,840	-	1,840
Amount paid	-	-	-
Other adjustments	-	-	-
Balance at March 31, 2013	$ 1,840	$ -	$ 1,840

9. Business interruption insurance recovery

During the three months ended March 31, 2012, the Company recorded $835,000 in insurance recovery related to a power outage at its Lansing, Michigan facility. The insurance recovery is classified in the Company's statement of operations as other income (expense), net.

10. Earnings per share

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

(in thousands, except share and per share data)	Three Months Ended March 31, 2013	2012
Numerator:		
Net loss	$ (8,062)	$ (6,829)
Denominator:		
Weighted-average number of shares—basic	35,968,064	36,045,839
Dilutive securities—equity awards	-	-
Weighted-average number of shares—diluted	35,968,064	36,045,839
Loss per share-basic	$ (0.22)	$ (0.19)
Loss per share-diluted	$ (0.22)	$ (0.19)

Stock options with exercise prices in excess of the average per share closing price during the period are not considered in the calculation of fully diluted earnings per share. For the three month periods ended March 31, 2013 and 2012, approximately 5.0 million and 4.5 million stock options, respectively, 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 operating 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 composed of business units that offer different products and product candidates and are managed separately because they manufacture and develop distinct products and product candidates with different development processes.

The Biodefense division is directed to government-sponsored development and supply of countermeasures against potential agents of bioterror or biowarfare and targets the infectious disease anthrax. 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 is directed to commercial opportunities and primarily targets oncology indications, and consists of two business units, therapeutics and vaccines. 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 activities that are not classified as Biodefense or Biosciences.

	Reportable Segments			
(in thousands)	Biodefense	Biosciences	All Other	Total
Three Months Ended March 31, 2013				
External revenue	$42,159	941	-	43,100
Net income (loss)	4,610	(11,372)	(1,300)	(8,062)
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)

12. Subsequent events

In April 2013, the Company entered into an asset purchase agreement to acquire the Healthcare Protective Products Division of Bracco Diagnostics Inc. for $26.0 million in cash, plus contingent payments based on sales and development milestones. The transaction is expected to close in the third quarter of 2013.

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

Emergent BioSolutions is a specialty pharmaceutical company seeking to protect and enhance life by developing and offering specialized products to healthcare providers and governments for use in addressing medical needs and emerging health threats. For financial reporting purposes, we operate in two business divisions or segments, Biodefense and Biosciences.

Our Biodefense division is directed to government-sponsored development and supply of countermeasures against potential agents of bioterror or biowarfare and primarily targets the infectious disease anthrax. Our programs in this division include 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, as well as investigational product candidates. Operations in this division include biologics manufacturing, regulatory and quality affairs in support of BioThrax and a product development and manufacturing infrastructure in support of our investigational product candidates.

Our Biosciences division is directed to commercial opportunities and primarily targets oncology indications. Our programs in this division include one clinical stage product candidate for chronic lymphocytic leukemia, or CLL, as

well as investigational product candidates and platform technologies. Operations in this division include product development in support of our CLL product candidate, our investigational product candidates, and manufacturing and related infrastructure initiatives in support of our platform technologies.

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, an operating division of the U.S. Department of Health and Human Services, or HHS, to supply up to 44.75 million doses of BioThrax for 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 sales of BioThrax to the U.S. government. Our total revenues from BioThrax sales were $30.4 million and $34.4 million for the three months ended March 31, 2013 and 2012, 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;
§ Large-scale manufacturing for BioThrax;
§ PreviThrax;
§ Thravixa; and
§ To establish a Center for Innovation in Advanced Development and Manufacturing, or CIADM.

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.

In 2009, we purchased a building in Baltimore, Maryland for product development and manufacturing purposes, and have completed 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. In June 2012, we entered into a contract with BARDA, which established us as a CIADM and provides funding for manufacturing and development activities relating to a clinical stage pandemic flu vaccine candidate. In addition, we expect this facility will support future CIADM development and manufacturing, activities for chemical, biological, radiological and nuclear countermeasures as well as our future product development and manufacturing needs. 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.

Financial Operations Overview

Revenues

We are currently a party to a contract with the CDC to supply up to 44.75 million doses of BioThrax to the CDC over a five-year period. The period of performance under the award is from September 30, 2011 through September 29, 2016. The total amount that could be paid to us under the contract is up to $1.25 billion, subject to availability of funding by the U.S. government. To date, the U.S. government has committed approximately $477 million for the procurement of BioThrax doses under this contract. Through March 31, 2013, we have delivered and, upon CDC acceptance, recognized revenue on approximately 10.0 million doses, representing approximately $265 million under this contract.

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

Development Programs	Funding Source	Award Date	Performance Period
Post-Exposure Prophylaxis indication for BioThrax	BARDA	9/2007	9/2007 — 3/2016
NuThrax	NIAID	7/2008	7/2008 — 6/2013
Thravixa	NIAID/BARDA	9/2008	9/2008 — 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
CIADM	BARDA	6/2012	6/2012 — 6/2037

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

Cost of Product Sales

The primary expense that we incur to deliver BioThrax to our customers is manufacturing cost, which primarily consists of fixed costs. These fixed manufacturing costs include facilities and utilities. Variable manufacturing costs for BioThrax consist primarily of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff 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, 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 intend to focus our product development efforts on promising late-stage candidates that we believe satisfy well-defined criteria and seek to utilize collaborations or non-dilutive funding. We plan to limit earlier stage

development activities unless funded by external sources and continue to partner with third parties, such as governments and non-governmental organizations for the funding of all our product development programs. We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development, the number of product candidates under development, the size, structure and duration of any follow-on clinical programs that we may initiate, the costs associated with manufacturing our product candidates on a large-scale basis for later-stage clinical trials, and our ability to use or rely on data generated by government agencies, such as studies involving BioThrax conducted by the CDC.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of 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, accounting and auditing 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 acquire additional product candidates or if we receive marketing approval for our product candidates, we expect that we will increase our spending for marketing and sales activities.

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, 2013. Refer to our Critical Accounting Policies and Estimates section in our Annual Report on Form 10-K for the year ended December 31, 2012 filed with the Securities and Exchange Commission, or SEC.

Results of Operations

Quarter Ended March 31, 2013 Compared to Quarter Ended March 31, 2012

Revenues

Product sales revenues decreased by $4.0 million, or 12%, to $30.4 million for the three months ended March 31, 2013 from $34.4 million for the three months ended March 31, 2012. This decrease in product sales revenues was primarily due to a 14% decrease in the number of doses of BioThrax delivered, primarily attributable to the timing of deliveries to the SNS. Product sales revenues during the three months ended March 31, 2013 consisted of BioThrax sales to the CDC of $29.3 million and aggregate international and other sales of $1.0 million. 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.

Contracts and grants revenues decreased by $3.2 million, or 20%, to $12.7 million in the three months ended March 31, 2013 from $16.0 million in the three months ended March 31, 2012. The decrease in contracts and grants revenues was primarily due to decreased revenues from our agreements with Abbott and Pfizer that terminated during 2012, along with decreased activity and associated revenue from our development contracts with BARDA and NIAID for our NuThrax and Thravixa product candidates and our contract for large-scale manufacturing for BioThrax. Contracts and grants revenues during the three months ended March 31, 2013 consisted of $12.7 million in development contract and grant revenue from NIAID and BARDA. Contracts and grants revenues during the three months ended March 31, 2012 consisted of $14.3 million in development contract and grant revenue from NIAID and BARDA and $1.7 million from Abbott and Pfizer.

Cost of Product Sales

Cost of product sales decreased by $1.8 million, or 24%, to $5.7 million for the three months ended March 31, 2013 from $7.5 million for the three months ended March 31, 2012. This decrease was attributable to the 14% decrease in the number of BioThrax doses delivered coupled with a reduction in the cost per dose associated with an adjustment to certain BioThrax testing specifications that allowed us to sell doses that were previously expensed.

Research and Development Expenses

Research and development expenses increased by $4.5 million, or 17%, to $30.7 million for the three months ended March 31, 2013 from $26.2 million for the three months ended March 31, 2012. This increase primarily reflects

higher contract service costs, and includes increased expenses of $5.0 million for product candidates and technology platform development activities categorized in the Biosciences segment, increased expenses of $75,000 in other research and development, which are in support of central research and development activities, offset by decreased expenses of $601,000 for product candidates and manufacturing development categorized in the Biodefense segment. Net of development contract and grant reimbursements along with the net loss attributable to noncontrolling interests, we incurred research and development expenses of $17.2 million and $9.1 million, respectively, during the three months ended March 31, 2013 and 2012.

Our principal research and development expenses during the three months ended March 31, 2013 and 2012 are shown in the following table:

	Three Months ended March 31,	
(in thousands)	2013	2012
Biodefense:		
Large-scale manufacturing for BioThrax	$4,726	$4,697
BioThrax related programs	2,793	2,464
PreviThrax	4,238	4,503
NuThrax	2,248	2,606
Thravixa	-	533
Other Biodefense	1,652	1,455
Total Biodefense	15,657	16,258
Biosciences:		
Tuberculosis vaccine	3,906	3,231
TRU-016	4,627	2,782
ES414 (formerly T-Scorp)	2,032	416
ES301 (formerly DRACO)	-	1,053
Other Biosciences	2,574	653
Total Biosciences	13,139	8,135
Other	1,928	1,853
Total	$30,724	$26,246

The decrease in spending on Biodefense product candidates, detailed in the table above, was primarily attributable to the timing of development efforts on several programs as we completed various studies and prepared for subsequent studies and trials. The increase in spending for our large-scale manufacturing for BioThrax program was primarily due to the manufacture of consistency lots. The increase in spending for BioThrax related programs was related to clinical studies to support applications for label expansion for BioThrax. The decrease in spending for PreviThrax was primarily due to the timing of model optimization and stability studies. The decrease in spending for NuThrax was primarily due to the timing of clinical and non-clinical trial activities. The spending for Thravixa in 2012 was for clinical trial activities. The increase in spending for our other Biodefense activities was primarily due to increased spending related to manufacturing development, partially offset by decreased spending associated with our double mutant recombinant protective antigen anthrax vaccine and Anthrivig product candidates.

The increase in spending on Biosciences product candidates, detailed in the table above, was primarily attributable to the timing of development efforts. The increase in spending for our tuberculosis vaccine product candidate is related to the timing of costs incurred to complete clinical trial and manufacturing development activities. As a result of clinical trial data published in February 2013, we expect future spending will decrease significantly as we close out our tuberculosis product development efforts. The increase in spending for our TRU-016 product candidate is primarily related to our Phase II CLL clinical trial activities. The increase in spending for our ES414 (formerly T-Scorp) product candidate was primarily due to process development and non-clinical studies. The spending for our ES301 product candidate in 2012 was primarily for process development and non-clinical activities. The increase in

spending for our other Biosciences activities was primarily due to a reduction of the contingent value right, or CVR, obligations associated with our agreement with Pfizer in 2012 and increased spending associated with development of platform technologies, partially offset by decreased spending associated with our preclinical product candidates.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $536,000, or 3%, to $20.0 million for the three months ended March 31, 2013 from $19.5 million for the three months ended March 31, 2012. This increase is primarily due to $2.0 million in costs related to a restructuring of our U.K. operations, partially offset by decreased spending related to professional services. The majority of the selling, general and administrative expenses are attributable to the Biodefense segment, which decreased by $520,000, or 4%, to $14.0 million during the three months ended March 31, 2013 from $14.5 million during the three months ended March 31, 2012. Selling, general and administrative expenses related to our Biosciences segment increased by $1.1 million, or 21%, to $6.1 million during the three months ended March 31, 2013 from $5.0 million during the three months ended March 31, 2012, prinicpally due to the U.K. restructuring charges.

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. The impairment charge for the three months ended March 31, 2012 resulted from the full impairment of our SBI-087 in-process research and development asset. There was no impairment for the three months ended March 31, 2013.

Total Other Income (Expense)

Total net other income decreased by $847,000, or 97%, to net other income of $29,000 for the three months ended March 31, 2013 from $876,000 for the three months ended March 31, 2012. The decrease was primarily due to a business interruption insurance recovery related to a power outage at our Lansing, Michigan facility during the three months ended March 31, 2012.

Income Taxes

Benefit from income taxes increased by $876,000, or 24%, to $4.5 million for the three months ended March 31, 2013 from $3.6 million for the three months ended March 31, 2012. The increase in the benefit from income taxes is primarily due to the $2.1 million increase 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 $450,000, or 38%, to $743,000 for the three months ended March 31, 2013 from $1.2 million for the three months ended March 31, 2012. 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 quarters ended March 31, 2013 and 2012, 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, 2013 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, and the net proceeds from our initial public offering and the sale of our common stock upon exercise of stock options. We have operated profitably for each of the five years ended December 31, 2012.

As of March 31, 2013 we had cash and cash equivalents of $130.2 million. Additionally, at March 31, 2013, our accounts receivable balance was $63.0 million.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2013 and 2012:

	Three Months ended March 31,	
(in thousands)	2013	2012
Net cash provided by (used in):		
Operating activities(1)	$(4,744)	$13,872
Investing activities	(7,679)	(8,598)
Financing activities	995	1,250
Net increase (decrease) in cash and cash equivalents	$(11,428)	$6,524

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

Net cash used in operating activities of $4.7 million for the three months ended March 31, 2013 was principally due to our net loss attributable to Emergent BioSolutions Inc. of $8.1 million, a decrease in income taxes of $12.4 million related to timing differences, a decrease in accrued compensation of $11.0 million primarily related to the payment of 2012 bonuses and a decrease in inventory of $7.0 million primarily related to the timing of deliveries to the SNS, partially offset by a decrease in accounts receivable of $33.1 million due to the timing of collection of amounts billed primarily to CDC and non-cash charges of $3.0 million for stock-based compensation and $4.2 million for depreciation and amortization.

Net cash provided by operating activities of $13.9 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 CVR obligations related to our agreement with Pfizer.

Net cash used in investing activities of $7.7 million for the three months ended March 31, 2013 was primarily due to capital expenditures, and includes construction and renovation of facilities at our Lansing, Michigan campus, and costs of other infrastructure and equipment investments.

Net cash used in investing activities of $8.6 million for the three months ended March 31, 2012 was 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, Maryland buildings of $11.8 million and the maturity of U.S. Treasury securities of $2.0 million.

Net cash provided by financing activities of $995,000 for the three months ended March 31, 2013 was primarily due to $1.6 million in excess tax benefits from the exercise of stock options and $504,000 in proceeds from stock option exercises, partially offset by principal payments on indebtedness of $1.1 million.

Net cash provided by financing activities of $1.3 million for the three months ended March 31, 2012 was primarily due to $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 and $1.1 million related to excess tax benefits from the exercise of stock options, partially offset by $8.2 million in principal payments on indebtedness, including $7.7 million in repayment of indebtedness related to our Frederick, Maryland buildings, and a $1.7 million CVR payment to former Trubion stockholders and option holders.

Debt Financing

As of March 31, 2013, we had $61.7 million principal amount of debt outstanding, comprised primarily of the following:

- $17.8 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;
- $4.1 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;
- $29.0 million outstanding under a construction loan from PNC Bank used to fund the renovations of our Baltimore, Maryland facility; and
- $10.8 million outstanding under an equipment loan from PNC Bank used to fund equipment purchases at our Baltimore, Maryland facility.

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, 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, among others:

- the level, timing and cost of sales of BioThrax and other products;
- the extent to which we acquire or invest in companies, businesses, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities, including Building 55, our large-scale manufacturing facility in Lansing, Michigan, and our manufacturing facility in Baltimore, Maryland;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs; and
- the extent to which we repurchase our common stock under our share repurchase program.

Our ability to borrow amounts under any line of credit we may establish will likely be subject to our satisfaction of specified conditions. 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 or debt offerings, bank loans or collaboration and licensing arrangements. We have an effective shelf registration statement on file with the Securities and Exchange Commission that allows us to issue up to an aggregate of $180 million of equity, debt and certain other types of securities through one or more offerings. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Public or bank 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, pursuing acquisition opportunities or declaring dividends. 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. Current economic conditions may make it difficult to obtain financing on attractive terms, or at all. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

Share Repurchase Program

On May 17, 2012, our board of directors authorized to repurchase from time to time up to an aggregate of $35 million of our common stock under a board-approved share repurchase program. We did not repurchase any shares of our common stock under this program during the three months ended March 31, 2013.

Corporate Headquarters

In March 2013, we terminated an agreement that we entered into in January 2013 to purchase an office building to be utilized as its corporate headquarters. In April 2013, we amended our Rockville headquarters lease agreement to reduce the total amount remaining under the lease agreement and provide for a one-time right to terminate the lease effective January 31, 2014.

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, 2013. 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, 2013, 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, 2013 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

A number of risk factors could cause our actual results to differ materially from those that are indicated by forward-looking statements. You should carefully consider these risk factors in evaluating our business because these risk factors may have a significant impact on our business, financial condition and results of operations. The risks described below are not the only risks we may face. Additional risks and uncertainties not presently apparent to us, or risks that we currently consider immaterial, could also negatively affect our business, financial condition and results of operations.

GOVERNMENT CONTRACTING RISKS

We derive substantially all of our revenue from sales of BioThrax to our principal customer, 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 and Prevention, or CDC, for the supply of up to 44.75 million doses of BioThrax for placement into the Strategic National Stockpile, or SNS, over a five year period ending in September 2016.

The procurement of doses of BioThrax by the CDC is subject to the availability of funding. Our existing contract with the CDC does not guarantee that funding for the procurement of doses will be made available. If the SNS priorities change, funding to procure doses of BioThrax may be limited or not available at all, and our business, financial condition and operating results would be materially harmed. The success of our business and our operating results for the foreseeable future are substantially dependent on the terms of our BioThrax sales to the U.S. government, including the price per dose, the number of doses and the timing of deliveries.

Our U.S. government contracts require ongoing funding decisions by the U.S. government. Reduced or discontinued funding of these contracts, including funding implications of the federal budget sequestration provisions, 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 or acquire. Additionally, a significant source of our revenue is from U.S. government development contracts and grants. 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, generally 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 are 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 and three successive one-year option periods valued at a total of approximately $110 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 would suffer.

In August 2011, Congress enacted the Budget Control Act of 2011, or BCA, committing the U.S. government to significantly reduce the federal deficit over ten years. The BCA contains provisions commonly referred to as "sequestration" which call for substantial, unspecified automatic federal spending cuts that may continue for a period of ten years. In addition, the federal debt ceiling is currently expected to be reached during the first half of 2013. We cannot predict the outcome of the budget process or whether such efforts will result in significant funding delays or cancellation of orders by the U.S. government that may adversely impact our business and results of operations.

The government contracting process is typically a competitive bidding process and involves risks and requirements that are not present in commercial contracting.

We expect that a significant portion of our near-term business will be under government contracts and grants, which may be 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:

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- the commitment of substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- the possibility that we may be ineligible to respond to a request for proposal issued by the government;
- the submission by third parties of protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- in the event our competitors protest or challenge contract or grant awards made to us pursuant to competitive bidding, the potential that we may incur expenses or delays, and that any such protest or challenge would result in the resubmission of bids based on modified specifications, or in the termination, reduction or modification of the awarded contract.

The U.S. government may choose not to award us future contracts for the development 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.

Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws could result in significant civil and criminal penalties and materially damage our relationship with the U.S. government.

We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts. Among the most significant government contracting regulations that affect our business are:

- the Federal Acquisition Regulation, or FAR, and agency-specific regulations supplemental to the FAR, 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, the Procurement Integrity Act, the False Claims Act and the Foreign Corrupt Practices Act;
- 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.

U.S. government agencies routinely audit and investigate government contractors for compliance with applicable laws and standards. If we are audited and such audit were to uncover improper or illegal activities, we could be subject to civil and criminal penalties, administrative sanctions, including suspension or debarment from government contracting, and significant reputational harm.

The amount we are paid under our fixed price government contracts is based on estimates we have made of the time, resources and expenses required for us to perform those contracts. If our actual costs exceed our estimates, we may not be able to earn an adequate return or may incur a loss under these contracts and our net income could be materially reduced.

Our current contract with the CDC for the procurement of BioThrax is a fixed price contract. We expect that our potential future contracts with the U.S. government for BioThrax, as well as contracts for other biodefense products, also may be fixed price contracts. Under a fixed price contract, we are required to deliver our products at a fixed price regardless of the actual costs we incur. Estimating costs that are related to performance in accordance with contract

specifications is difficult, particularly where the period of performance is over several years. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of a fixed price contract or cause a loss, which could harm our operating results and materially reduce our net income.

Unfavorable provisions in government contracts, some of which may be customary, may subject our business to material limitations, restrictions and uncertainties and may have a material adverse impact on or financial condition and operating results.

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

§ terminate existing contracts, in whole or in part, for any reason or no reason;
§ unilaterally reduce or modify contracts or subcontracts, including by imposing equitable price adjustments;
§ cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
§ decline, in whole or in part, to exercise an option to purchase product under a contract or renew a contract;
§ claim rights to facilities or to products, including intellectual property, developed under the contract;
§ require repayment of contract funds spent on construction of facilities in the event of contract default;
§ take actions that result in a longer development timeline than expected;
§ direct the course of a development program in a manner not chosen by the government contractor;
§ suspend or debar the contractor from doing business with the government or a specific government agency;
§ pursue civil or criminal remedies under acts such as the False Claims Act and False Statements Act; and
§ control or prohibit the export of products.

Generally, government contracts, including our CDC contract for procurement of 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 government contractor may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the U.S. government terminates a contract for default, the government contractor is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. 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.

MANUFACTURING RISKS

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

BioThrax and all of our current 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. Problems may arise during manufacturing for a variety of reasons, including problems with raw materials, equipment malfunction and failure to follow specific protocols and procedures. In addition, slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation, filtration, filling, labeling, packaging, storage

and shipping, and quality control testing, may result in lot failures or manufacturing shut-down, delays in the release of lots, product recalls, spoilage or regulatory action. Additionally, as our equipment ages, it will need to be replaced. Replacement of equipment has the potential to introduce variations in the manufacturing process that may result in lot failures or manufacturing shut-down, delay in the release of lots, product recalls, spoilage or regulatory action. Success rates can also vary dramatically at different stages of the manufacturing process, which can reduce yields and increase costs. From time to time, we may experience deviations in the manufacturing process that may take significant time and resources to resolve and if unresolved may affect manufacturing output and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation or regulatory action against us or cause the FDA to cease releasing product until the deviations are explained and corrected, any of which could be costly to us, damage our reputation and negatively impact our business.

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. For example, we must provide the FDA with the results of certain tests, including potency tests, 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 would not be able to release product, and therefore would not be able to sell any more BioThrax doses until the problem was resolved.
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. If we are not able to produce and qualify a new reference lot or otherwise satisfy the FDA's requirements for release of BioThrax, our ability to sell BioThrax would be impaired until such time as we become able to meet the FDA's requirements, which would significantly impact our revenues, require us to utilize our cash balances to help fund our ongoing operations and otherwise harm our business.
We are contractually required to ship BioThrax at a prescribed temperature range, and variations from that temperature range could result in loss of 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.
We are in the process of expanding our manufacturing facilities. Delays in completing our facilities, or delays or failures in obtaining regulatory approvals for our new manufacturing facilities, could limit our ability to expand our revenues.

We have constructed Building 55, a large-scale manufacturing facility on our Lansing, Michigan campus for which we received an award from 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, including projects performed under our contract with BARDA to establish a Center for Innovation in Advanced Development and Manufacturing. The process for qualifying and validating these facilities 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. In addition, if we experience delays, we may be in breach of the obligations under our government funded development contracts. If our qualification, validation and facility licensure activities are delayed, we may not be able to utilize Building 55 to increase our production of BioThrax or manufacture product candidates in our Baltimore facility, which could limit our ability to grow our revenue.

Currently, only our manufacturing facility in Lansing, Michigan has regulatory approval to manufacture BioThrax. A significant interruption of the ability of that facility to manufacture BioThrax would reduce our revenues and materially harm our business, financial condition and operating results.

We currently rely on our manufacturing facility 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 demand of the U.S. government or other BioThrax customers. A number of factors could cause interruptions, including:

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

Providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. The U.S. government has designated our Lansing facility as a facility requiring additional security. However, there can be no assurance that any additional security measures would protect our facility from terrorist efforts determined to disrupt our BioThrax manufacturing activities.

The factors listed above could also cause disruptions at our other facilities, including our research and product development facilities and our additional manufacturing facility in Baltimore, Maryland. Any such disruption, damage, or destruction of our facilities could impede our ability to manufacture BioThrax and our products in development, result in losses and delays, including delay in the performance of our contractual obligations or delay in our clinical trials, any of which could be costly to us and materially harm our business, financial condition and operating results.

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.

We are currently dependent on third party manufacturers for the manufacture of most of our product candidates. Certain of our third party manufacturers currently constitute the sole source of one or more of our product candidates, and we have and will continue to have limited control over the manufacturing process and costs of these product candidates.

Third party manufacturers currently supply a significant amount of our product candidates pursuant to contractual arrangements. Certain manufacturers currently constitute the sole source of several of our product candidates. For example, CMC Biologics is our sole source manufacturer for Thravixa and Grifols our sole source manufacturer for Anthrivig. Because of contractual restraints and the lead-time necessary to obtain FDA approval of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of product candidates for use in clinical trials. As a result, any such delay could adversely affect our ability to satisfy current development contractual requirements and our product development efforts in general.

We have a limited ability to control the manufacturing process or costs related to the third party manufacture of our product candidates. Increases in the prices we pay our manufacturers, interruptions in the supply of our product candidates or lapses in quality could adversely impact our clinical and non-clinical trials, margins, profitability and cash flows. We are reliant on our third party manufacturers to maintain the facilities at which they manufacture our product candidates in compliance with FDA and all other applicable regulatory requirements. If these manufacturers fail to maintain compliance with FDA or other critical regulations, they could be ordered to cease manufacturing, which would have a materially adverse impact on the supply of our product candidates to satisfy the demand for our clinical and non-clinical trials. For example, in 2008, the initial manufacturer of Thravixa informed us it was discontinuing contract manufacturing operations and we were forced to secure an alternative manufacturing source to continue development and trials of this product candidate.

We may be forced to consider entering into additional manufacturing arrangements with other third party manufacturers. In each case, we will incur significant costs in obtaining the regulatory approvals for these third party facilities and in taking the necessary steps to prepare these third parties for the manufacture of our products and product candidates.

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

Our operations involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials on and manufacture our product candidates on our behalf are subject to federal, state, local and foreign laws and regulations that govern 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. Compliance with current or future laws and regulations can require significant costs and we could be subject to substantial fines and penalties in the event of noncompliance. Although we believe that our safety procedures for handling and disposing of these materials comply with regulatory requirements, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials. Any related liability might not be fully covered by insurance, could exceed our resources and could have a material adverse effect on our business. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, Health and Human Services, or HHS, U.S. Department of Agriculture and the Department of Defense, or DoD.

PRODUCT DEVELOPMENT RISKS

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

We have invested significant efforts and financial resources in the development of our vaccines and therapeutic product candidates and the acquisition of additional product candidates. In addition to BioThrax sales, our ability to generate revenue is dependent on the success of our development 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 and other commercial entities in providing grant funding for development of certain

of our product candidates and on the commercial viability of our developed or acquired 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 completion of clinical or non-clinical development, including toxicology studies and studies in approved animal models;
- receipt of marketing approvals from the FDA and equivalent foreign regulatory authorities;
- establishment of commercial manufacturing processes and product supply of our own or arrangements with contract manufacturers;
- establishment of a commercial sales force for the product, whether alone or in collaboration with others; and
- acceptance of the product by potential government customers, physicians, patients, healthcare payors and others in the medical community.

If we are delayed or prevented from developing or commercializing a product candidate in an economically acceptable manner, or if doing so requires us to incur significant unanticipated costs, our growth could be materially and adversely affected.

Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. We must invest substantial amounts of time and financial resources to these trials, which may not yield viable products.

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 and demonstrate the safety and efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing.

For certain of our Biodefense product candidates, we expect to rely on FDA regulations known as the "animal rule" to obtain approval. The animal rule permits, in certain limited circumstances, the use of animal efficacy studies together with human clinical safety and immunogenicity trials to support an application for marketing approval. 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 product candidates in humans. Under the Project BioShield Act of 2004, the Secretary of HHS can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the FDA commisioner to authorize the emergency use of medical products that have not yet been approved by the FDA. If our Biodefense product candidates are not selected under this Project BioShield authority, they generally will have to be approved by the FDA through traditional regulatory mechanisms.

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

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

For example, in February 2013, we announced results of a Phase IIb clinical trial evaluating the safety and efficacy of MVA85A in preventing tuberculosis in infants, which indicated that a single dose of MVA85A is not sufficent to confer statisically significant protection against tuberculosis in infants. As a consequence of these results, we are ceasing further development work on MVA85A.

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

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

In certain cases, government entities and non-government organizations conduct studies of our product candidates, and we may seek to rely on these studies in applying for marketing approval for certain of our product candidates. These government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. Furthermore, government entities depend on annual Congressional appropriations to fund their development efforts.

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

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

We continue to evaluate our business strategy and, as a result, may modify our strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different product candidates or may delay or halt the development of various product candidates. For example, in February 2013, as a consequence of clinical trial results, we determined to cease further development work on our MVA85A tuberculosis vaccine candidate. As a result of changes in our strategy, we may change or refocus our existing product development, commercialization and manufacturing activities. This could require changes in our facilities and our personnel. Any product development changes that we implement may not be successful. In particular, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates. Our decisions to allocate our research and development, management, and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate product development programs may also be incorrect and could cause us to miss valuable opportunities.

RISKS RELATED TO STRATEGIC ACQUISITIONS AND COLLABORATIONS

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

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

Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote resources to potential acquisitions that are never completed. Even if we are successful in acquiring a product or company, it may not result in a successfully developed or commercialized product or, even if an acquired product is commercialized, competing products or technologies could render a product noncompetitive, uneconomical or obsolete. Moreover, the cost of acquiring other companies or in-licensing products could be substantial and in order to acquire companies or new products, we may need to incur substantial debt or issue dilutive securities. If we are unsuccessful in our efforts to acquire other companies or in-license and develop additional products, or if we acquire or in-license unproductive assets, it could have a material adverse effect on the growth of our business.

Our failure to successfully integrate acquired assets into our operations could adversely affect our business.

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

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

§ conforming internal controls, policies and procedures, business cultures and compensation structures;
§ consolidating corporate and administrative infrastructures;
§ consolidating sales and marketing operations;
§ retaining existing customers and attracting new customers;
§ retaining key employees;
§ identifying and eliminating redundant and underperforming operations and assets;
§ coordinating geographically dispersed organizations; and
§ managing tax costs or inefficiencies associated with integrating operations.

If we are unable to successfully integrate our acquisitions with our existing business, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect our business and our ability to develop and introduce new products.

We may not be successful in establishing and maintaining collaborations to leverage our capabilities to develop and commercialize our product candidates.

For each of our product candidates, we plan to evaluate the merits of entering into collaboration arrangements with leading biopharmaceutical companies or non-governmental organizations. We expect to selectively pursue collaboration arrangements with collaborators that have particular technology, expertise or resources for the development or commercialization of our product candidates or for accessing particular markets. We face, and will continue to face, significant competition in seeking appropriate partners for our product candidates. If we are unable to identify partners whose capabilities complement and integrate well with ours and reach collaboration arrangements with such partners on acceptable terms, or if the arrangements we establish turn out to be unproductive for us, we may fail to meet our business objectives for the particular product candidate.

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 any of our collaborations include the following, among others:

- our collaborators may not commit adequate resources to the development, marketing and distribution of any collaboration products, limiting our potential revenues from these products;
- our collaborators may experience financial difficulties and may therefore be unable to meet their commitments to us;
- our collaborators may pursue a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- our collaborators may terminate our relationship.

For example, our previous collaborative partner Pfizer Inc. terminated its collaboration with us for the development of SBI-087 following a portfolio reprioritization process. As a result, we experienced a charge of $9.6 million attributable to impairment of our SBI-087 in-process research and development asset. Similarly, our previous collaborative partner Abbott Laboratories terminated its collaboration with us for the development of TRU-016 following a similar portfolio reprioritization process.

Failure of any of our collaborative partners to perform as expected could place us at a competitive disadvantage and adversely affect us financially, including delay and increased costs of development, loss of market opportunities, lower than expected revenues and impairment of the value of the related product candidate.

REGULATORY AND COMPLIANCE RISKS

Our long term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize product candidates, and if we are not successful, our business and operating results may suffer.

Our product candidates and the activities associated with their development, including testing, manufacture, recordkeeping, storage and approval, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have limited experience in preparing, filing and prosecuting the applications necessary to gain regulatory approvals and expect to rely on third party contract research organizations and consultants to assist us in this process.

In the United States, BioThrax and our product candidates are regulated by the FDA as biologics. To obtain approval from the FDA to market our Biosciences 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. Our Biodefense product candidates are subject to 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 are required 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 Biodefense product candidates under the animal rule. Even if we are able to proceed pursuant to the animal rule, the FDA may decide that our data are insufficient 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 these regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Changes in the regulatory approval process during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review 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.

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

Any vaccine or 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 prior notice at reasonable times and in a reasonable manner. The FDA conducts periodic inspections of our Lansing facilities, most recently in August 2011. Following each of these inspections, the FDA has issued inspectional observations, all of which have been resolved, but some of which were significant. 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, which may include:

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

Similar action may be taken against us upon our failure to comply with regulatory requirements, or later discovery of previously unknown problems with our products or manufacturing processes. If we experience any of these post-approval events, our business, financial condition and operating results could be materially and adversely affected. 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.

Failure to obtain regulatory approval in international jurisdictions could prevent us from marketing our products abroad and could limit the growth of our business.

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. Approval by the FDA does not ensure approval by foreign regulatory authorities. The approval procedure in foreign jurisdictions can vary widely and can involve additional clinical trials and data review. We and our collaborators may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and therefore we may be unable to commercialize our products internationally.

COMMERCIALIZATION RISKS

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

An element of our business strategy is to establish a market for the sale of BioThrax to customers in addition to the U.S. government. These potential customers include foreign governments, multinational companies, non-governmental organizations and hospitals, as well as domestic state and local governments, which we anticipate may be interested in BioThrax.

The market for sales of BioThrax to customers other than the U.S. government is undeveloped, and we may not be successful in generating interest or meaningful sales of BioThrax to these potential customers. To date, we have supplied only small amounts of BioThrax directly to foreign governments and these sales represent a small portion of our revenue.

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 our supplies of BioThrax available for sale to non-U.S. government customers. For example, our efforts to further 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.

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

Products developed to treat diseases caused by or to combat the threat of bioterrorism are subject to changing political and social environments. The political responses and social awareness of the risks of bioterrorism attacks on military personnel or civilians may vary over time. We do not believe that 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. This perception, as well as political or social pressures, could delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, any of which could negatively affect our revenues.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Lawsuits brought against us by third parties or activists, even if not successful, could require us to spend significant management time and financial resources defending the related litigation and could potentially damage the public's perception of us and our products. 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 our license for BioThrax and 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 created negative publicity about BioThrax. Additional lawsuits, publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of BioThrax and thereby limit the demand for BioThrax and any of our other Biodefense product candidates, which would adversely affect our revenues.

We have a small sales and marketing group with limited experience commercializing products, other than BioThrax. 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.

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 acquire or develop. This small sales group would not be capable of supporting sales efforts for our Biosciences product candidates, which we intend to market through arrangements with collaborative partners or third parties able to perform these services for us. We may encounter difficulties in retaining such third-parties with appropriate commercialization capabilities at an acceptable cost, and we will rely, in whole or in part, on the marketing capabilities of those third parties. If we are not successful in our efforts to establish appropriate arrangements with collaborative partners or other third parties, our ability to sell any of our product candidates that we successfully develop or acquire will be limited, which could negatively impact our revenue from sales of such products.

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, any products that we acquire, our current product candidates and any products we may seek to develop or commercialize in the future from other biopharmaceutical companies and governments, universities and other non-profit research organizations, who are increasingly aware of the commercial value of their research. Our competitors may develop products that are safer, more effective, more convenient or less costly than any products that we may develop or market. Our competitors may devote greater resources to market or sell their products, adapt more quickly to new technologies and scientific advances, initiate or withstand substantial price competition more successfully than we can, or more effectively negotiate third-party licensing and collaborative arrangements.

In addition, there are a number of companies with anthrax therapeutic products or product candidates competing with us for both U.S. government procurement and development resources. For example, in terms of additional procurement of licensed countermeasures, HHS awarded a development and SNS procurement contract to GlaxoSmithKline, or GSK, for an anthrax monoclonal antibody therapeutic. In addition, HHS has assisted another company in its production efforts by providing it with BioThrax doses that we delivered for placement into the SNS so the competitor could immunize donors and obtain plasma for its anthrax immune globulin product candidate.

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 Soligenix, Pfenex, Dynport Vaccine Company, Elusys, Bavarian Nordic and PharmAthene. With respect to the protein therapeutics we are developing, we are aware of existing products and products in research or development by others that address the diseases we are targeting. Any of these products may compete with our product candidates.

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

INTELLECTUAL PROPERTY RISKS

If we are unable to protect our proprietary rights, 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. 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.

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 financial resources. Intellectual property lawsuits are expensive and unpredictable and would consume time and other resources, including the attention of our management, 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 related to CPG 7909 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.

Third parties may choose to file patent infringement claims against us; defending ourselves from such allegations would be costly, time-consuming, distracting to management and could be materially adverse to our business.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents and other intellectual property rights of third parties under which we do not hold 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 may have substantially greater financial resources than us and could bring claims against us that would cause us to incur substantial expenses to defend against these claims and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement or other similar suit were brought against us, we could be forced

to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit. Intellectual property litigation in the pharmaceutical industry is common, and we expect this trend to continue.

As a result of patent infringement or other similar claims, or to avoid potential claims, we may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms or if an injunction is granted against us, which could harm our business significantly.

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

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, 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 cyber security breach, or may be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

FINANCIAL RISKS

Our current indebtedness and any additional debt financing may restrict the operation of our business and limit cash flow available to invest in the ongoing needs of our business.

As of March 31, 2013, we had $61.7 million principal amount of debt outstanding. We may seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing could have significant adverse consequences for our business, including:

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

- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing;
- requiring us to pledge our assets as collateral, which could limit our ability to obtain additional debt financing;
- limiting our flexibility in planning for, or reacting to, general adverse economic and industry conditions; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

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

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

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

As of March 31, 2013, we had $193.3 million of cash, cash equivalents and accounts receivable. Our future capital requirements will depend on many factors, including, among others:

- the level, timing and cost of sales of BioThrax and other products;
- the extent to which we acquire or invest in companies, businesses, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities, including Building 55, our large-scale manufacturing facility in Lansing, Michigan, and our manufacturing facility in Baltimore, Maryland;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs; and
- the extent to which we repurchase our common stock under our share repurchase program.

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements. We have an effective shelf registration statement on file with the Securities and Exchange Commission that allows us to issue up to an aggregate of $180 million of equity, debt and certain other types of securities through one or more future offerings. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Public or bank 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, pursuing acquisition opportunities or declaring dividends. 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.

Current economic conditions may make it difficult to obtain financing on attractive terms, or at all. If financing is unavailable or lost, our business, results of operations and financial condition would be adversely affected and we

could be forced to delay, reduce the scope of or eliminate many of our planned activities.

We have a substantial amount of debt that we may not be able to extend, refinance or repay on favorable terms or at all.

As of March 31, 2013, we have $61.7 million principal amount of debt outstanding, including balloon payments of $3.5 million due in November 2014 and $15.3 million due in December 2014. We will need to extend, refinance or satisfy this debt as it matures. We may not be able to refinance our maturing debt on favorable terms, or at all, based on general economic or market conditions, our historical or projected growth or other factors, including those beyond our control. If our cash flow from operations or other liquidity sources are not sufficient to make required interest payments or we are not able to refinance maturing debt on favorable terms, we may have to take actions such as seeking additional equity or debt capital on commercially unreasonable terms or modifying or delaying execution of our business strategy.

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 both 2012 and 2013. Our profitability is substantially dependent on BioThrax product sales, which historically have fluctuated significantly from quarter to quarter, and we expect that they will continue to fluctuate significantly based primarily on the timing of our fulfillment of orders from the U.S. government. 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.

OTHER BUSINESS RISKS

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

We face an inherent risk of product liability exposure related to the sale of BioThrax, any other products that we successfully develop or acquire 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. Although we successfully defended these lawsuits, we cannot ensure that we will be able to do so in the future.

One measure of protection against such lawsuits is coverage under the Public Readiness and Emergency Preparedness Act, or PREP Act, which was signed into law in December 2005. The PREP Act creates immunity for manufacturers of biodefense countermeasures when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is meant to provide immunity from all claims under federal or state law for loss arising out of the administration or use of a covered countermeasure. The Secretary of HHS has issued PREP Act declarations identifying BioThrax, Anthrivig and pandemic Influenza A vaccines as covered countermeasures. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct.

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 under the PREP Act, or if the U.S. government does not honor its indemnification obligations to us under the PREP Act, we may incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

§ decreased demand or withdrawal of a product;
§ injury to our reputation;
§ withdrawal of clinical trial participants;
§ costs to defend the related litigation;

§ substantial monetary awards to trial participants or patients;
§ loss of revenue; and
§ an inability to commercialize products that we may develop.

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 the aggregate. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Further product liability insurance may be difficult and expensive to obtain. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy all potential liabilities. For example, 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 would provide adequate coverage against potential liabilities associated with a possible large scale deployment of BioThrax as a countermeasure to a bioterrorism threat. We rely on PREP Act protection in addition to our insurance coverage to help mitigate our liability exposure for BioThrax. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

Our success is dependent on our continued ability to attract, motivate and retain key personnel. If we fail to attract or retain key personnel, we may be unable to maintain or expand our business.

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

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

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

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his significant beneficial ownership of our shares. As of April 30, 2013, Mr. El-Hibri was the beneficial owner of approximately 18% of our outstanding common stock. Because of Mr. El-Hibri's significant beneficial ownership 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. In addition, Mr. El-Hibri's significant beneficial ownership of our shares could present the potential for a conflict of interest.

Provisions in our certificate of incorporation and by-laws and under Delaware law may discourage acquisition proposals, delay a change in control or prevent transactions that stockholders may consider favorable.

Provisions 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 of candidates for election to the Board of Directors and other proposals;
- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue a new series of preferred stock without stockholder approval.

The affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. The affirmative vote of either a majority of the directors present at a meeting of our Board of Directors or holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws.

In addition, Section 203 of the General Corporation Law of Delaware prohibits a corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns or within the last three years has owned 15% or more of the corporation's voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us.

Our stockholder rights plan could prevent a change in control of us in instances in which some stockholders may believe a change in control is in their best interests.

Under 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, 2013, 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, among others:

§ the success of competitive products or technologies;
§ results of clinical and non-clinical trials of our product candidates;
§ decisions and procurement policies by the U.S. government affecting BioThrax;
§ announcements of acquisitions, collaborations, financings or other transactions by us;
§ public concern as to the safety of our products;
§ termination or delay of a development program;
§ disputes concerning patents or other proprietary rights;
§ the recruitment or departure of key personnel;
§ variations in our product revenue and profitability; and
§ the other factors described in this "Risk Factors" section.

Because we have no current intention to pay dividends in the foreseeable future, investors will benefit from an investment in our common stock only if it appreciates in value.

Although our Board of Directors has authorized a share repurchase program under which we may repurchase our shares from time to time, we currently intend to retain our resulting future earnings, if any, to fund the development and growth of our business and do not anticipate paying dividends on our common stock. 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.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 6.5 million shares of our common stock outstanding as of April 30, 2013 have the right to require us to register these shares of common stock under specified circumstances. In 2012, we registered 3.0 million of these shares to be sold by these holders from time to time.

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

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

Not applicable.

Purchases of Equity Securities

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

EMERGENT BIOSOLUTIONS INC.

By: /s/ Daniel Abdun-Nabi
Daniel Abdun-Nabi
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 2, 2013

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

Date: May 2, 2013

EXHIBIT INDEX

Exhibit Number	Description
10.1#	Fourth Amendment to Lease Agreement, dated March 27, 2013, between Brandywine Research LLC and the Company (the "Rockville Lease").
10.2#	Fifth Amendment to the Rockville Lease, dated April 12, 2013, between Brandywine Research LLC and the Company.
12#	Ratio of Earnings to Fixed Charges
31.1#	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)
31.2#	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)
32.1#	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101. INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linksbase Document
101.DEF	XBRL Taxonomy Definition Linksbase Document
101.LAB	XBRL Taxonomy Label Linksbase Document
101.PRE	XBRL Taxonomy Presentation Linksbase Document

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

(i) Consolidated Statements of Operations for the three months ended March 31, 2013 and March 31, 2012, (ii) Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2013 and March 31, 2012, (iii) Consolidated Balance Sheets at March 31, 2013 and December 31, 2012, (iv) Consolidated Statements of Cash Flows for the three months ended March 31, 2013 and 2012 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.