Emergent BioSolutions Inc.
Form 10-Q
August 03, 2012

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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2012

OR

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

For the transition period from to

Commission file number: 001-33137

EMERGENT BIOSOLUTIONS INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	14-1902018
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
2273 Research Boulevard, Suite 400 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 repor
(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 July 31, 2012, the registrant had 36,203,917 shares of common stock outstanding.

Emergent BioSolutions Inc.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q and the documents incorporated by reference herein contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. All statements, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," "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, including our ability to obtain funding for our existing procurement contract with the U.S. government;
- our plans to pursue label expansions and other improvements for BioThrax;
- our ability to perform under our development contract with the U.S. government for our product candidate PreviThrax™ (Recombinant Protective Antigen Anthrax Vaccine, Purified);
- our ability to perform under our contract with the U.S. government to develop and obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55, our large-scale vaccine manufacturing facility in Lansing, Michigan;
- our ability to perform under our contract with the U.S. government to establish a Center for Innovation in Advanced Development and Manufacturing to facilitate advanced development of certain chemical, biological, radiological and nuclear medical countermeasures;
- 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 successfully integrate and develop the products or product candidates, programs, operations and personnel of any entities or businesses that we acquire;
- the timing of and our ability to obtain and maintain regulatory approvals for our products and product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property portfolio; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in this cautionary statement and elsewhere in this quarterly report, particularly in the "Risk Factors" section in Item 1A of this quarterly report, 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. Any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Balance Sheets
(in thousands, except share and per share data)

	June 30, 2012 (Unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 161,843	$ 143,901
Investments	-	1,966
Accounts receivable	46,815	74,153
Inventories	16,008	14,661
Deferred tax assets, net	638	1,735
Income tax receivable, net	10,422	9,506
Restricted cash	-	220
Prepaid expenses and other current assets	7,489	8,276
Total current assets	243,215	254,418
Property, plant and equipment, net	224,894	208,973
In-process research and development	41,800	51,400
Goodwill	5,502	5,502
Assets held for sale	-	11,765
Deferred tax assets, net	11,016	13,999
Other assets	713	807
Total assets	$ 527,140	$ 546,864
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 23,301	$ 40,530
Accrued expenses and other current liabilities	1,623	1,170
Accrued compensation	13,980	20,884
Contingent value rights, current portion	-	1,748
Long-term indebtedness, current portion	4,057	5,360
Deferred revenue	1,504	1,362
Total current liabilities	44,465	71,054
Contingent value rights, net of current portion	-	3,005
Long-term indebtedness, net of current portion	58,140	54,094
Other liabilities	2,013	1,984
Total liabilities	104,618	130,137
Commitments and contingencies		
Stockholders' equity:		

Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 36,203,917 and 36,002,698 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively	36	36
Additional paid-in capital	225,231	220,654
Accumulated other comprehensive loss	(3,249)	(3,313)
Retained earnings	197,670	196,869
Total Emergent BioSolutions Inc. stockholders' equity	419,688	414,246
Noncontrolling interest in subsidiaries	2,834	2,481
Total stockholders' equity	422,522	416,727
Total liabilities and stockholders' equity	$ 527,140	$ 546,864

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012 (Unaudited)	2011	2012 (Unaudited)	2011
Revenues:				
Product sales	$53,161	$71,479	$87,518	$77,076
Contracts and grants	17,218	16,662	33,172	29,598
Total revenues	70,379	88,141	120,690	106,674
Operating expense:				
Cost of product sales	13,186	16,069	20,697	17,137
Research and development	30,645	31,481	56,891	66,240
Selling, general and administrative	17,895	20,384	37,387	38,596
Impairment of in-process research and development	-	-	9,600	-
Income (loss) from operations	8,653	20,207	(3,885)	(15,299)
Other income (expense):				
Interest income	29	24	54	59
Interest expense	-	(6)	(6)	(6)
Other income (expense), net	907	(39)	1,761	(40)
Total other income (expense)	936	(21)	1,809	13
Income (loss) before provision for (benefit from) income taxes	9,589	20,186	(2,076)	(15,286)
Provision for (benefit from) income taxes	4,043	7,663	403	(4,636)
Net income (loss)	5,546	12,523	(2,479)	(10,650)
Net loss attributable to noncontrolling interest	2,086	1,687	3,279	3,463
Net income (loss) attributable to Emergent BioSolutions Inc.	$7,632	$14,210	$800	$(7,187)
Income (loss) per share - basic	$0.21	$0.40	$0.02	$(0.20)
Income (loss) per share - diluted	$0.21	$0.39	$0.02	$(0.20)
Weighted-average number of shares - basic	36,182,826	35,619,514	36,114,400	35,400,906
Weighted-average number of shares - diluted	36,556,697	36,667,452	36,301,335	35,400,906

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
	(Unaudited)		(Unaudited)	
Net income (loss) attributable to Emergent BioSolutions Inc.	$7,632	$14,210	$800	$(7,187)
Foreign currency translations	(20)	31	64	(662)
Comprehensive income (loss)	$7,612	$14,241	$864	$(7,849)

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

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

	Six Months Ended June 30,	
	2012	2011
Cash flows from operating activities:	(Unaudited)	
Net loss	$ (2,479)	$ (10,650)
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	5,425	5,150
Depreciation and amortization	4,909	4,514
Deferred income taxes	4,080	3,129
Non-cash development expenses from joint ventures	3,632	3,348
Change in fair value of contingent value rights	(3,005)	1,408
Impairment of in-process research and development	9,600	-
Impairment of long-lived assets	-	193
Excess tax benefits from stock-based compensation	1,247	(1,786)
Other	(55)	43
Changes in operating assets and liabilities:		
Accounts receivable	27,338	(7,937)
Inventories	(1,347)	(4,540)
Income taxes	(2,163)	(8,408)
Prepaid expenses and other assets	888	1,401
Accounts payable	(7,068)	(1,143)
Accrued expenses and other liabilities	488	3
Accrued compensation	(6,900)	(10,160)
Deferred revenue	142	(3,973)

Net cash provided by (used in) operating activities	34,732	(29,408)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(30,921)	(16,795)
Proceeds from sale of assets	11,765	-
Proceeds from maturity of investments	1,966	2,250
Purchase of investments	-	(5,269)
Net cash used in investing activities	(17,190)	(19,814)
Cash flows from financing activities:		
Proceeds from borrowings on long-term indebtedness	11,413	-
Issuance of common stock subject to exercise of stock options	401	8,695
Excess tax benefits from stock-based compensation	(1,247)	1,786
Principal payments on long-term indebtedness	(8,670)	(8,123)
Contingent value right payment	(1,748)	-
Release of restricted cash deposit	220	-
Net cash provided by financing activities	369	2,358
Effect of exchange rate changes on cash and cash equivalents	31	(61)
Net increase (decrease) in cash and cash equivalents	17,942	(46,925)
Cash and cash equivalents at beginning of period	143,901	169,019
	$ 161,843	$ 122,094

Cash and cash equivalents at end of period	

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

EMERGENT BIOSOLUTIONS INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Basis of presentation and consolidation

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

The unaudited consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X issued by the Securities and Exchange Commission. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the Securities and Exchange Commission.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of June 30, 2012 and the results of operations, comprehensive income (loss) and cash flows for the three and six months ended June 30, 2012 and 2011. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

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

2. Fair value measurements

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

	At June 30, 2012			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Investment in money market funds (1)	$55,612	$-	$-	$55,612
Total assets	$55,612	$-	$-	$55,612

	At December 31, 2011	
(in thousands)	Level 1	Total

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

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

As of June 30, 2012 and 2011, the Company did not have any transfers between Level 1 and Level 2 assets or liabilities.

The fair value of the contingent value right ("CVR") obligations is based on management's assessment of certain development and collaboration milestones, which are inputs that have no observable market (Level 3). The obligation is measured using a discounted cash flow model. For the three and six months ended June 30, 2012 and 2011, the changes in the fair value of the CVR obligations resulted from an update to the probability and estimated timing of achievement for certain development milestones along with an adjustment to the discount rates.

For the three months ended June 30, 2012, the Company recorded no adjustment to the fair value of the CVR obligations. For the six months ended June 30, 2012, the Company recorded decreases in the CVR obligations of $3.0 million due to notification from Pfizer Inc. ("Pfizer") of Pfizer's intent to cease development of programs related to the CVR milestones and a $1.7 million payment related to the Company's collaboration with Abbott Laboratories ("Abbott"). For the three and six months ended June 30, 2011, the Company recorded an increase in the fair value of the CVR obligations of $827,000 and $1.4 million, respectively. The adjustments to fair value are classified in the Company's statements of operations as research and development expense within the Company's Biosciences 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 six months ended June 30, 2012 and the year ended December 31, 2011.

(in thousands)	
Balance at January 1, 2011	$14,532
Expense (income) included in earnings	221
Expense (income) included in comprehensive income (loss)	-
Settlements	(10,000)
Purchases, sales, issuances and settlements	-
Transfers in/(out) of Level 3	-
Balance at December 31, 2011	$4,753
Expense (income) included in earnings	(3,005)
Expense (income) included in comprehensive income (loss)	-
Settlements	(1,748)
Purchases, sales and issuances	-
Transfers in/(out) of Level 3	-
Balance at June 30, 2012	$-

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. During the six months ended June 30, 2012, the Company's SBI-087 in-process research and development ("IPR&D") asset and goodwill were measured at fair value on a nonrecurring basis, as a result of the notification from Pfizer of its intent to cease development on the SBI-087 program and the Company's intent not to pursue further development of this asset. As of June 30, 2012, the Company had no other assets or liabilities that were measured at fair value on a nonrecurring basis.

Both the carrying value and fair value of long-term indebtedness at June 30, 2012 and December 31, 2011 were $62.2 million and $59.5 million, respectively.

3. Inventories

Inventories consist of the following:

(in thousands)	June 30, 2012	December 31, 2011
Raw materials and supplies	$2,740	$ 2,313
Work-in-process	9,572	10,149
Finished goods	3,696	2,199
Total inventories	$16,008	$ 14,661

4. In-process research and development and goodwill

During the six months ended June 30, 2012, Pfizer notified the Company of its intent to terminate its current development programs with respect to the Company's SBI-087 product candidate. The Company considered the notification as a potential indicator of impairment of the related SBI-087 IPR&D asset, and as a result 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 intent not to pursue further development of this asset. As a result of the impairment analysis, the Company recorded an impairment charge of $9.6 million during the during the six months ended June 30, 2012, which represented the entire carrying value of the SBI-087 IPR&D. This charge is classified in the Company's statements of operations as impairment of in-process research and development, within the Company's Biosciences segment.

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

As a result of the impairment of the SBI-087 IPR&D asset, the Company also performed an interim impairment analysis of the Biosciences therapeutic reporting unit, which contains all goodwill reported on the Company's consolidated balance sheets as of June 30, 2012. Based on the interim impairment assessment, the estimated fair value of the Biosciences therapeutic reporting unit was in excess of carrying value, and therefore no impairment of goodwill was recorded.

5. Assets held for sale

During the six months ended June 30, 2012, the Company completed the sale of two buildings in Frederick, Maryland for $12.2 million. These buildings had been classified as assets held for sale. The Company realized proceeds equal to the carrying value, less cost to sell, of these buildings and there was no gain or loss on the sale.

6. Long-term debt

The components of long-term indebtedness are as follows:

(in thousands)	June 30, 2012	December 31, 2011
Construction loan dated July 2011; LIBOR plus 3%, due July 2017	$30,000	$ 26,095
Equipment loan dated August 2011; variable, due December 2017	8,935	1,426
Term loan dated December 2009; three month LIBOR plus 3.25%, due December 2014	18,958	19,717
Term loan dated November 2009; three month LIBOR plus 3.25%, due November 2014	4,304	4,478
Loan dated October 2004; 3.0%, repaid in March 2012	-	2,500
Term loan dated October 2004; 3.48%, repaid in March 2012	-	5,238
Total long-term indebtedness	62,197	59,454
Less current portion of long-term indebtedness	(4,057)	(5,360)
Noncurrent portion of long-term indebtedness	$58,140	$ 54,094

On June 28, 2012, the Company amended the financial covenants of the construction loan and the equipment loan with PNC Bank to include a revised definition of earnings before income taxes, depreciation and amortization that excludes certain non-cash charges. As of June 30, 2012, the Company was in compliance with all debt covenenants.

On July 11, 2012, the Company amended the equipment loan with PNC to extend the drawdown period to December 15, 2012 and extend the maturity date of the loan from July 2017 to December 2017.

7. Stockholders' equity

Preferred stock

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

Common stock

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

Stock options and restricted stock units

As of June 30, 2012, the Company had two stock-based employee compensation plans, 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") (together, the "Emergent Plans"). The Company has granted options to purchase shares of common stock under the Emergent Plans and has granted restricted stock units under the 2006 Plan. The Emergent Plans have both incentive and non-qualified stock option features. The Company no longer grants equity awards under the 2004 Plan.

On May 17, 2012, the Company's shareholders approved the 2006 Plan, which increased the number of shares of common stock available for issuance under plan awards by 2,500,000. As of June 30, 2012, an aggregate of 11,178,826 shares of common stock were authorized for issuance under the 2006 Plan, of which a total of 3,757,296 shares of common stock remain available for future awards to be made to plan participants. As part of the May 2012 amendment, awards of restricted stock units after May 17, 2012 are counted against the maximum aggregate number of shares of common stock available for issuance under the 2006 Plan as 1.86 shares of common stock for every one restricted stock unit granted. The maximum number of shares subject to awards that may be granted per year under the 2006 Plan to a single participant is 287,700. The exercise price of each option must be not less than 100% of the fair market value of the shares underlying such option on the date of grant. Awards granted under the 2006 Plan have a contractual life of no more than 10 years. The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Emergent Plans are determined by the compensation committee of the Company's board of directors, which administers the Emergent Plans. Each equity award granted under the Emergent Plans vests as specified in the relevant agreement with the award recipient and no option can be exercised after ten years from the date of grant.

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

	2006 Plan		2004 Plan		
	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2011	3,090,909	$ 17.35	53,156	$ 8.86	$ 6,238,427
Granted	726,291	15.75	-	-	
Exercised	(43,491)	9.23	-	-	
Forfeited	(125,678)	19.52	-	-	
Outstanding at June 30, 2012	3,648,031	$ 17.06	53,156	$ 8.86	$ 4,227,300
Exercisable at June 30, 2012	2,176,650	$ 16.09	53,156	$ 8.86	$ 4,200,518

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

	Number of Shares	Weighted-Average Grant Price	Aggregate Intrinsic Value
Outstanding at December 31, 2011	635,500	$ 20.89	$ 10,714,450
Granted	363,197	15.75	
Vested	(228,369)	20.26	
Forfeited	(33,545)	20.10	
Outstanding at June 30, 2012	736,783	$ 18.58	$ 11,162,262

8. Variable interest entities

In July 2008, the Company entered into a collaboration with the University of Oxford ("Oxford") and certain Oxford researchers to conduct clinical trials to advance a vaccine product candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium ("OETC"). The Company has a 51% equity interest in OETC and controls the OETC Board of Directors. In addition, the Company has certain funding and service obligations related to its investment. In July 2011, the Company entered into an intercompany loan agreement with OETC, under which the Company agreed to provide OETC with a loan of up to $14.0 million to fund future clinical and development costs for the tuberculosis vaccine product candidate. The loan value can be increased to up to $23.0 million at the sole discretion of the Company. The loan bears interest at the rate of 8% per annum. Principal and interest on the outstanding balance will be due and payable in December 2014 or upon occurrence of either an event of default or the closing of a debt or equity financing by OETC that results in net proceeds equal to or in excess of $30.0 million in a

single transaction or a series of related transactions. Under the terms of the loan, OETC is required to comply with certain non-financial covenants. As of June 30, 2012, OETC was in compliance with all non-financial covenants. As of June 30, 2012, $4.0 million has been drawn by OETC under the loan facility. The Company evaluates its variable interests in OETC on a quarterly basis and has determined that it is the primary beneficiary as it has the power to direct the activities of OETC that most significantly impact OETC's economic performance and will absorb the majority of expected losses. Accordingly, the Company consolidates OETC. As of June 30, 2012 and 2011, respectively, assets of $3.5 million and $394,000 and liabilities of $5.3 million and $910,000 related to OETC were included within the Company's consolidated balance sheets. During the three and six months ended June 30, 2012, respectively, OETC incurred net losses of $4.2 million and $6.5 million, of which $2.1 million and $3.3 million are included in the Company's consolidated statements of operations. During the three and six months ended June 30, 2011, respectively, OETC incurred net losses of $3.2 million and $6.8 million, of which $1.6 million and $3.4 million are included in the Company's consolidated statements of operations.

In conjunction with the establishment of OETC, the Company granted a put option to Oxford and certain Oxford researchers whereby the Company may be required to acquire all of the OETC shares held by Oxford and the Oxford researchers at the fair market value of the underlying shares. This put option is contingent upon the satisfaction of a number of conditions that must exist or occur subsequent to the granting by the European Commission of marketing authorization for the OETC-sponsored vaccine product candidate for tuberculosis. The Company accounts for the put option in accordance with the accounting provisions related to derivatives and distinguishing liabilities from equity. In accordance with these provisions, the Company has determined that the put option had a de minimis fair value as of June 30, 2012.

In July 2010, the Company entered into a collaboration with Temasek Life Sciences Ventures Pte Limited to advance the development of vaccine and monoclonal products for worldwide prophylaxis or treatment of infection caused by existing or anticipated future pandemic influenza strains via a hemagglutinin-based medical countermeasure, resulting in the formation of EPIC Bio Pte Limited ("EPIC"). The Company has a 60% equity interest in EPIC and controls the EPIC Board of Directors. The Company evaluates its variable interests in EPIC on a quarterly basis and has determined that it is the primary beneficiary as it has the power to direct the activities of EPIC that most significantly impact EPIC's economic performance and will absorb the majority of expected losses. Accordingly, the Company consolidates EPIC. As of June 30, 2012 and 2011, respectively, assets of $317,000 and $1.9 million and liabilities of $99,000 and $741,000 related to EPIC were included within the Company's consolidated balance sheets. During the three and six months ended June 30, 2012, respectively, EPIC incurred net losses of $111,000 and $210,000, of which $67,000 and $126,000 are included in the Company's consolidated statements of operations. During the three and six months ended June 30, 2011, EPIC incurred net losses of $352,000 and $375,000, respectively, of which $211,000 and $225,000 are included in the Company's consolidated statements of operations.

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

(in thousands)	Emergent BioSolutions Inc.	Noncontrolling Interests	Total
Stockholders' equity at December 31, 2011	$ 414,246	$ 2,481	$ 416,727
Non-cash development expenses from variable interest entities	-	3,632	3,632
Net income (loss)	800	(3,279)	(2,479)
Other	4,642	-	4,642
Stockholders' equity at June 30, 2012	$ 419,688	$ 2,834	$ 422,522

9. Collaboration agreements

Abbott Laboratories

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

During the three and six months ended June 30, 2012, the Company recognized revenue of $1.4 million and $2.7 million, respectively, for research and development services pursuant to the Abbott collaboration, which are included in the Company's statements of operations as contracts and grants revenue within the Company's Biosciences segment.

Pfizer Inc.

In December 2005, Trubion entered into an agreement (the "Pfizer Agreement") with Wyeth Pharmaceuticals, now a wholly-owned subsidiary of Pfizer, for the development and worldwide commercialization of CD20-directed therapeutics. In May 2011, the Company and Pfizer entered into a third amendment to the Pfizer Agreement (the "Biosimilar Amendment") in which the Company released certain restrictions related to the development and commercialization of biosimilar CD20 antibodies. Under the terms of this amendment, the Company received a $2.5 million non-refundable payment upon execution of the Biosimilar Amendment, and is entitled to receive royalty payments in the low-single digits on net sales of certain Pfizer biosimilar products directed to CD20, subject to the satisfaction of specified conditions. In April 2012, Pfizer notified the Company of its intent to terminate the Pfizer Agreement, and in June 2012 the Company received formal written notice of termination of the Pfizer Agreement. The Company's right to receive royalty payments under the Biosimiliar Amendment survives termination of the Pfizer Agreement.

For the three and six months ended June 30, 2012, the Company recognized revenue of $512,000 and $877,000, respectively, for research and development services pursuant to the Pfizer Agreement, which are included in the Company's statements of operations as contracts and grants revenue within the Company's Biosciences segment.

10. Business interruption insurance recovery

During the six months ended June 30, 2012, the Company recorded $1.7 million in insurance recovery related to a power outage at its Lansing, Michigan facility. The insurance recovery is classified in the Company's statements of operations as other income (expense), net.

11. Earnings per share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands, except share and per share data)	2012	2011	2012	2011
Numerator:				
Net income (loss)	$7,632	$14,210	$800	$(7,187)
Denominator:				
Weighted-average number of shares-basic	36,182,826	35,619,514	36,114,400	35,400,906
Dilutive securities-equity awards	373,871	1,047,938	186,935	-
Weighted-average number of shares-diluted	36,556,697	36,667,452	36,301,335	35,400,906
Income (loss) per share-basic	$0.21	$0.40	$0.02	$(0.20)
Income (loss) per share-diluted	$0.21	$0.39	$0.02	$(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 month periods ended June 30, 2012 and 2011, approximately 3.0 million and 719,000 stock options, respectively, and 3.0 million stock options for the six month period ended June 30, 2012 were excluded from the calculation. These stock options were excluded because the exercise prices were in excess of the average per share closing price.

For the six month period ended June 30, 2011, approximately 4.0 million shares pursuant to equity awards were excluded from the calculation of diluted earnings per share because the net loss attributable to Emergent BioSolutions Inc. would make these awards antidilutive.

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

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

	Reportable Segments			
(in thousands)	Biodefense	Biosciences	All Other	Total
Three Months Ended June 30, 2012				
External revenue	$66,964	$ 3,415	$-	$70,379
Net income (loss)	24,335	(14,963)	(1,740)	7,632
Total assets	257,377	129,565	140,198	527,140
Three Months Ended June 30, 2011				
External revenue	$83,685	$ 4,456	$-	$88,141
Net income (loss)	36,902	(20,580)	(2,112)	14,210
Total assets	217,057	121,209	155,718	493,984

	Reportable Segments			
(in thousands)	Biodefense	Biosciences	All Other	Total
Six Months Ended June 30, 2012				
External revenue	$115,600	$ 5,090	$-	$120,690
Net income (loss)	38,601	(34,854)	(2,947)	800
Total assets	257,377	129,565	140,198	527,140
Six Months Ended June 30, 2011				
External revenue	$99,185	$ 7,489	$-	$106,674

Net income (loss)	30,810	(35,705)	(2,292)	(7,187)
Total assets	217,057	121,209	155,718	493,984

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

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

Overview

Product Portfolio

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

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

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

Our Biodefense segment has generated net income for each of the last five fiscal years. Over this timeframe, our Biosciences segment has generated revenue through development contracts and collaborative funding, but none of our Biosciences product candidates have received marketing approval and, therefore, our Biosciences segment has not generated any product sales revenues. As a result, our Biosciences segment has incurred a net loss for each of the last five fiscal years.

Product Sales

We have derived substantially all of our product sales revenues from BioThrax sales to the U.S. government. We are currently a party to a contract with the Centers for Disease Control and Prevention, or CDC, to supply 44.75 million doses of BioThrax for placement into the Strategic National Stockpile, or SNS, over a five-year period. We expect for

the foreseeable future to continue to derive substantially all of our product sales revenues from our sales of BioThrax to the U.S. government. Our total revenues from BioThrax sales were $87.5 million and $77.1 million for the six months ended June 30, 2012 and 2011, respectively. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers domestically and internationally and pursuing label expansions and improvements for BioThrax.

Contracts and Grants

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

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

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

Manufacturing Infrastructure

We conduct our BioThrax 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 a contract 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 November 2009, we purchased a building in Baltimore, Maryland for product development and manufacturing purposes, and are in the process of completing validation and qualification at this facility. We have entered into two loan agreements with PNC Bank totaling up to $42.0 million to fund these renovations, improvements and equipment acquisitions and have drawn approximately $38.9 million under the loan agreements. Our specific plans for this facility will be contingent on the progress of our existing development programs, the outcome of our efforts to acquire new product candidates and the recently awarded contract to establish a Center for Innovations in Advanced Development Manufacturing.

On June 15, 2012, we received the ADM contract award from BARDA to establish a Center for Innovation in Advanced Development and Manufacturing, or the Center. We expect that the Center will facilitate advanced development of chemical, biological, radiological, and nuclear medical countermeasures, develop domestic pandemic influenza vaccine manufacturing surge capacity, and provide workforce development training programs to address the U.S. government's preparedness priorities and needs. The contract consists of an 8-year base period of performance with funding up to approximately $160 million. Under the contract, our obligations include securing a pandemic influenza vaccine candidate and obtaining access to all necessary intellectual property rights for process development and manufacturing, expanding current facilities to support production of pandemic influenza vaccine and additional countermeasures and obtaining facility licensure to manufacture a pandemic influenza vaccine at our Baltimore facility. Novartis and Texas A&M University, which is partnered with GlaxoSmithKline, also received contract

awards from BARDA to establish additional Centers.

Critical Accounting Policies and Estimates

There have been no significant changes to our Critical Accounting Policies and Estimates during the six months ended June 30, 2012. Refer to our Critical Accounting Policies and Estimates section in our Annual Report on Form 10-K for the year ended December 31, 2011 filed with the Securities and Exchange Commission, or SEC.

Financial Operations Overview

Revenues

On September 30, 2011, we received a contract award from the CDC, and on March 8, 2012, entered into the related contract with the CDC to supply up to 44.75 million doses of BioThrax to the CDC over a five-year period. The maximum amount that could be paid to us under the contract is approximately $1.25 billion, subject to availability of funding. The period of performance under the contract is from September 30, 2011 through September 29, 2016. We began delivery of doses under the contract in December 2011. Through June 30, 2012, we have delivered and recognized revenue on approximately 4.0 million doses under this contract.

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

Development Programs	Funding Source	Award Date	Performance Period
Post-Exposure Prophylaxis indication for BioThrax	BARDA	9/2007	9/2007 - 3/2016
Recombinant botulinum vaccine	NIAID	6/2008	6/2008 - 5/2012
NuThrax	NIAID	7/2008	7/2008 - 6/2013
Thravixa	NIAID/BARDA	9/2008	9/2008 - 8/2012
NuThrax	NIAID/BARDA	9/2008	9/2008 - 7/2012
Double mutant recombinant protective antigen anthrax vaccine	NIAID	9/2009	9/2009 - 8/2012
Large-scale manufacturing for BioThrax	BARDA	7/2010	7/2010 - 7/2015
NuThrax	NIAID	7/2010	8/2010 - 8/2014
PreviThrax	BARDA	9/2010	9/2010 - 9/2015
Tuberculosis vaccine	NIAID	3/2012	3/2012 - 9/2017

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

Cost of Product Sales

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

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

Research and Development Expenses

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

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

We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to be in a position to realize the potential of our product candidates. We expect that spending for our product pipeline will increase as our product development activities continue based on ongoing advancement of our product candidates, and as we prepare for regulatory submissions and other regulatory activities. We expect that the magnitude of any increase in our research and development spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, participation of current or potential future third-party collaborators, number of product candidates under development, the size, structure and duration of any follow-on clinical programs that we may initiate, costs associated with manufacturing our product candidates on a large-scale basis for later-stage clinical trials, and our ability to use or rely on data generated by third parties.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, sales and marketing, business development, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales or research and development expense and professional fees for legal and accounting services. We currently market and sell BioThrax directly to the U.S. government with a small, targeted marketing and sales group. As we seek to broaden the market for BioThrax, and if we receive marketing approval for additional products, we expect that we will increase our spending for marketing and sales activities.

In-process Research and Development and Goodwill

During the six months ended June 30, 2012, Pfizer Inc., or Pfizer, notified us of their intent to terminate its current development programs with respect to our SBI-087 product candidate. We considered the notification a potential indicator of impairment of the related SBI-087 in-process research and development, or IPR&D, asset. As a result of the notification, we assessed the fair value of this asset. As part of the assessment, we considered the impact of Pfizer's decision, along with our intent not to pursue further development of this asset. As a result of the impairment analysis, we recorded an impairment charge of $9.6 million, which represented the entire carrying value of the SBI-087 IPR&D asset during the six months ended June 30, 2012. On June 22, 2012, we received formal written notice of Pfizer's termination of their license agreement with us, including development programs with respect to our SBI-087 product candidate, effective September 20, 2012.

As a result of the impairment of the SBI-087 IPR&D asset, we also performed an interim impairment analysis of the Biosciense therapeutic reporting unit, which containes all goodwill reported on our consolidated balance sheets as of June 30, 2012. Based on the interim impairment assessment, the estimated fair value of the Biosciences reporting unit was in excess of carrying value, and therefore no impairment of goodwill was recorded.

Results of Operations

Quarter Ended June 30, 2012 Compared to Quarter Ended June 30, 2011

Revenues

Product sales revenues decreased by $18.3 million, or 26%, to $53.2 million for the three months ended June 30, 2012 from $71.5 million for the three months ended June 30, 2011. This decrease in product sales revenues was primarily due to a 20% decrease in the number of doses of BioThrax delivered coupled with a 7% decrease in the sales price per dose. The decrease in the number of doses delivered was primarily attributable to the timing of doses sold. The decrease in the sales price per dose was due to slightly lower price per dose under the current CDC contract compared to our prior contract with Health and Human Services, or HHS. Product sales revenues during the three months ended June 30, 2012 consisted of BioThrax sales to the CDC of $53.1 million and aggregate international and other sales of $111,000. Product sales revenues for the three months ended June 30, 2011 consisted of BioThrax sales to HHS of $70.7 million and aggregate international and other sales of $738,000.

Contracts and grants revenues increased by $556,000, or 3%, to $17.2 million for the three months ended June 30, 2012 from $16.7 million for the three months ended June 30, 2011. The increase in contracts and grants revenues was primarily due to increased activity and associated revenue from our development contract with BARDA for large-scale manufacturing of BioThrax, a milestone paymemt recieved related to our post-exposure prophylaxis, or PEP, indication for BioThrax and the sale of our spi-VEC™ (live attuenated bacterial vaccine vector) technology, partially offset by decreased activity and associated revenue under our NuThrax contracts along with the one-time payment received in 2011 related to the Pfizer biosimilar amendment. Contracts and grants revenues during the three months ended June 30, 2012 consisted of $13.8 million in development contract and grant revenues from BARDA and NIAID, $1.9 million from Abbott Laboratories, or Abbott, and Pfizer, and $1.5 million from the sale of patent and trademark rights and related materials pertaining to our spi-VEC technology platform. Contracts and grants revenues for the three months ended June 30, 2011 consisted of $12.1 million in development contract and grant revenue from NIAID and BARDA and $4.5 million from Abbott and Pfizer.

Cost of Product Sales

Cost of product sales decreased by $2.9 million, or 18%, to $13.2 million for the three months ended June 30, 2012 from $16.1 million for the three months ended June 30, 2011. This decrease was primarily attributable to the 20% decrease in the number of BioThrax doses sold.

Research and Development Expenses

Research and development expenses decreased by $836,000, or 3%, to $30.6 million for the three months ended June 30, 2012 from $31.5 million for the three months ended June 30, 2011. This decrease primarily reflects lower contract service expenses, and includes decreased expenses of $2.5 million development activities categorized in the Biosciences segment, partially offset by increased expenses of $1.5 million for product candidates that are categorized in the Biodefense segment and increased expenses of $128,000 in other research and development, which are in support of central research and development activities. During the three months ended June 30, 2012 and 2011, we incurred research and development expenses net of development contract and grant revenues along with the net loss attributable to noncontrolling interests of $11.3 million and $13.1 million, respectively.

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

and initiation of manufacturing of consistency lots. The spending for BioThrax related programs was related to clinical and non-clinical studies to support applications for label expansion for BioThrax. The increase in spending for PreviThrax was primarily due to model optimization. The decrease in spending for Anthrivig™ (Human Anthrax Immunglobulin) was primarily due to the completion of clinical trial activities. The decrease in spending for Thravixa was primarily due to the timing of clinical trial activities. The decrease in spending for our other Biodefense activities was primarily due to decreased spending associated with our double mutant recombinant protective antigen anthrax vaccine in light of reduced funding by the U.S. government for this product candidate.

The decrease in spending on Biosciences product candidates, detailed in the table below, was primarily attributable to the timing of development efforts. The increase in spending for our tuberculosis vaccine product candidate is related to the timing of costs incurred for the continued conduct of a Phase IIb clinical trial along with process development and manufacturing activities. The decrease in spending for our TRU-016 product candidate is primarily due to the timing of clinical manufacturing and clinical trial activities. The decrease in spending for our ES301 product candidate is primarily due to the timing of non-clinical activities. The increase in spending for our T-Scorp product candidate, a treatment for castrate resistant prostate cancer, was primarily due to characterization studies. The decrease in spending for our zanolimumab product candidate was primarily due to upfront and milestones payments incurred in 2011 related to our May 2011 acquisition of certain assets of TenX BioPharma, Inc. The decrease in spending for our X1 product candidate is primarily related to reduced non-clinical activities. The decrease in spending for our influenza vaccine product candidate is primarily due to the timing of process and analytical development. The decrease in spending for Typhella was primarily due to the completion of manufacturing and clinical studies. The increase in spending for our other Biosciences activities was primarily due to increased spending associated with the development of platform technologies along with 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.

Our principal research and development expenses for the three months ended June 30, 2012 and 2011 are shown in the following table:

	Three Months ended June 30,	
(in thousands)	2012	2011
Biodefense:		
NuThrax	$2,011	$3,083
Large-scale manufacturing for BioThrax	4,105	2,855
BioThrax related programs	3,104	1,626
PreviThrax	4,242	3,042
Anthrivig	2	386
Thravixa	280	947
Other Biodefense	235	546
Total Biodefense	13,979	12,485
Biosciences:		
Tuberculosis vaccine	5,544	3,932

TRU-016	3,241	3,450
ES301 (formerly DRACO)	790	1,985
T-Scorp	1,011	-
Zanolimumab	311	3,149
X1	-	914
Influenza vaccine	119	692
Typhella	53	262
Other Biosciences	4,113	3,256
Total Biosciences	15,182	17,640
Other	1,484	1,356
Total	$30,645	$31,481

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $2.5 million, or 12%, to $17.9 million for the three months ended June 30, 2012 from $20.4 million for the three months ended June 30, 2011. This decrease is primarily due to $2.2 million in charges incurred in 2011 related to the restructuring of our UK operations. The majority of the expense is attributable to the Biodefense segment, in which selling, general and administrative expenses decreased by $84,000, or 1%, to $13.0 million for the three months ended June 30, 2012 from $13.1 million for the three months ended June 30, 2011. Selling, general and administrative expenses related to our Biosciences segment decreased by $2.4 million, or 33%, to $4.9 million for the three months ended June 30, 2012 from $7.3 million during the three months ended June 30, 2011.

Total Other Income (Expense)

Total net other income increased by $957,000 to net other income of $936,000 for the three months ended June 30, 2012 from net other expense of $21,000 for the three months ended June 30, 2011. The net increase was primarily due to a business interruption insurance recovery related to a power outage at our Lansing, Michigan facility.

Income Taxes

Provision for income taxes decreased by $3.6 million, or 47%, to $4.0 million for the three months ended June 30, 2012 from $7.7 million for the three months ended June 30, 2011. The decrease in the provision for income taxes is due to the $10.2 million decrease in our income before provision for income taxes and the loss attributable to noncontrolling interests.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest increased by $399,000, or 24%, to $2.1 million for the three months ended June 30, 2012 from $1.7 million for the three months ended June 30, 2011. The increase resulted primarily from the timing of clinical and development activities and related expenses incurred by our joint ventures. These amounts represent the portion of the losses incurred by the joint ventures for the three months ended June 30, 2012 and 2011, respectively, that is attributable to our joint venture partners.

Six Months Ended June 30, 2012 Compared to Six Months Ended June 30, 2011

Revenues

Product sales revenues increased by $10.4 million, or 14%, to $87.5 million for the six months ended June 30, 2012 from $77.1 million for the six months ended June 30, 2011. This increase in product sales revenues was primarily due to a 23% increase in the number of doses of BioThrax delivered partially offset by an 8% decrease in the sales price per dose. The increase in doses delivered is primarily attributable to the timing of deliveries to the SNS. The decrease in the sales price per dose was due to slightly lower price per dose under the current CDC contract versus our prior contract with HHS. Product sales revenues for the six months ended June 30, 2012 consisted of BioThrax sales to CDC of $87.3 million and aggregate international and other sales of $199,000. Product sales revenues for the six months ended June 30, 2011 consisted of BioThrax sales to HHS of $75.8 million and aggregate international and other sales of $1.3 million.

Contracts and grants revenues increased by $3.6 million, or 12%, to $33.2 million for the six months ended June 30, 2012 from $29.6 million for the six months ended June 30, 2011. The increase in contract and grant revenues was primarily due to increased activity and associated revenue from our development contracts with BARDA for large-scale manufacturing for BioThrax and development of PreviThrax along with a milestone payment received for our PEP indication for BioThrax and the sale of our spi-VEC technology, partially offset by decreased activity under our NuThrax contracts with NIAID and BARDA and decreased revenue from Pfizer and Abbott. Contracts and grants revenues for the six months ended June 30, 2012 consisted of $28.1 million in development contract and grant revenues from NIAID and BARDA, $3.6 million from Abbott and Pfizer and $1.5 million from the sale of our spi-VEC platform technology. Contracts and grants revenues for the six months ended June 30, 2011 consisted of $22.0 million in development contract and grant revenue from NIAID and BARDA and $7.5 million from Abbott and Pfizer.

Cost of Product Sales

Cost of product sales increased by $3.6 million, or 21%, to $20.7 million for the six months ended June 30, 2012 from $17.1 million for the six months ended June 30, 2011. This increase was primarily attributable to the 23% increase in the number of doses of BioThrax sold.

Research and Development Expenses

Research and development expenses decreased by $9.3 million, or 14%, to $56.9 million for the six months ended June 30, 2012 from $66.2 million for the six months ended June 30, 2011. This decrease primarily reflects lower contract service and personnel-related costs, and includes decreased expenses of $12.0 million for product candidates and technology platform development activities categorized in the Biosciences segment, increased expenses of $2.0 million for product candidates categorized in the Biodefense segment, and increased expenses of $722,000 in other research and development, which are in support of central research and development activities. For the six months ended June 30, 2012 and 2011, we incurred research and development expenses net of development contract and grant reimbursements along with the net loss attributable to noncontrolling interests of $20.4 million and $33.2 million, respectively.

The increase in spending on Biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on several programs as we completed various studies and prepared for subsequent studies and trials. The decrease in spending for NuThrax was primarily due to the timing of clinical trial activities. The increase in spending for our large-scale manufacturing for BioThrax program was primarily due to non-clinical studies and preparation for and initiation of manufacturing of consistency lots. 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 increase in spending for PreviThrax was primarily due to model optimization. The decrease in spending for Anthrivig was primarily due to the completion of clinical trial activities. The decrease in spending for Thravixa was primarily due to the timing of clinical trial activities. The decrease in spending for our other Biodefense activities was primarily

due to decreased spending associated with our double mutant recombinant protective antigen anthrax vaccine.

The decrease in spending on Biosciences product candidates, detailed in the table below, was primarily attributable to the timing of development efforts. The decrease in spending for our tuberculosis vaccine product candidate is related to the timing of costs incurred for the continued conduct of a Phase IIb clinical trial along with process development and manufacturing activities. The decrease in spending for our TRU-016 product candidate is primarily due to the timing of clinical manufacturing and clinical trial activities. The decrease in spending for our ES301 product candidate is primarily due to the timing of non-clinical activities. The increase in spending for our T-Scorp product candidate was primarily due to characterization studies. The decrease in spending for our zanolimumab product candidate was primarily due to upfront and milestones payments incurred in 2011 related to our May 2011 acquisition of certain assets of TenX BioPharma, Inc., partially offset by process and clinical development activities in 2012. The decrease in spending for our X1 product candidate is primarily related to reduced non-clinical activities. The decrease in spending for our influenza vaccine product candidate is primarily due to the timing of process and analytical development. The decrease in spending for Typhella was primarily due to the completion of manufacturing and clinical studies. The decrease in spending for our other Biosciences activities was primarily due to a reduction of the contingent value right obligations associated with our agreement with Pfizer, partially offset by increased spending associated with development of platform technologies along with preclinical product candidates.

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

Our principal research and development expenses for the six months ended June 30, 2012 and 2011 are shown in the following table:

	Six Months ended June 30,	
(in thousands)	2012	2011
Biodefense:		
NuThrax	$4,617	$6,782
Large-scale manufacturing for BioThrax	8,802	6,100
BioThrax related programs	5,568	3,336
PreviThrax	8,745	6,157
Anthrivig	105	1,021
Thravixa	813	2,255
Other Biodefense	496	1,526
Total Biodefense	29,146	27,177
Biosciences:		
Tuberculosis vaccine	8,775	9,836
TRU-016	6,024	8,475
ES301 (formerly DRACO)	1,842	3,946
T-Scorp	1,427	-
Zanolimumab	903	3,149

X1	65	1,822
Influenza vaccine	220	1,517
Typhella	186	1,102
Other Biosciences	4,967	6,602
Total Biosciences	24,409	36,449
Other	3,336	2,614
Total	$56,891	$66,240

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $1.2 million, or 3%, to $37.4 million for the six months ended June 30, 2012 from $38.6 million for the six months ended June 30, 2011. This decrease is primarily due to approximately $2.6 million in restructuring charges related to our UK operations in 2011 partially offset by increased personnel and professional services to support growth of our business. The majority of the expense is attributable to the Biodefense segment, in which selling, general and administrative expenses increased by $369,000, or 1%, to $27.5 million for the six months ended June 30, 2012 from $27.2 million for the six months ended June 30, 2011. Selling, general and administrative expenses related to our Biosciences segment decreased by $1.6 million, or 14%, to $9.9 million for the six months ended June 30, 2012 from $11.4 million for the six months ended June 30, 2011.

Impairment of in-process research and development

Impairment of in-process research and development was $9.6 million for the six months ended June 30, 2012. The impairment charge for the six months ended June 30, 2012, resulted from the full impairment of our SBI-087 in-process research and development asset during the six months ended June 30, 2012. There was no impairment for the six months ended June 30, 2011.

Total Other Income (Expense)

Total other income increased by $1.8 million to $1.8 million for the six months ended June 30, 2012 from $13,000 for the six months ended June 30, 2011. The increase was due primarily to a business interruption insurance recovery related to a power outage at our Lansing, Michigan facility.

Income Taxes

Provision for (benefit from) income taxes increased by $5.0 million to a provision for income taxes of $403,000 for the six months ended June 30, 2012 from a benefit from income taxes of $4.6 million for the six months ended June 30, 2011. The estimated annual effective tax rate for the six months ended June 30, 2012 and 2011 was 34% and 39%, respectively. The increase in income taxes is primarily due to a $13.0 million increase in our income before provision for income taxes and the loss attributable to noncontrolling interests.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest decreased by $184,000, or 5%, to $3.3 million for the six months ended June 30, 2012 from $3.5 million for the six months ended June 30, 2011. The decrease resulted primarily from the timing of clinical and development activities and related expenses incurred by our joint ventures. These amounts represent the portion of the loss incurred by the joint venture for the six months ended June 30, 2012 and 2011, respectively, that is attributable to our joint venture partners.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our cash requirements from inception through June 30, 2012 principally with a combination of revenues from BioThrax product sales, debt financings and facilities leases, development funding from government entities and non-government and philanthropic organizations and collaborative partners, the net proceeds from our initial public offering and from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the five years ended December 31, 2011.

As of June 30, 2012, we had cash and cash equivalents of $161.8 million. Additionally, at June 30, 2012, our accounts receivable balance was $46.8 million.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2012 and 2011:

	Six Months ended June 30,	
(in thousands)	2012	2011
Net cash provided by (used in):		
Operating activities(1)	$34,763	$(29,469)
Investing activities	(17,190)	(19,814)
Financing activities	369	2,358
Total net cash provided by (used in)	$17,942	$(46,925)

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

Net cash provided by operating activities of $34.8 million for the six months ended June 30, 2012 was principally due to a decrease in accounts receivable of $27.3 million related to the timing of collection of amounts billed to the CDC, non-cash charges of $9.6 million for the impairment of in-process research and development, $5.4 million for stock-based compensation, $4.9 million for depreciation and amortization, and $3.6 million for development expenses primarily from our joint ventures, partially offset by a decrease in accrued compensation of $6.9 million associated with the payment of 2011 bonuses and a net decrease in accounts payable of $7.0 million related to the timing of payments for ongoing construction projects and operational activities.

Net cash used in operating activities of $29.5 million for the six months ended June 30, 2011 was principally due to our net loss attributable to Emergent BioSolutions Inc. of $7.2 million, a $4.5 million increase in inventory related to the timing of BioThrax shipments, a net decrease in income taxes of $5.3 million related to timing differences, a decrease in accrued compensation of $10.2 million primarily due to the payment of 2010 bonuses, an increase in accounts receivable of $7.9 million due to the timing of collection of amounts billed primarily to HHS, partially offset by non-cash charges of $5.2 million for stock-based compensation, $4.5 million for depreciation and amortization, and $3.3 million for development expenses primarily from our joint venture with the University of Oxford.

Net cash used in investing activities for the six months ended June 30, 2012 was $17.2 million, primarily due to capital expenditures of $30.9 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 used in investing activities for the six months ended June 30, 2011 was $19.8 million, primarily due to capital expenditures of $16.8 million related to the construction and related costs for our facility in Baltimore,

Maryland, and infrastructure investments and other equipment, along with the purchase of U.S. Treasury securities of $5.3 million partially offset by proceeds from the maturity of U.S. Treasury securities of $2.3 million.

Net cash provided by financing activities of $369,000 for the six months ended June 30, 2012 resulted primarily from $11.4 million in advances under our construction and equipment loans with PNC Bank related to the renovation, improvement and equipment purchases at our Baltimore facility, partially offset by $8.7 million in principal payments on indebtedness, including $7.7 million in repayment of debts related to our Frederick, MD buildings, a $1.7 million CVR payment and $1.3 million related to excess tax benefits from the exercise of stock options.

Net cash provided by financing activities of $2.4 million for the six months ended June 30, 2011 resulted primarily from $8.7 million in proceeds from stock option exercises and $1.8 million related to excess tax benefits from the exercise of stock options, partially offset by $8.1 million in principal payments on indebtedness.

Debt Financing

As of June 30, 2012, we had $62.2 million principal amount of debt outstanding, comprised primarily of the following:

- § $19.0 million outstanding under a term loan from HSBC Realty Credit Corporation used to finance a portion of the costs of our facility expansion in Lansing, Michigan;
- § $4.3 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance a portion of the purchase price of our facility in Gaithersburg, Maryland;
- § $30.0 million outstanding under a construction loan from PNC Bank used to fund the ongoing renovation of our Baltimore, Maryland facility; and
- § $8.9 million outstanding under an equipment loan from PNC Bank used to fund equipment purchases at our Baltimore, Maryland facility.

On June 28, 2012, we amended the financial covenants of the construction loan and equipment loan with PNC Bank to include a revised definition of earnings before income taxes, depreciation and amortization ("EBITDA"). EBITDA is now defined as net income of Emergent BioSolutions Inc. plus:

- § interest expense;
- § income taxes;
- § depreciation and amortization;
- § extraordinary or non-recurring non-cash expenses;
- § non-cash stock based compensation expense;
- § non-cash development expenses from joint ventures;
- § total impairment of long-lived assets, change in fair value of contingent value rights, amortization or impairment of intangible assets and impairment of goodwill (provided that maximum addback shall not exceed $15.0 million for any four fiscal quarter period).

On July 11, 2012, we amended the equipment loan with PNC to extend the drawdown period to December 15, 2012 and extend the maturity date of the loan from July 2017 to December 2017.

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

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures and debt service requirements from existing cash and cash equivalents, revenues from BioThrax product sales, collaboration funding, development contract and grant funding, and any lines of credit we may establish from time to time. There are numerous risks and uncertainties associated with BioThrax product sales and with the development and commercialization of our product candidates. We may seek additional external financing to provide additional financial flexibility. Our future capital requirements will depend on many factors, including:

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

We may require additional sources of funds for future acquisitions that we may make or, depending on the size of the obligation, to meet balloon payments upon maturity of our current borrowings. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. As of the date of the filing of this quarterly report on Form 10-Q, 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. Current economic conditions may make it difficult to obtain financing on attractive terms or at all. Lenders may be able to impose covenants on us that could be difficult to satisfy, which could put us at increased risk of defaulting on debt. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

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

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 three or six months ended June 30, 2012.

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 June 30, 2012. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2012, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the quarter ended June 30, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Not applicable.

ITEM 1A. RISK FACTORS

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

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

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales to the U.S. government of BioThrax, our FDA-approved anthrax vaccine and only marketed product. We are currently party to a contract with the Centers for Disease Control, or CDC, for the supply of 44.75 million doses of BioThrax for placement into the SNS over a five year period through September 2016.

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

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 or subcontracts awarded through competitive bidding. Competitive bidding for government contracts presents a number of risks or requirements, some of which are not typically present in the commercial contracting process, including:

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

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

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

Our principal customer for BioThrax is the U.S. government. We anticipate that the U.S. government will also be the principal customer for any other biodefense products that we successfully develop. Over its lifetime, a U.S. government program may be implemented through the award of many different individual contracts and subcontracts. The funding for government programs is subject to Congressional appropriations, often made on a fiscal year basis,

even for programs designed to continue for several years. These appropriations can be subject to political considerations and stringent budgetary constraints. For example, sales of BioThrax supplied under our multi-year procurement contract with the CDC will be subject to available funding, mostly from annual appropriations. Additionally, our government-funded development contracts typically give the U.S. government the right, exercisable in its sole discretion, to extend these contracts for successive option periods following a base period of performance. The value of the services to be performed during these option periods may constitute the majority of the total value of the underlying contract. For example, the development contract we were awarded in September 2010 for development of PreviThrax consists of a two-year base period of performance valued at approximately $51 million, three successive one-year option periods valued at approximately $126 million and funding for optional non-clinical studies valued at approximately $9 million. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the U.S. government otherwise declines to exercise its options under our contracts with it, our business, revenues and operating results may suffer.

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

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

§ procurement integrity;
§ export control;
§ government security;
§ employment practices;
§ protection of the environment;
§ accuracy of records and the recording of costs; and
§ foreign corrupt practices.

Compliance with these obligations increases our costs. Failure to comply with these regulations and requirements could lead to suspension or debarment, from government contracting or subcontracting for a period of time. The termination of a government contract or relationship as a result of our failure to satisfy any of these obligations could have a negative impact on our operations and harm our reputation and ability to procure other government contracts in the future.

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

Our prior contracts for the supply of BioThrax with HHS and the DoD, as well as our current contract for the procurement of 44.75 million doses of BioThrax by the CDC, are fixed price contracts. We expect that our potential future contracts with the U.S. government for BioThrax, as well as contracts for biodefense product candidates that we successfully develop, if any, also may be fixed price contracts. Under a fixed price contract, we are required to deliver our products at a fixed price regardless of the actual costs we incur and to absorb any costs in excess of the fixed price. Estimating costs that are related to performance in accordance with contract specifications is difficult, particularly where the period of performance is over several years. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of a fixed price contract or cause a loss, which could in turn harm our operating results.

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

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

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including by imposing equitable price adjustments;
- cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- decline to exercise an option to renew a contract;
- exercise an option to purchase only the minimum amount, if any, specified in a contract;
- decline to exercise an option to purchase the maximum amount, if any, specified in a contract;
- claim rights to 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;
- change the course of a development program in a manner that differs from the contract's original terms or from our desired development plan, including decisions regarding our partners in the program;
- pursue criminal or civil remedies under the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

Generally, government contracts, including our CDC contract for BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the U.S. government's convenience. Under general principles of government contracting law, if the U.S. government terminates a contract for convenience, the other party to that contract may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the U.S. government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. One or more of our government contracts could be terminated under these circumstances. Some U.S. government contracts grant the U.S. government the right to use, for or on behalf of the U.S. government, any technologies developed by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the U.S. government.

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

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

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

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

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

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

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

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

- the Federal Acquisition Regulations, and agency-specific regulations supplemental to the Federal Acquisition Regulations, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act and the Foreign Corrupt Practices Act, or FCPA;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

In addition, qui tam lawsuits have been brought against us in which the plaintiffs argued that we defrauded the U.S. government by distributing non-compliant doses of BioThrax. Although we ultimately prevailed in this litigation, we spent significant time and money defending the litigation. U.S. states, many municipalities and foreign governments typically also have laws and regulations governing contracts with their respective agencies. These domestic and foreign laws and regulations affect how we and our customers conduct business and, in some instances, impose additional costs on our business. Any changes in applicable laws and regulations could restrict our ability to maintain our existing contracts and obtain new contracts, which could limit our ability to conduct our business and materially and adversely affect our revenues and results of operations.

Risks Related to Our Financial Position and Need for Additional Financing

We may not maintain profitability in future periods or on a consistent basis.

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

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

As of June 30, 2012, we had $62.2 million principal amount of debt outstanding. We may seek to raise substantial external debt financing to provide additional financial flexibility. The assumption of debt could have significant adverse consequences, including:

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

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

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

We expect our development expenses to increase in connection with our ongoing activities, particularly as we conduct additional and later stage clinical trials for our product candidates. We also expect our commercialization expenses to increase in the future as we seek to broaden the market for BioThrax and if we receive marketing approval for additional products. We also may undertake additional facility projects in the future. In the event that our ability to sell BioThrax to the U.S. government is interrupted for an extended period of time, we will utilize our cash balances to help fund our ongoing operations.

As of June 30, 2012, we had $208.7 million of cash, cash equivalents and accounts receivable. Our future capital requirements will depend on many factors, including:

- the level and timing of BioThrax product sales and cost of product sales;
- our ability to obtain funding from government entities, non-government and philanthropic organizations and potential collaborative partners for our development programs;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to Building 55, our large-scale manufacturing facility in Lansing, Michigan, and our facility in Baltimore, Maryland, and any capital improvements to the existing facilities;