Emergent BioSolutions Inc.
Form 10-Q
November 08, 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 September 30, 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 October 31, 2013, the registrant had 36,367,254 shares of common stock outstanding.

Emergent BioSolutions Inc.
Index to Form 10-Q

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 contract with the U.S. government related to BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, including the timing of deliveries;
- our plans for future sales of BioThrax and RSDL, including our ability to obtain funding for our existing procurement contracts with the U.S. government;
- our ability to successfully execute our growth strategy and achieve our financial and operational goals;
- our ability to identify and acquire companies 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 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 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)

	September 30, 2013 (Unaudited)	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 172,561	$ 141,666
Accounts receivable	30,093	96,043
Inventories	16,325	15,161
Deferred tax assets, net	1,264	1,264
Income tax receivable, net	588	-
Prepaid expenses and other current assets	13,184	9,213
Total current assets	234,015	263,347
Property, plant and equipment, net	263,056	241,764
In-process research and development	41,800	41,800
Intangible assets, net	30,771	-
Goodwill	14,294	5,502
Deferred tax assets, net	11,087	11,087
Other assets	441	730
Total assets	$ 595,464	$ 564,230
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 29,018	$ 31,297
Accrued expenses and other current liabilities	1,359	1,603
Accrued compensation	18,421	22,726
Long-term indebtedness, current portion	4,470	4,470
Contingent purchase consideration, current portion	1,326	-
Deferred revenue	2,038	1,811
Total current liabilities	56,632	61,907
Long-term indebtedness, net of current portion	54,952	58,304
Contingent purchase consideration, net of current portion	15,255	-
Other liabilities	1,768	1,891
Total liabilities	128,607	122,102
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	-	-
	37	36

Common stock, $0.001 par value; 100,000,000 shares authorized, 36,714,299 shares issued and 36,311,141 shares outstanding at September 30, 2013; 36,272,550 shares issued and 35,869,392 shares outstanding at December 31, 2012		
Treasury stock, at cost, 403,158 common shares at September 30, 2013 and December 31, 2012	(5,906)	(5,906)
Additional paid-in capital	240,372	230,964
Accumulated other comprehensive loss	(3,502)	(4,129)
Retained earnings	236,305	220,393
Total Emergent BioSolutions Inc. stockholders' equity	467,306	441,358
Noncontrolling interest in subsidiaries	(449)	770
Total stockholders' equity	466,857	442,128
Total liabilities and stockholders' equity	$ 595,464	$ 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 September 30,		Nine Months Ended September 30,	
	2013 (Unaudited)	2012	2013 (Unaudited)	2012
Revenues:				
Product sales	$76,297	$54,011	$172,252	$141,529
Contracts and grants	12,805	12,581	42,386	45,753
Total revenues	89,102	66,592	214,638	187,282
Operating expense:				
Cost of product sales	20,063	10,230	42,706	30,927
Research and development	28,937	27,390	89,939	84,281
Selling, general and administrative	21,955	19,155	62,484	56,542
Impairment of in-process research and development	-	-	-	9,600
Income from operations	18,147	9,817	19,509	5,932
Other income (expense):				
Interest income	88	55	121	103
Interest expense	-	-	(14)	-
Other income (expense), net	58	(16)	93	1,745
Total other income (expense)	146	39	200	1,848
Income before provision for income taxes	18,293	9,856	19,709	7,780
Provision for income taxes	4,802	4,236	4,667	4,639
Net income	13,491	5,620	15,042	3,141
Net loss attributable to noncontrolling interest	-	997	871	4,276
Net income attributable to Emergent BioSolutions Inc.	$13,491	$6,617	$15,913	$7,417
Income per share – basic	$0.37	$0.18	$0.44	$0.21
Income per share – diluted	$0.36	$0.18	$0.44	$0.20
Weighted-average number of shares – basic	36,272,579	36,202,801	36,129,183	36,144,242
Weighted-average number of shares – diluted	37,015,529	36,670,094	36,504,230	36,424,630

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(Unaudited)		(Unaudited)	
Net income attributable to Emergent BioSolutions Inc.	$13,491	$6,617	$15,913	$7,417
Foreign currency translations, net of tax	11	(652)	627	(588)
Comprehensive income	$13,502	$5,965	$16,540	$6,829

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

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

	Nine Months Ended September 30,	
	2013	2012
Cash flows from operating activities:	(Unaudited)	
Net income	$15,042	$3,141
Adjustments to reconcile to net cash provided by operating activities:		
Stock-based compensation expense	8,459	8,417
Depreciation and amortization	13,547	7,679
Current and deferred income taxes	4,667	8,679
Non-cash development expenses from joint venture	(348)	3,163
Change in fair value of contingent value rights	-	(3,005)
Change in fair value of contingent purchase consideration	349	-
Impairment of in-process research and development	-	9,600
Excess tax benefits from stock-based compensation	(1,949)	(1,482)
Other	(19)	(39)
Changes in operating assets and liabilities:		
Accounts receivable	65,950	57,006
Inventories	(1,164)	(3,584)
Income taxes	(6,927)	(1,597)
Prepaid expenses and other assets	(3,532)	(1,544)
Accounts payable	(1,622)	(3,495)
Accrued expenses and other liabilities	(240)	301
Accrued compensation	(4,164)	(4,790)
Deferred revenue	278	212
Net cash provided by operating activities	88,327	78,662
Cash flows from investing activities:		
Purchases of property, plant and equipment	(34,420)	(40,943)
Acquisition of Healthcare Protective Products Division	(24,120)	-
Proceeds from sale of assets	-	11,765
Proceeds from maturity of investments	-	1,966
Net cash used in investing activities	(58,540)	(27,212)
Cash flows from financing activities:		
Proceeds from borrowings on long-term indebtedness	-	12,946
Issuance of common stock subject to employee equity plans	2,505	495
Excess tax benefits from stock-based compensation	1,949	1,482
Principal payments on long-term indebtedness	(3,352)	(9,386)
Contingent value right payment	-	(1,748)
Purchase of treasury stock	-	(1,457)
Restricted cash	-	220
Net cash provided by financing activities	1,102	2,552
Effect of exchange rate changes on cash and cash equivalents	6	(2)
Net increase in cash and cash equivalents	30,895	54,000
Cash and cash equivalents at beginning of period	141,666	143,901

Cash and cash equivalents at end of period	$172,561	$197,901

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

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

1. Summary of significant accounting policies

Basis of presentation and consolidation

The accompanying unaudited consolidated financial statements include the accounts of Emergent BioSolutions Inc. (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 ("SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2012, as filed with the SEC.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of September 30, 2013 and the results of operations, comprehensive income and cash flows for the three and nine months ended September 30, 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.

There have been no significant changes to the Company's summary of significant accounting policies, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2012, as filed with the SEC, during the three and nine months ended September 30, 2013, except for the addition of the Company's policy for multiple element revenue-generating arrangements and its revenue recognition policy related to the Company's contract with the Biomedical Advanced Research and Development Authority ("BARDA") to establish a Center for Innovation in Advanced Development and Manufacturing ("CIADM") and the addition of a policy for contingent purchase consideration obligations.

Revenue recognition

The Company analyzes its multiple element revenue-generating arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. An item can generally be considered a separate unit of accounting if both of the following criteria are met: the delivered item(s) has value to the customer on a stand-alone basis and if the arrangement includes a general right of return and delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the Company. Items that cannot be divided into separate units are combined with other units of accounting, as appropriate. Consideration received is allocated among the separate units based on the unit's selling price and is recognized in full when the criteria are met. The Company deems services to be rendered if no continuing obligation exists on the part of the Company.

The Company's contract with the BARDA to establish a CIADM is a service arrangement that includes multiple elements. The CIADM contract requires the Company to provide a flexible infrastructure to supply medical countermeasures to the U.S. government over the contract period and includes such items as construction and facility

design, workforce development and licensure of a pandemic flu vaccine. Since none of the individual elements by themselves satisfy the purpose of the contract, the Company has concluded that the CIADM contract elements cannot be separated as they do not have stand-alone value to the U.S. government. Therefore, the Company has concluded that there is a single unit of accounting associated with the CIADM contract. The Company recognizes revenue under the CIADM contract on a straight-line basis, based upon its estimate of the total payments to be received under the contract. The Company analyzes the estimated payments to be received on a quarterly basis to determine if an adjustment to revenue is required. Changes in estimates attributed to modifications in the estimate of total payments to be received are recorded prospectively.

Contingent purchase consideration obligations

In accordance with the terms of the Company's August 2013 acquisition of the Healthcare Protective Products Division ("HPPD"), a division of Bracco Diagnostics Inc. ("Bracco"), the Company has committed to make potential payments to Bracco based on achievement of certain net sales thresholds of RSDL through 2028. The Company records this obligation at fair value. Contingent purchase consideration is based on a percentage of future net RSDL sales. The fair value model used to calculate this obligation is based on the income approach (a discounted cash flow model) that has been risk adjusted based on the probability of achievement of net sales.

The inputs the Company uses for determining the fair value of the contingent purchase consideration are Level 3 fair value measurements. The Company re-evaluates the fair value on a quarterly basis. Changes in the fair value can result from adjustments to the discount rates and updates in the assumed timing of or achievement of net sales. Any future increase in the fair value of the contingent purchase consideration obligation is based on an increased likelihood that the underlying net sales will be achieved and the associated payment or payments which will therefore become due and payable, which will result in a charge to cost of product sales in the period in which the increase is determined. Similarly, any future decrease in the fair value of the contingent purchase consideration obligation will result in a reduction in cost of product sales.

2. Acquisition of Healthcare Protective Products Division

On August 1, 2013, the Company acquired substantially all of the assets of the HPPD, a division of Bracco, for approximately $24.1 million in cash along with contingent purchase consideration obligations to Bracco. The assets acquired in this acquisition include HPPD's product, RSDL, and a majority of the customer and distributor agreements associated with RSDL. In addition, as part of the acquisition, the Company will acquire from Bracco, for approximately $1.8 million, the remaining HPPD assets, which primarily include manufacturing equipment. These remaining HPPD assets and the associated liability, have been included in the Company's consolidated balance sheets as of September 30, 2013. The Company anticipates the acquisition of the remaining assets will occur during the fourth quarter of 2013. The acquisition diversifies the Biodefense segment by adding product sales from RSDL.

The contingent purchase consideration obligations is based on a percentage of RSDL net sales, ranging from 5-10%, for the period August 1, 2013 through July 31, 2028. At August 1, 2013, the contingent purchase consideration obligation was recorded at a fair value of $16.2 million. The Level 3 fair value of these obligations are based on management's assessment of the potential future realization of the contingent purchase consideration payments. This assessment is based on inputs that have no observable market. The obligation is measured using the income approach (a discounted cash flow model).

The total preliminary purchase price is summarized below:

(in thousands)	
Amount of cash paid to Bracco Diagnostics Inc.	$24,120
Fair value of contingent purchase consideration	16,232

Total estimated purchase price	$40,352

The table below summarizes the preliminary allocation of the purchase price based upon fair values of assets acquired and liabilities assumed at August 1, 2013. This preliminary allocation is based upon information that was available to management at the time the financial statements were prepared. Accordingly, the allocation may change. The allocation is not yet final pending the valuation of acquired property, plant and equipment, intangible assets and pre-acquistion contingent liabilites, as well as the assessment of amoritzation periods for intangible assets.

(in thousands)	
Acquired intangible assets	$31,549
Goodwill	8,792
Other	11
Total estimated purchase price	$40,352

A substantial portion of the assets acquired from Bracco consisted of intangible assets associated with the RSDL product. As of the date of acquisition, the Company has recorded intangible assets of approximately $28.1 million related to RSDL and $3.5 million related to a manufacturing agreement with Bracco. For each of the three and nine month periods ended September 30, 2013, the Company recorded $779,000 in amortization for intangible assets, which have been recorded in cost of product sales within the Company's Biodefense segment.

The Company recorded approximately $8.8 million in goodwill related to the HPPD acquisition representing the purchase price paid in the acquisition in excess of the fair value of the tangible and intangible assets acquired. This goodwill is included in the Company's Biodefense segment. None of the goodwill generated from the HPPD acquisition is expected to be deductible for tax purposes.

The Company has incurred transaction costs related to the HPPD acquisition of approximately $283,000 and $800,000, respectively, for the three and nine month periods ended September 30, 2013, which have been recorded in selling, general and administrative expenses within the Company's Biodefense segment.

The Company has determined that the transaction was not significant, and as such no proforma disclosures were required.

3. Fair value measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value, include:

Level 1 — Observable inputs for identical assets or liabilities such as quoted prices in active markets;
Level 2 — Inputs other than quoted prices in active markets that are either directly or indirectly observable; and
Level 3 — Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

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 September 30, 2013		
(in thousands)	Level 1	Level 3	Total

		Level 2		
Assets:				
Investment in money market funds (1)	$32,723	$ -	$-	$32,723
Total assets	$32,723	$ -	$-	$32,723
Liabilities:				
Contingent purchase consideration	$-	$ -	$16,581	$16,581
Total liabilities	$-	$ -	$16,581	$16,581

	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.

During the periods ended September 30, 2013 and December 31, 2012, the Company did not have any transfers between Level 1 and Level 2 assets or liabilities.

As of September 30, 2013 and 2012, the Company had no assets or liabilities measured at fair value using significant unobservable inputs (Level 3) except for contingent value right ("CVR") and contingent purchase consideration obligations.

The fair value of the 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. During the nine months ended September 30, 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 adjustment to fair value is classified in the Company's statement of operations as research and development expense within the Company's Biosciences segment.

The fair value of contingent purchase consideration obligations are based on management's assessment of changes as a result of adjustments to the discount rates and updates in the assumed and actual achievement of net sales for RSDL, which are inputs that have no observable market (Level 3). For the three and nine months ended September 30, 2013, the contingent purchase consideration increased by $349,000 primarily due to an adjustment to the discount rate and the timing of RSDL sales. The adjustment to fair value is classified in the Company's statement of operations as cost of product sales within the Company's Biodefense segment.

The following table is a reconciliation of the beginning and ending balance of the liabilities measured at fair value using significant unobservable inputs (Level 3) during the year ended September 30, 2013 and December 31, 2012:

(in thousands)	
Balance at January 1, 2012	$4,753
Expense (income) included in earnings	(3,005)
Expense (income) included in comprehensive income (loss)	-
Settlements	(1,748)
Purchases, sales, issuances and settlements	-
Transfers in/(out) of Level 3	-

Balance at December 31, 2012	$-
Expense included in earnings	349
Expense (income) included in comprehensive income (loss)	-
Settlements	-
Purchases, sales and issuances	16,232
Transfers in/(out) of Level 3	-
Balance at September 30, 2013	$16,581

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as described above, from those measured at fair value on a nonrecurring basis. For the nine months ended September 30, 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 5).

4. Inventories

Inventories consist of the following:

(in thousands)	September 30, 2013	December 31, 2012
Raw materials and supplies	$ 2,353	$ 2,733
Work-in-process	7,299	9,813
Finished goods	6,673	2,615
Total inventories	$ 16,325	$ 15,161

5. In-process research and development and goodwill

During the nine months ended September 30, 2012, Pfizer terminated its development program 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 nine months ended September 30, 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 at September 30, 2012, and concluded that the $5.5 million in goodwill was not more likely than not impaired and therefore an interim impairment analysis was deemed unnecessary. As of September 30, 2013 and December 31, 2012, the Company had goodwill assocated with the Biosciences Therapurtic reporting unit of $5.5 million.

6. 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	926,610	14.84	-		
Exercised	(185,173)	11.57	-		
Forfeited	(392,588)	18.53	-		
Outstanding at September 30, 2013	3,899,691	$ 16.66	53,156	$ 8.86	$12,844,035
Exercisable at September 30, 2013	2,363,426	$ 16.92	53,156	$ 8.86	$7,580,433

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	463,304	14.84	
Vested	(329,877)	14.81	
Forfeited	(70,896)	15.84	
Outstanding at September 30, 2013	778,140	$ 16.33	$14,823,567

During the nine months ended September 30, 2013, the Company corrected an immaterial prior period classification error for the nine months ended September 30, 2012 of approximately $3.0 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 and had no impact on the Company's consolidated cash flows, consolidated statements of operations and comprehensive income 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.

7. 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. In February 2013, the Company published data from the Phase IIb clinical trial 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 has ceased development work on this product candidate and expects future funding of OETC to be minimal while the OETC entity is liquidated.

The Company evaluates its variable interests in OETC on a quarterly basis and has determined that it is the primary beneficiary as it has directed the activities of OETC that most significantly impact OETC's economic performance and, as a result, will absorb the majority of expected losses. Accordingly, the Company consolidates OETC. As of September 30, 2013 and 2012, respectively, assets of $308,000 and $1.6 million, respectively, and liabilities of $243,000 and $2.8 million, respectively, related to OETC were included within the Company's consolidated balance sheets. During the three months ended September 30, 2013, OETC did not incur any net losses. During the nine months ended September 30, 2013, OETC incurred a net loss of $1.8 million, of which, $905,000 is included in the Company's consolidated statement of operations. During the three and nine months ended September 30, 2012, OETC incurred net losses of $2.0 million and $8.5 million, respectively, of which $1.0 million and $4.3 million, respectively, are 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 September 30, 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	-	(348)	(348)
Net income (loss)	15,913	(871)	15,042
Other	10,035	-	10,035
Stockholders' equity at September 30, 2013	$ 467,306	$ (449)	$466,857

8. 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 otlertuzumab (formerly TRU-016). The collaboration agreement was terminated on March 20, 2012 and all rights to otlertuzumab and other CD37-directed protein therapeutics under the collaboration agreement reverted back to the Company.

During the nine months ended September 30, 2012, respectively, the Company recorded revenue of $2.7 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. There was no revenue for the three months ended September 30, 2013 and 2012 and the nine months ended September 30, 2013.

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 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. In September 2012, the Pfizer Agreement was terminated. The Company's right to receive royalty payments under the Biosimilar Amendment survives termination of the Pfizer Agreement.

During the three and nine months ended September 30, 2012, the Company recorded revenue of $356,000 and $1.2 million for research and development services pursuant to the Pfizer agreement, which is included in the Company's

statement of operations as contracts and grants revenue within the Company's Biosciences segment. There was no revenue for the three and nine months ended September 30, 2013.

9. Restructuring

In February 2013, the Company adopted a plan to restructure the operations of Emergent Product Development UK Limited ("EPDU") and OETC due to the results of the Phase IIb clinical trial for the Company's tuberculosis vaccine product candidate. The Company completed this restructuring as of June 30, 2013, except for the payment of certain termination benefit obligations that remain payable as of September 30, 2013.

The restructuring plan included a headcount reduction of 14 employees at EPDU, the termination of a facility lease, and the impairment of leasehold improvements and equipment. These costs, which are included in selling, general and administrative expense in the Company's statement of operations and are included within the Biosciences segment, are detailed below:

(in thousands)	Incurred during the three months ended September 30, 2013	Incurred during the nine months ended September 30, 2013	Total Expected to be Incurred
Termination benefits	$ -	$ 2,114	$ 2,114
Contract termination costs	-	431	431
Other costs	-	261	261
Total	$ -	$ 2,806	$ 2,806

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

(in thousands)	Termination Benefits	Contract Termination Costs	Other Costs	Total
Balance at December 31, 2012	$ -	$ -	$-	$-
Expenses incurred	2,114	431	134	2,679
Amount paid	(1,660)	(431)	(134)	(2,225)
Other adjustments	-	-	-	-
Balance at September 30, 2013	$ 454	$ -	$-	$454

10. Business interruption insurance recovery

During the nine months ended September 30, 2012, the Company recorded $1.7 million from an 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.

11. Earnings per share

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

(in thousands, except share and per share data)	Three Months Ended September 30, 2013	2012	Nine Months Ended September 30, 2013	2012
Numerator:				

Net income	$13,491	$6,617	$15,913	$7,417
Denominator:				
Weighted-average number of shares—basic	36,272,579	36,202,801	36,129,183	36,144,242
Dilutive securities—equity awards	742,950	467,293	375,047	280,388
Weighted-average number of shares—diluted	37,015,529	36,670,094	36,504,230	36,424,630
Income per share-basic	$0.37	$0.18	$0.44	$0.21
Income per share-diluted	$0.36	$0.18	$0.44	$0.20

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 and nine month periods ended September 30, 2013, approximately 1.4 million and 1.5 million stock options, respectively, were excluded from the calculation of diluted earnings per share. For the three and nine month periods ended September 30, 2012, approximately 3.0 million and 2.9 million stock options, respectively, were excluded from the calculation of diluted earnings per share.

12. 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. 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 September 30, 2013				
External revenue	$89,102	$ -	$-	$89,102
Net income (loss)	27,175	(12,491)	(1,193)	13,491
Three Months Ended September 30, 2012				
External revenue	$66,238	$ 354	$-	$ 66,592
Net income (loss)	20,760	(12,165)	(1,978)	6,617

	Reportable Segments			
(in thousands)	Biodefense	Biosciences	All Other	Total
Nine Months Ended September 30, 2013				
External revenue	$213,663	$ 975	$-	$ 214,638

Net income (loss)	56,780	(38,019)	(2,848)	15,913
Nine Months Ended September 30, 2012				
External revenue	$181,838	$5,444	$-	$187,282
Net income (loss)	59,361	(47,019)	(4,925)	7,417

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. Our programs in this division include two marketed products: BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax disease and RSDL® (decontamination lotion), or RSDL, which we acquired in August 2013 from Bracco Diagnostics, Inc., or Bracco. RSDL has been cleared by the FDA, Health Canada, the United Kingdom's Medicines and Healthcare products Regulatory Agency and Australia's Therapeutics Goods Administration for the removal or neutralization of chemical warfare agents from the skin, including nerve agents, mustard gas and toxins. Our Biodefense division also includes investigational product candidates. Operations in this division include manufacturing, regulatory and quality affairs in support of BioThrax and RSDL; and 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 and our investigational product candidates, and manufacturing and related infrastructure initiatives in support of our therapeutics and vaccine platform technologies.

Our Biodefense segment has generated revenue, from product sales and development funding, and net income for each of the last five fiscal years. During this time, 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 beginning in September 2011. We expect for the foreseeable future to continue to derive the majority of our product sales revenues from sales of BioThrax to the U.S. government. Our total revenues from BioThrax sales were $165.3 million and $141.5 million for the nine months ended September 30, 2013 and 2012, respectively. In addition, we had RSDL product sales of $7.0 million during the period ended September 30, 2013. We are focused on increasing sales of BioThrax and RSDL to U.S. government customers, expanding the market for BioThrax and RSDL to other customers domestically and internationally and pursuing label expansions and improvements.

Contracts and Grants

We seek to advance development of our product candidates through external funding arrangements. We have received funding from the U.S. government for a number of development programs, including the following:

- BioThrax as a post-exposure prophylaxis, or PEP;
- NuThrax;
- Large-scale manufacturing for BioThrax;
- PreviThrax; and
- Establishment of 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. We may slow down development programs or place them on hold during periods that are not covered by external funding.

Manufacturing Infrastructure

We conduct our primary biodefense 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. 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 that we in-licensed from a third party. We expect this facility will support future CIADM development and manufacturing activities for chemical, biological, radiological and nuclear countermeasures as well as for our current and future product development and manufacturing needs. Our specific plans for this facility will be contingent on the requirements of BARDA under our CIADM contract, 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 SNS 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 $704 million for the procurement of BioThrax doses under this contract. Through September 30, 2013, we have delivered approximately 15.0 million doses to the CDC resulting in approximately $399 million in revenue recognized under this contract.

As part of the August 2013 acquisition of the assets of the Healthcare Protective Products Division, or HPPD, a division of Bracco, we assumed responsibility for an indefinite delivery/indefinite quantity contract with the U.S. Department of Defense, or DoD, to provide RSDL to active military personnel. The contract term runs through 2017. Through September 30, 2013, we recognized revenue of approximately $6.2 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
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, consisting of fixed and variable costs. 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. Fixed manufacturing costs include facilities and utilities.. 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.

The primary expense that we incur to deliver RSDL to our customers is the cost per unit of production from our third-party contract manufacturer. Other associated expenses include shipping, logistics and the cost of support functions.

Research and Development Expenses

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

§ personnel-related expenses;
§ fees to professional service providers for, among other things, analytical testing, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies;

- costs of contract manufacturing services for clinical trial material;
- 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 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 spending, 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 and RSDL directly to the U.S. and foreign governments with a small, targeted marketing and sales group. As we seek to broaden the market for BioThrax, RSDL and we acquire additional product candidates or 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 and nine months ended September 30, 2013, except for the addition of our revenue recognition policy for our contract with BARDA to establish a CIADM and our policy for contingent purchase consideration obligations, which are detailed below. 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.

Revenue Recognition

Our contract with BARDA to establish a CIADM, is a service arrangement that includes multiple elements. The CIADM contract requires us to provide a flexible infrastructure to supply medical countermeasures to the U.S. government over the contract period and currently includes such items as construction and facility design, workforce development and licensure of a pandemic flu vaccine. Since none of the individual elements by themselves satisfy the purpose of the contract, we have concluded that the CIADM contract elements cannot be separated as they do not have stand-alone value to the U.S. government. Therefore, we have concluded that there is a single unit of accounting associated with the CIADM contract. We recognize revenue under the CIADM contract on a straight-line basis, based upon our estimate of the total payments to be received under the contract. We analyze the estimated payments to be received on a quarterly basis to determine if an adjustment to revenue is required. Changes in estimates attributed to modifications in the estimate of total payments to be received are recorded prospectively.

Contingent Purchase Consideration Obligations

In accordance with the terms of our August 2013 acquisition of the Healthcare Protective Products Division, or HPPD, a division of Bracco, we have committed to make potential payments to Bracco based on achievement of certain net sales thresholds of RSDL through 2028. We record this obligation at fair value. Contingent purchase consideration is based on a percentage of future net RSDL sales. The fair value model used to calculate this obligation is based on the income approach (a discounted cash flow model) that has been risk adjusted based on the probability of achievement of net sales.

The inputs we use for determining the fair value of the contingent purchase consideration are Level 3 fair value measurements. We re-evaluate the fair value on a quarterly basis. Changes in the fair value can result from adjustments to the discount rates and updates in the assumed timing of or achievement of net sales. Any future increase in the fair value of the obligation is based on an increased likelihood that the underlying net sales will be achieved and the associated payment or payments will therefore become due and payable, which will result in a charge to cost of product sales in the period in which the increase is determined. Similarly, any future decrease in the fair value of the obligation will result in a reduction in cost of product sales.

Results of Operations

Quarter Ended September 30, 2013 Compared to Quarter Ended September 30, 2012

Revenues

Product sales revenues increased by $22.3 million, or 41%, to $76.3 million for the three months ended September 30, 2013 from $54.0 million for the three months ended September 30, 2012. This increase in product sales revenues was due to a 26% increase in the number of doses of BioThrax delivered, attributable to the timing of deliveries to the SNS, along with $7.0 million in sales from RSDL, which we acquired in August 2013. BioThrax product sales revenues during the three months ended September 30, 2013 consisted of sales to the CDC of $69.1 million and aggregate international and other sales of $262,000. RSDL sales during the three months ended September 30, 2013 consisted of sales to the DoD of $6.2 million and aggregate international and other sales of $800,000. Product sales revenues during the three months ended September 30, 2012 consisted of BioThrax sales to the CDC of $53.8 million and aggregate international and other sales of $247,000.

Contracts and grants revenues increased by $224,000, or 2%, to $12.8 million in the three months ended September 30, 2013 from $12.6 million for the three months ended September 30, 2012. The increase in contracts and grants revenues was primarily due to increased revenues from our contracts with BARDA related to the establishment of our CIADM and our large-scale manufacturing of BioThrax. Contracts and grants revenues during the three months ended September 30, 2013 consisted of $12.8 million in development contract and grant revenue from NIAID and BARDA. Contracts and grants revenues during the three months ended September 30, 2012 consisted of $12.2 million in development contract and grant revenues from BARDA and NIAID and $356,000 from Pfizer.

Cost of Product Sales

Cost of product sales increased by $9.8 million, or 96%, to $20.1 million for the three months ended September 30, 2013 from $10.2 million for the three months ended September 30, 2012. This increase was attributable to the 26% increase in the number of BioThrax doses delivered coupled with a lower average cost per dose sold in 2012 associated with an adjustment to certain BioThrax testing specifications that allowed us to sell doses for which the cost has been expensed in a prior period. Additionally, cost of product sales for the three months ended September 30, 2013, also includes $3.8 million in costs attributable to RSDL.

Research and Development Expenses

Research and development expenses increased by $1.5 million, or 6%, to $28.9 million for the three months ended September 30, 2013 from $27.4 million for the three months ended September 30, 2012. This increase primarily reflects increased depreciation expense related to our Baltimore facility, and includes increased expenses of $997,000 for product candidates and manufacturing development categorized in the Biodefense segment, increased expenses of $576,000 for product candidates and technology platform development activities categorized in the Biosciences segment, and decreased expenses of $26,000 in other research and development, which are in support of central research and development activities for technology platform development. Net of development contract and grant reimbursements along with the net loss attributable to noncontrolling interests, we incurred research and development expenses of $16.1 million and $13.8 million, during the three months ended September 30, 2013 and 2012, respectively.

Our principal research and development expenses during the three months ended September 30, 2013 and 2012 are shown in the following table:

	Three Months Ended September 30,	
(in thousands)	2013	2012
Biodefense:		
Large-scale manufacturing for BioThrax	$4,865	$4,521
BioThrax related programs	2,750	2,376
PreviThrax	3,795	4,054
NuThrax	2,434	1,752
Thravixa	-	491
Other Biodefense	2,293	1,946
Total Biodefense	16,137	15,140
Biosciences:		
Tuberculosis vaccine	84	3,217
otlertuzumab (formerly TRU-016)	6,658	3,372
ES414 (formerly T-Scorp)	1,810	1,375
ES301 (formerly DRACO)	-	175
Other Biosciences	2,522	2,359
Total Biosciences	11,074	10,498
Other	1,726	1,752
Total	$28,937	$27,390

The increase in spending for our large-scale manufacturing for BioThrax was primarily due to the timing of manufacturing development activities. The increase in spending for BioThrax related programs was related to the timing of 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 non-clinical studies. The increase in spending for NuThrax was primarily related to the timing of 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.

The decrease in spending for our tuberculosis vaccine product candidate was related to the costs incurred during 2012 to complete the Phase IIb clinical trial. As a result of clinical trial data published in February 2013, future spending will decrease significantly as we cease our tuberculosis product development efforts. The increase in spending for our otlertuzumab (formerly TRU-016) product candidate was primarily related to manufacturing activities in support of clinical trials. 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 spending for our other Biosciences activities was 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 $2.8 million, or 15%, to $22.0 million for the three months ended September 30, 2013 from $19.2 million for the three months ended September 30, 2012. This increase is due to increased spending related to professional services, along with additional costs associated with RSDL sales and our acquisition of HPPD from Bracco. The majority of the selling, general and administrative expenses are attributable to the Biodefense segment, which increased by $408,000, or 3%, to $14.4 million during the three months ended September 30, 2013 from $14.0 million during the three months ended September 30, 2012. This increase is primarily due to RSDL selling costs and other expenses related to the acquisition of HPPD. Selling, general and administrative expenses related to our Biosciences segment increased by $2.4 million, or 46%, to $7.6 million during the three months ended September 30, 2013 from $5.2 million during the three months ended September 30, 2012 due to an increase in professional fees to support due diligence and other acquisition-related activities in accordance with our growth plan.

Total Other Income (Expense)

Total other income increased by $107,000 to $146,000 for the three months ended September 30, 2013 from $39,000 for the three months ended September 30, 2012.

Income Taxes

Provision for income taxes increased by $566,000, or 13%, to $4.8 million for the three months ended September 30, 2013 from $4.2 million for the three months ended September 30, 2012. The increase in the provision for income taxes was primarily due to the $7.4 million increase in our income before provision for income taxes and the loss attributable to noncontrolling interests; coupled with a decrease in the estimated effective annual tax rate, primarily due to adjustments related to state taxes and the extension of the 2012 research and development tax credit that was signed into law and recorded in 2013.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest decreased by $997,000. The decrease resulted primarily from the termination of clinical and development activities and related expenses related to our tuberculosis vaccine candidate. These amounts represent the portion of the losses incurred by the OETC joint venture for the quarters ended September 30, 2013 and 2012, respectively, that was attributable to our joint venture partners.

Nine Months Ended September 30, 2013 Compared to Nine Months Ended September 30, 2012

Revenues

Product sales revenues increased by $30.7 million, or 22%, to $172.3 million for the nine months ended September 30, 2013 from $141.5 million for the nine months ended September 30, 2012. This increase in product sales revenues was due to a 14% increase in the number of doses of BioThrax delivered, attributable to the timing of deliveries to the SNS, along with $7.0 million in sales of RSDL, which we acquired in August 2013. BioThrax product sales revenues during the nine months ended September 30, 2013 consisted of sales to the CDC of $164.0 million and aggregate international and other sales of $1.3 million. RSDL sales during the nine months ended September 30, 2013 consisted of sales to the DoD of $6.2 million and aggregate international and other sales of $800,000. Product sales revenues for the nine months ended September 30, 2012 consisted of BioThrax sales to CDC of $141.1 million and aggregate

international and other sales of $447,000.

Contracts and grants revenues decreased by $3.4 million, or 7%, to $42.4 million for the nine months ended September 30, 2013 from $45.8 million for the nine months ended September 30, 2012. The decrease in contracts and grants revenues was primarily due to decreased milestone revenue received for our PEP indication for BioThrax, decreased revenue from BARDA for our PreviThrax product candidate, and the sale of our spi-VEC technology during 2012, along with decreased revenues from our agreements with Abbott and Pfizer that terminated during 2012, partially offset by increased revenues from BARDA related to the establishment of our CIADM. Contracts and grants revenues for the nine months ended September 30, 2013 consisted of $42.4 million in development contract and grant revenues from NIAID and BARDA. Contracts and grants revenues for the nine months ended September 30, 2012 consisted of $40.3 million in development contract and grant revenues from NIAID and BARDA, $4.0 million from Abbott and Pfizer and $1.5 million from the sale of patent and trademark rights and related materials pertaining to our spi-VEC platform technology.

Cost of Product Sales

Cost of product sales increased by $11.8 million, or 38%, to $42.7 million for the nine months ended September 30, 2013 from $30.9 million for the nine months ended September 30, 2012. This increase was attributable to the 14% increase in the number of BioThrax doses delivered coupled with an increase in the costs per dose associated with lower production yields in the period in which the doses were produced. Additionally, cost of product sales also includes $3.8 million in costs attributable to RSDL.

Research and Development Expenses

Research and development expenses increased by $5.7 million, or 7%, to $89.9 million for the nine months ended September 30, 2013 from $84.3 million for the nine months ended September 30, 2012. This increase primarily reflects higher contract service and increased depreciation expense related to our Baltimore facility, and includes increased expenses of $2.2 million for product candidates and manufacturing development categorized in the Biodefense segment and increased expenses of $3.7 million for product candidates and technology platform development activities categorized in the Biosciences segment, offset by decreased expenses of $223,000 in other research and development, which are in support of central research and development activities. For the nine months ended September 30, 2013 and 2012, we incurred research and development expenses net of development contract and grant reimbursements along with the net loss attributable to noncontrolling interests of $46.7 million and $34.3 million, respectively.

Our principal research and development expenses for the nine months ended September 30, 2013 and 2012 are shown in the following table:

	Nine Months Ended September 30,	
(in thousands)	2013	2012
Biodefense:		
Large-scale manufacturing for BioThrax	$13,595	$13,323
BioThrax related programs	8,307	7,944
PreviThrax	11,825	12,799
NuThrax	6,766	6,369
Pandemic influenza	2,500	-
Thravixa	-	1,304
Other Biodefense	5,785	4,819
Total Biodefense	48,778	46,558
Biosciences:		

Tuberculosis vaccine	4,269	11,993
otlertuzumab (formerly TRU-016)	18,308	9,396
ES414 (formerly T-Scorp)	5,675	2,802
ES301 (formerly DRACO)	-	2,017
Other Biosciences	8,044	6,427
Total Biosciences	36,296	32,635
Other	4,865	5,088
Total	$89,939	$84,281

The spending for our large-scale manufacturing for BioThrax was primarily due to non-clinical studies and the timing of manufacturing development activities. The increase in spending for BioThrax related programs was related to clinical and non-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 non-clinical studies. The spending for NuThrax was primarily due to clinical trial activities. The increase in pandemic influenza was related to an upfront payment for an exclusive license to the rights to manufacture and sell pandemic influenza products. 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, which includes increased depreciation expense related to our Baltimore facility.

The decrease in spending for our tuberculosis vaccine product candidate is related to the substantial completion of the Phase IIb clinical trial activities during 2012 partially offset by manufacturing development activities during 2013. The increase in spending for our otlertuzumab (formerly TRU-016) product candidate is primarily related to our clinical trial activities for CLL along with manufacturing 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 increased costs associated with the development of platform technologies, as well as a reduction in 2012 of the contingent value right, or CVR, obligations associated with our agreement with Pfizer, which was cancelled in 2012.

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 $5.9 million, or 11%, to $62.5 million for the nine months ended September 30, 2013 from $56.5 million for the nine months ended September 30, 2012. This increase was primarily due to $2.8 million in costs related to the restructuring of our U.K. operations, increased spending related to professional services along with additional costs associated with our RSDL sales and acquisition of HPPD from Bracco. The majority of the expense is attributable to the Biodefense segment, in which selling, general and administrative expenses increased by $1.6 million, or 4%, to $43.1 million for the nine months ended September 30, 2013 from $41.5 million for the nine months ended September 30, 2012. The increase is primarily due to RSDL selling costs and other expenses related to our acquisition of HPPD. Selling, general and administrative expenses related to our Biosciences segment increased by $4.3 million, or 28%, to $19.4 million for the nine months ended September 30, 2013 from $15.0 million for the nine months ended September 30, 2012, due to our UK restructuring and increased professional services to support due diligence and other acquisition-related activities associated with our growth plan.

Impairment of In-Process Research and Development

Impairment of in-process research and development was $9.6 million for the nine months ended September 30, 2012. The impairment charge for the nine months ended September 30, 2012, resulted from the full impairment of our

SBI-087 in-process research and development asset during the nine months ended September 30, 2012. There was no impairment for the nine months ended September 30, 2013.

Total Other Income (Expense)

Total other income decreased by $1.6 million, or 89%, to $200,000 for the nine months ended September 30, 2013 from $1.8 million for the nine months ended September 30, 2012. The decrease was due primarily to a business interruption insurance recovery related to a power outage at our Lansing, Michigan facility in 2012.

Income Taxes

Provision for income taxes increased by $28,000, or 1%, to $4.7 million for the nine months ended September 30, 2013 from $4.6 million for the nine months ended September 30, 2012. The increase in the provision for income taxes was primarily due to the $8.5 million increase in our income before provision for income taxes and the loss attributable to noncontrolling interests, coupled with a decrease in the estimated effective annual tax rate. The decrease in the estimated effective tax rate was primarily due to adjustments related to state taxes and the extension of the 2012 research and development tax credit that was signed into law and recorded in 2013.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest decreased by $3.4 million, or 80%, to $871,000 for the nine months ended September 30, 2013 from $4.3 million for the nine months ended September 30, 2012. The decrease resulted primarily from the termination of clinical and development activities and related expenses related to our tuberculosis vaccine candidate. These amounts represent the portion of the loss incurred by the joint ventures for the nine months ended September 30, 2013 and 2012, respectively, that was attributable to our joint venture partners.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our cash requirements from inception through September 30, 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 September 30, 2013 we had cash and cash equivalents of $172.6 million. Additionally, at September 30, 2013, our accounts receivable balance was $30.1 million.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2013 and 2012:

	Nine Months Ended September 30,	
(in thousands)	2013	2012
Net cash provided by (used in):		
Operating activities(1)	$88,333	$78,660
Investing activities	(58,540)	(27,212)
Financing activities	1,102	2,552

Net increase in cash and cash equivalents	$30,895	$54,000

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

Net cash provided by operating activities of $88.3 million for the nine months ended September 30, 2013 was primarily due to our net income of $15.0 million, a decrease in accounts receivable of $66.0 million related to the timing of collection of amounts billed primarily to the CDC, along with the effect of non-cash charges of $8.5 million for stock-based compensation and $13.5 million for depreciation and amortization.

Net cash provided by operating activities of $78.7 million for the nine months ended September 30, 2012 was primarily due to a decrease in accounts receivable of $57.0 million related to the timing of collection of amounts billed to the CDC and non-cash charges of $9.6 million for the impairment of in-process research and development, $8.4 million for stock-based compensation, $7.7 million for depreciation and amortization, and $3.2 million for development expenses primarily from our joint ventures, partially offset by a decrease in accrued compensation of $4.8 million associated with the payment of 2011 bonuses 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 $58.5 million for the nine months ended September 30, 2013 was primarily due to the acquisition of HPPD from Bracco for $24.1 million and capital expenditures of $34.4 million, which includes the purchase of a new headquarters facility for $10.5 million, 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 $27.2 million for the nine months ended September 30, 2012 was primarily due to capital expenditures of $40.9 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 of $11.8 million from the sale of our two Frederick, Maryland buildings and the maturity of U.S. Treasury securities of $2.0 million.

Net cash provided by financing activities of $1.1 million for the nine months ended September 30, 2013 was primarily due to $1.9 million in excess tax benefits from the exercise of stock options and $2.5 million in proceeds from employee equity plans, partially offset by principal payments on indebtedness of $3.4 million.

Net cash provided by financing activities of $2.6 million for the nine months ended September 30, 2012 was primarily due to $12.9 million in advances under our construction and equipment loans with PNC Bank related to the renovation, improvement and equipment purchases at our Baltimore, Maryland facility, partially offset by $9.4 million in principal payments on indebtedness, including $7.7 million in repayment of debts related to our Frederick, Maryland buildings.

Debt Financing

As of September 30, 2013, we had $59.4 million principal amount of debt outstanding, comprised primarily of the following:

- $17.1 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;
- $3.9 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;
- $28.2 million outstanding under a construction loan from PNC Bank used to fund the renovations of our Baltimore, Maryland facility; and
- $10.2 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, revenues from RSDL 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 and RSDL 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, RSDL 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 offerings. If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities or declaring dividends. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us. 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.

Acquisition of HPPD Assets

On August 1 2013, we acquired substantially all of the assets of HPPD, a division of Bracco for approximately $24.1 million in cash. The assets acquired in this acquisition include HPPD's product RSDL, along with a majority of the customer and distributor agreements for the RSDL product. In addition, as part of the acquisition, we will pay approximately $1.8 million for the remaining assets of HPPD, which primarily includes manufacturing equipment. We anticipate the acquisition of the remaining assets will occur during the fourth quarter of 2013.

Share Repurchase Program

On May 17, 2012, our board of directors authorized us 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 nine months ended September 30, 2013. During the nine months ended September 30, 2012, we repurchased 399,000 shares for $5.8 million.

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 September 30, 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 September 30, 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 September 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's assessment of and conclusion on the effectiveness of disclosure controls and procedures and internal controls over financial reporting did not include the internal controls related to the operations acquired in the acquisition of the Health Protective Products Division, or HPPD, from Bracco Diagnostics Inc. Included in our consolidated financial statements related to the operations of HPPD are total assets and net assets of $48.8 million and $26.6 million, respectively, as of September 30, 2013 and $7.0 million and $2.5 million of revenues and net income for the period since acquisition, or August 1, 2013 through September 30, 2013.

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 the majority of our revenue from sales of BioThrax to our principal customer, the U.S. government. If the U.S. government's demand for 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 the majority of our revenue from sales to the U.S. government of BioThrax, our FDA-approved anthrax vaccine. 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 and RSDL is the U.S. government. We anticipate that the U.S. government will also be a principal customer for other biodefense products that we successfully develop or acquire. Additionally, the majority 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 an approximately three-year base period of performance valued at approximately $51 million and three successive one-year option periods valued at a total of approximately $101 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. On October 16, 2013, Congress passed legislation suspending the federal debt ceiling until February 7, 2014 and establishing a Congressional conference committee to deliver a budget recommendation by December 13,

2013. We cannot predict the ultimate outcome of the budget process or whether such efforts will result in significant funding delays or cancellation of orders by the U.S. government, any of which 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:

- 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 was to uncover improper or illegal activities, we could be subject to civil and criminal penalties, administrative sanctions, including suspension or debarment from government

contracting, and significant reputational harm.

The amount we are paid under our fixed price government 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, which could harm our operating results and materially reduce our net income.

Our current contracts with the CDC for the procurement of BioThrax and with the DoD for procurement of RSDL are fixed price contracts. We expect that our potential future contracts with the U.S. government for BioThrax and RSDL, 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 our financial condition and operating results.

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

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including by imposing equitable price adjustments;
- cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- decline, in whole or in part, to exercise an option to purchase product under a 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. Our CDC contract is, and other future government contracts are likely to be, terminable at the U.S. government's convenience with these potential consequences.

Our U.S. government contracts grant the U.S. government the right to use technologies developed by us under the government contract or the right to share data related to our technologies, for or on behalf of the U.S. government. Under our U.S. government contracts, we might not be able to prohibit third parties, including our competitors, from access to such technology or data in providing products and services to the U.S. government.

MANUFACTURING RISKS

BioThrax and our biologic 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 control lot that we maintain. We continually monitor the status of our control lot and periodically produce and qualify a new control lot to replace the existing control lot. If we are not able to produce and qualify a new control lot or otherwise satisfy the FDA's requirements for release of BioThrax, our ability to sell BioThrax would be impaired until such time as we become able to meet the FDA's requirements, which would significantly impact our revenues, require us to utilize our cash balances to help fund our ongoing operations and otherwise harm our business.

We are contractually required to ship BioThrax at a prescribed temperature range, and variations from that temperature range could result in loss of product and could significantly impact our revenues. Delays, lot failures, shipping deviations, spoilage or other loss during shipping could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in 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 a development contract 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 a separate development contract from 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 foreign regulatory requirements for sales of our products 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 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 significantly impact our revenues.

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 both our Lansing, Michigan and Baltimore, Maryland facilities as facilities requiring additional security. Although, we continually evaluate and update security measures, there can be no assurance that any additional security measures would protect our facilities from terrorist efforts determined to disrupt our manufacturing activities.

The factors listed above could also cause disruptions at our other facilities, including our research and product development facilities. Any such disruption, damage, or destruction of our facilities could impede our ability to manufacture BioThrax and our other products and product candidates, 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 the manufacture of BioThrax or our other products and product candidates in sufficient quantities and at an acceptable cost, our ability to manufacture BioThrax or to develop and commercialize our other products and product candidates could be impaired, which could harm our revenues, lead to a termination of one or more of our contracts, lead to delays in clinical trials or otherwise harm our business.

We depend on certain single-source suppliers for materials and services necessary for the manufacture of BioThrax and our other products and 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 other products and product candidates could be adversely affected and could harm our revenues, cause us to fail to satisfy contractual commitments, lead to a termination of one or more of our contracts or lead to delays in our clinical trials, any of which could be costly to us

and otherwise harm our business, financial condition and operating results.

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

Third party manufacturers currently supply a significant amount of our products and product candidates, other than BioThrax, pursuant to contractual arrangements. Certain manufacturers currently constitute the sole source of several of our products and product candidates. For example, Therapex Inc. is our sole source manufacturer for RSDL. 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 products to our customers or our product candidates for use in clinical trials. As a result, any such delay could adversely affect our ability to satisfy current 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 products and product candidates. Increases in the prices we pay our manufacturers, interruptions in the supply of our products and 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 products and product candidates in compliance with all FDA and other applicable regulatory requirements. If these manufacturers fail to maintain compliance with FDA or other applicable regulatory requirements, they could be ordered to cease manufacturing, which would have a materially adverse impact on the supply of these products and product candidates to satisfy government and commercial demand and 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, forcing us 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 and time 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 products and product candidates on our behalf are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, 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 and RSDL 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 commissioner 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 sufficient to confer statistically 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 or desired timeframe. We also may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider, which may prove difficult, costly and result in a delay of our trials. Any delay in or inability to complete our trials could delay or prevent the development, approval and commercialization of our product candidates.

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

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

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

We continue to evaluate our business strategy and, as a result, may modify our strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different product candidates or may delay or halt the development of various product candidates. For example, in February 2013, as a consequence of clinical trial results, we determined to cease further development work on MVA85A, our 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 and commercializing additional products on favorable terms or at all. Competition for attractive product opportunities is intense, and may require us to devote substantial resources, both managerial and financial, to 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 programs;
§ 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 future 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 in 2012. As a result, we experienced a charge of $9.6 million in 2012 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 otlertuzumab (formerly TRU-016) following a similar portfolio reprioritization process.

Failure of any of our future 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 efficacy in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted. 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 efficacy 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, 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, therapeutic product or medical device for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product will be subject to continual requirements of and review by the FDA and other regulatory bodies. As approved or cleared products, BioThrax and RSDL are subject to these requirements and ongoing review. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance 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, some which were significant, but all of which have been addressed through corrective actions. 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 observations resulting from 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; and
- 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. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. If we experience any of these post-approval events, our business, financial condition and operating results could be materially and adversely affected.

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

We currently sell and intend to sell our products outside the United States. To market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by foreign regulatory authorities. The approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review. We and our collaborators may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and therefore we may be unable to commercialize our products internationally.

Our growing international operations increase our risk of exposure to potential claims of bribery and corruption.

As we expand our commercialization activities outside of the United States, we will be subject to an increased risk of inadvertently conducting activities in a manner that violates the U.K. Bribery Act, the U.S. Foreign Corrupt Practices Act, or FCPA, or other similar foreign laws which prohibit corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. In the course of establishing and expanding our commercial operations and seeking regulatory approvals outside of the United States, we will need to establish and expand business relationships with various third parties and will interact more frequently with foreign officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be foreign officials under the FCPA. If our business practices outside the United States are found to be in violation of the FCPA, we and our senior management may be subject to significant civil and criminal penalties, potential debarment from public procurement, and reputational damage, which could have a material adverse effect on our business, financial condition, results of operations, liquidity and growth prospects.

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 and regulations 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, RSDL 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 prevailed in those challenges, 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 products or product candidates, which would adversely affect our revenues.

We have a small sales and marketing group with limited experience commercializing products, other than BioThrax and RSDL. 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 and RSDL 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 products or 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 products or 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, RSDL, 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 plc 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., Inc., GlaxoSmithKline plc, Sanofi Pasteur SA, Pfizer Inc. and Novartis AG, as well as smaller, more focused companies engaged in vaccine and immune therapeutics development, such as Soligenix, Inc., Pfenex Inc., DynPort Vaccine Company LLC, Elusys Therapeutics, Inc., Bavarian Nordic A/S and PharmAthene, Inc.. 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 management's time and attention and other resources, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions covered by them. There is also a risk that, even if the validity of a patent were upheld, a court would refuse to stop the other party from using the invention(s), including on the grounds that its activities do not infringe the patent. If any of these events were to occur, our business, financial condition and operating results could be materially and adversely affected.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend 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 sufficient licenses or other rights. Additionally, third parties may be successful in obtaining patent protection for technologies that cover development and commercialization activities in which we are already engaged. Third parties may own or control these patents and intellectual property rights in the 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, if at all, or if an injunction is granted against us, which could harm our business significantly.

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

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, 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 RSDL or the label expansions and improvements that we are pursuing for BioThrax, our only intellectual property protection for BioThrax and RSDL, other than trademarks, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and unique starting materials. However, these types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, through agreements with our employees, consultants and third parties.

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 the cash available for investment in our business operations.

As of September 30, 2013, we had $59.4 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 September 30, 2013, we had $202.7 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, RSDL 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 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 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 September 30, 2013, we have $59.4 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 or principal 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 or unfavorable 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, RSDL, or 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.

Additionally, BioThrax and RSDL are certified anti-terrorism products covered under the protections of the Support Anti-Terrorism by Fostering Effective Technology Act of 2002, or SAFETY Act. The SAFETY Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. Although we are entitled to the benefits of the SAFETY Act for BioThrax and RSDL, the SAFETY Act may not provide adequate protection from claims made against us.

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

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

We currently have product liability insurance with 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 and SAFETY 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. We believe part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including equity incentive awards. If we cannot offer a competitive compensation package 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 common stock, including an ability to significantly influence the election of the members of our Board of Directors, or delay or prevent a change of control of us.

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his significant beneficial ownership of our common stock. As of October 31, 2013, Mr. El-Hibri was the beneficial owner of approximately 16% of our outstanding common stock. Because of Mr. El-Hibri's significant beneficial ownership of our common stock, Mr. El-Hibri also has 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 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 October 31, 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 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 million shares of our common stock outstanding as of October 31, 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 J. Abdun-Nabi
Daniel J. Abdun-Nabi
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 8, 2013

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

Date: November 8, 2013

EXHIBIT INDEX

Exhibit Number	Description
10.1#††	Modification No. 7 to Contract No. 200-2011-42084 (the "CDC BioThrax Procurement Contract"), effective September 26, 2013, between Emergent BioDefense Operations Lansing LLC and the Centers for Disease Control and Prevention.
10.2#††	Modification No. 8 to the CDC BioThrax Procurement Contract, effective September 30, 2013, between Emergent BioDefense Operations Lansing LLC and the Centers for Disease Control and Prevention.
12#	Ratio of Earnings to Fixed Charges.
31.1#	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).
31.2#	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).
32.1#	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101. INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linksbase Document
101.DEF	XBRL Taxonomy Definition Linksbase Document
101.LAB	XBRL Taxonomy Label Linksbase Document
101.PRE	XBRL Taxonomy Presentation Linksbase Document

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

(i) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2013 and September 30, 2012, (ii) Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2013 and 2012 (iii) Condensed Consolidated Balance Sheets at September 30, 2013 and December 31, 2012, (iv) Condensed Consolidated Statements of Cash Flows for the three and nine months ended September 30, 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.

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