

# Emergent BioSolutions Inc. (EBS)

## 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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

Form 10-Q

(Mark One)

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

**For the quarterly period ended September 30, 2011**

**OR**

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

**For the transition period from** \_\_\_\_\_ **to** \_\_\_\_\_

**Commission file number: 001-33137**

**EMERGENT BIOSOLUTIONS INC.**

*(Exact Name of Registrant as Specified in Its Charter)*

**Delaware**

*(State or Other Jurisdiction of  
Incorporation or Organization)*

**14-1902018**

*(I.R.S. Employer  
Identification No.)*

**2273 Research Boulevard, Suite 400**

**Rockville, Maryland**

*(Address of Principal Executive Offices)*

**20850**

*(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.  Yes  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).  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of October 28, 2011, the registrant had 35,952,794 shares of common stock outstanding.

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**Emergent BioSolutions Inc.**

**Index to Form 10-Q**

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our ability to perform under our contracts with the U.S. government related to BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, including the timing of deliveries;
- our plans for future sales of BioThrax, including our ability to obtain new contracts or modifications to existing contracts 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 plans to expand our manufacturing facilities and capabilities;
- the rate and degree of market acceptance of our products and product candidates;
- the success of preclinical studies and clinical trials of our product candidates and post-approval clinical utility of our products;
- our ongoing and planned development programs, preclinical studies and clinical trials;
- our ability to identify and acquire or in-license products and product candidates that satisfy our selection criteria;
- our ability to successfully integrate and develop the products or product candidates, programs, operations and personnel of any entities or businesses that we acquire;
- the potential benefits of our existing collaborations and our ability to selectively enter into additional collaborative arrangements;
- the timing of and our ability to obtain and maintain regulatory approvals for our products and product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property portfolio; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

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

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

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**PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

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

	<b>September 30,</b>	<b>December 31,</b>
	<b>2011</b>	<b>2010</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 125,346	\$ 169,019
Investments	3,499	2,029
Accounts receivable	48,994	39,326
Inventories	17,979	12,722
Deferred tax assets, net	7,209	2,638
Income tax receivable, net	24,488	8,728
Restricted cash	217	217
Prepaid expenses and other current assets	9,033	8,814
<b>Total current assets</b>	<b>236,765</b>	<b>243,493</b>
Property, plant and equipment, net	188,245	152,701
In-process research and development	51,400	51,400
Goodwill	5,502	5,029
Assets held for sale	12,065	12,741
Deferred tax assets, net	18,278	33,757
Other assets	707	1,198
<b>Total assets</b>	<b>\$ 512,962</b>	<b>\$ 500,319</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 33,902	\$ 25,409
Accrued expenses and other current liabilities	1,150	1,309
Accrued compensation	14,735	23,975
Contingent value rights, current portion	9,865	-
Long-term indebtedness, current portion	4,920	17,187
Deferred revenue, current portion	4,359	7,839
<b>Total current liabilities</b>	<b>68,931</b>	<b>75,719</b>
Contingent value rights, net of current portion	5,992	14,532
Long-term indebtedness, net of current portion	48,873	30,239
Deferred revenue, net of current portion	2,781	4,386
Other liabilities	1,882	1,882
<b>Total liabilities</b>	<b>128,459</b>	<b>126,758</b>
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock, \$0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	-	-
Common stock, \$0.001 par value; 100,000,000 shares authorized, 35,869,025 and 35,011,423 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	36	35
Additional paid-in capital	215,938	197,689
Accumulated other comprehensive loss	(2,894)	(2,110)
Retained earnings	168,212	173,850
<b>Total Emergent BioSolutions Inc. stockholders' equity</b>	<b>381,292</b>	<b>369,464</b>
Noncontrolling interest in subsidiaries	3,211	4,097
<b>Total stockholders' equity</b>	<b>384,503</b>	<b>373,561</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 512,962</b>	<b>\$ 500,319</b>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(Unaudited)		(Unaudited)	
<b>Revenues:</b>				
Product sales	\$ 43,663	\$ 67,266	\$ 120,739	\$ 161,991
Contracts and grants	15,099	6,720	44,697	20,933
<b>Total revenues</b>	<u>58,762</u>	<u>73,986</u>	<u>165,436</u>	<u>182,924</u>
<b>Operating expenses:</b>				
Cost of product sales	10,706	11,532	27,843	30,116
Research and development	29,216	21,156	95,456	59,680
Selling, general and administrative	17,432	20,693	56,028	54,534
<b>Income (loss) from operations</b>	<u>1,408</u>	<u>20,605</u>	<u>(13,891)</u>	<u>38,594</u>
<b>Other income (expense):</b>				
Interest income	22	38	81	802
Interest expense	-	-	-	-
Other income (expense), net	37	(1,003)	(9)	(1,012)
<b>Total other income (expense)</b>	<u>59</u>	<u>(965)</u>	<u>72</u>	<u>(210)</u>
<b>Income (loss) before provision for (benefit from) income taxes</b>	1,467	19,640	(13,819)	38,384
<b>Provision for (benefit from) income taxes</b>	<u>1,604</u>	<u>7,696</u>	<u>(3,032)</u>	<u>15,088</u>
<b>Net income (loss)</b>	(137)	11,944	(10,787)	23,296
Net loss attributable to noncontrolling interests	1,686	1,176	5,149	2,155
<b>Net income (loss) attributable to Emergent BioSolutions Inc.</b>	<u>\$ 1,549</u>	<u>\$ 13,120</u>	<u>\$ (5,638)</u>	<u>\$ 25,451</u>
<b>Earnings (loss) per share - basic</b>	\$ 0.04	\$ 0.42	\$ (0.16)	\$ 0.82
<b>Earnings (loss) per share - diluted</b>	\$ 0.04	\$ 0.41	\$ (0.16)	\$ 0.80
<b>Weighted-average number of shares - basic</b>	35,855,217	31,301,796	35,552,900	31,094,616
<b>Weighted-average number of shares - diluted</b>	36,447,933	32,113,313	35,552,900	31,816,900

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

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

**Nine Months Ended**  
**September 30,**  
**2011      2010**  
**(Unaudited)**

<b>Cash flows from operating activities:</b>		
Net income (loss)	\$ (10,787)	\$ 23,296
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	7,911	5,206
Depreciation and amortization	6,926	4,020
Deferred income taxes	11,937	4,516
Non-cash development expenses from variable interest entities	4,263	2,241
Impairment of long-lived assets	676	1,029
Change in fair value of contingent value rights	1,325	-
Excess tax benefits from stock-based compensation	(1,502)	(1,077)
Other	60	(31)
Changes in operating assets and liabilities:		
Accounts receivable	(9,668)	46,935
Inventories	(5,257)	(3,799)
Income taxes	(15,760)	(10,632)
Prepaid expenses and other assets	270	(794)
Accounts payable	119	5,990
Accrued expenses and other liabilities	(159)	(1,177)
Accrued compensation	(9,240)	(356)
Deferred revenue	(5,085)	(2)
Net cash (used in) provided by operating activities	<u>(23,971)</u>	<u>75,365</u>
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(34,153)	(14,042)
Proceeds from maturity of investments	3,750	-
Purchase of investments	(5,220)	-
Net cash used in investing activities	<u>(35,623)</u>	<u>(14,042)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from borrowings on long-term indebtedness and line of credit	21,298	15,000
Issuance of common stock subject to exercise of stock options	8,836	4,056
Principal payments on long-term indebtedness and line of credit	(14,931)	(32,454)
Excess tax benefits from stock-based compensation	1,502	1,077
Net cash provided by (used in) financing activities	<u>16,705</u>	<u>(12,321)</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(784)</u>	<u>(697)</u>
Net increase (decrease) in cash and cash equivalents	(43,673)	48,305
Cash and cash equivalents at beginning of period	<u>169,019</u>	<u>102,924</u>
Cash and cash equivalents at end of period	<u>\$ 125,346</u>	<u>\$ 151,229</u>

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 of 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, 2010, 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 September 30, 2011, results of operations for the three and nine month periods ended September 30, 2011 and 2010, and cash flows for the nine month periods ended September 30, 2011 and 2010. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

**2. Fair value measurements**

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

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

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

<b>At September 30, 2011</b>				
<b>(in thousands)</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets:</b>				
Investment in money market funds (1)	\$ 85,893	\$ -	\$ -	\$ 85,893
U.S. Treasury securities (2)	-	3,499	-	3,499
<b>Total assets</b>	<b>\$ 85,893</b>	<b>\$ 3,499</b>	<b>\$ -</b>	<b>\$ 89,392</b>

<b>Liabilities:</b>				
Contingent value rights	\$ -	\$ -	\$ 15,857	\$ 15,857
<b>Total liabilities</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 15,857</b>	<b>\$ 15,857</b>

<b>At December 31, 2010</b>				
<b>(in thousands)</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets:</b>				
Investment in money market funds (1)	\$ 102,360	\$ -	\$ -	\$ 102,360
U.S. Treasury securities (2)	-	2,029	-	2,029
<b>Total assets</b>	<b>\$ 102,360</b>	<b>\$ 2,029</b>	<b>\$ -</b>	<b>\$ 104,389</b>

<b>Liabilities:</b>				
Contingent value rights	\$ -	\$ -	\$ 14,532	\$ 14,532
<b>Total liabilities</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 14,532</b>	<b>\$ 14,532</b>

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

The fair value of U.S. Treasury securities (Level 2) is obtained from an independent pricing service and is based on recent sales of similar securities and other observable market data.

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 nine months ended September 30, 2011, the changes in the fair value of the CVR obligations resulted from an adjustment to the discount rates along with an update to the probability and estimated timing of achievement for certain development milestones. For the three months ended September 30, 2011, the Company recorded a reduction of \$84,000 in the value for the CVRs. For the nine months ended September 30, 2011, the Company recorded a charge of \$1.3 million to increase the CVRs to fair value. These adjustments to fair value are classified in the Company’s statement 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) for the nine months ended September 30, 2011. There were no Level 3 assets or liabilities at September 30, 2010.

<b>(in thousands)</b>	
Balance at January 1, 2010	\$ -
Fair value of CVRs issued	14,532



Expense (income) included in earnings	-
Purchases, sales, issuances and settlements	-
Transfers in/(out) of Level 3	-
Balance at December 31, 2010	<u>\$14,532</u>
Expense (income) included in earnings	1,325
Purchases, sales, issuances and settlements	-
Transfers in/(out) of Level 3	-
Balance at September 30, 2011	<u>\$15,857</u>

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. As of September 30, 2011 and December 31, 2010, the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis.

The carrying amounts of the Company's short-term financial instruments, which include cash, accounts receivable and accounts payable, approximate their fair values due to their short maturities. The fair value of the Company's long-term indebtedness is estimated based on the quoted prices for the same or similar issues or on the current rates offered to the Company for debt of the same remaining maturities. Both the carrying value and fair value of long-term indebtedness at September 30, 2011 was \$53.8 million. The carrying value and fair value of long-term indebtedness was \$48.3 million and \$48.1 million, respectively, at September 30, 2010.

### 3. Investments

The Company invests in a variety of highly liquid investment-grade securities. The following is a summary of the Company's available for sale securities:

At September 30, 2011				
(in thousands)	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Market Value
U.S. Treasury securities	\$ 3,498	\$ 1	\$ -	\$ 3,499

  

At December 31, 2010				
(in thousands)	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Market Value
U.S. Treasury securities	\$ 2,030	\$ -	\$ 1	\$ 2,029

### 4. Inventories

Inventories consist of the following:

(in thousands)	September 30, 2011	December 31, 2010
Raw materials and supplies	\$ 2,118	\$ 2,311
Work-in-process	13,663	7,917
Finished goods	2,198	2,494
Total inventories	<u>\$ 17,979</u>	<u>\$ 12,722</u>

### 5. Assets held for sale

The Company currently owns two buildings in Frederick, Maryland that it determined in 2009 would not be placed into service. Accordingly, the Company committed to a plan to sell the buildings, along with associated improvements. These buildings are classified on the Company's balance sheets as assets held for sale. Assets held for sale are recorded at the lower of the carrying amount or fair market value less costs to sell, and are no longer depreciated once classified as held for sale. The Company recorded the assets held for sale at fair market value, based on factors that include recent purchase offers, less estimated selling costs. The Company recorded impairment charges of \$483,000 and \$676,000, respectively, for the three and nine months ended September 30, 2011. The Company recorded no impairment charge for the three months ended September 30, 2010 and recorded an impairment charge of \$1.0 million for the nine months ended September 30, 2010. These charges were classified in the Company's statement of operations as selling, general and administrative expense within the Company's biosciences segment. The Company continues to actively seek to sell these buildings.

### 6. Long-term indebtedness

The components of long-term indebtedness are as follows:

(in thousands)	September 30, 2011	December 31, 2010
Construction loan dated July 2011; one month LIBOR plus 3.0 %, due July 2017	\$ 21,298	\$ -
Term loan dated December 2009; three month LIBOR plus 3.25%, due December 2014	20,096	21,233
Term loan dated November 2009; three month LIBOR plus 3.25%, repaid in July 2011	-	6,513
Term loan dated November 2009; three month LIBOR plus 3.25%, due November 2014	4,565	4,825
Term loan dated April 2006; three month LIBOR plus 3.0%, repaid in April 2011	-	6,686
Loan dated October 2004; 3.0%, due March 2012	2,500	2,500
Term loan dated October 2004; 3.48%, due October 2013	5,334	5,669
Total long-term indebtedness	53,793	47,426
Less current portion of long-term indebtedness	(4,920)	(17,187)
Noncurrent portion of long-term indebtedness	<u>\$ 48,873</u>	<u>\$ 30,239</u>

In August 2011, the Company entered into a loan agreement with PNC Bank ("PNC") to provide the Company with an equipment loan of up to \$12.0 million to fund equipment purchases at the Company's Baltimore, Maryland product development and manufacturing facility. Under the equipment loan agreement, PNC agreed to make advances to the Company of up to \$12.0 million through August 2012 based on periodic requests from the Company. The loan is collateralized by the equipment purchased. As of September 30, 2011, the Company has not drawn on this loan.

In July 2011, the Company entered into a loan agreement and related agreements with PNC, under which PNC agreed to provide the Company with a construction loan of up to \$30.0 million, primarily to fund the ongoing build-out of the Baltimore facility. A portion of the loan was also used to repay the Company's loan with HSBC Bank, which the Company used to finance a portion of the purchase price of the facility. Under the Company's loan agreement with PNC, PNC agreed to make advances to the Company of up to \$30.0 million through July 2012. The Company is required to make interest only payments through July 2012. Beginning in July 2012, the Company will be required to make monthly payments of principal and interest based upon a 20-year amortization schedule with a balloon payment for the remaining unpaid principal and interest due in July 2017. Payment of the loan is secured by the

Baltimore building along with Emergent BioDefense Operations Lansing LLC accounts receivable under the Company's BioThrax supply contracts. As of September 30, 2011, the Company has drawn \$21.3 million under this loan.

Under the terms of the construction and equipment loans with PNC, the Company is required to maintain certain financial covenants including minimum cash and liquid investments balance of \$50.0 million, a leverage ratio of less than 2.0 and a debt coverage ratio of not less than 1.25 to 1.

In October 2004, the Company entered into a Secured Conditional Loan with the Maryland Economic Development Assistance Fund for \$2.5 million. In October 2011, the Company amended the agreement to extend the paid in full date to March 2012.

In connection with the 2004 purchase of the building in Frederick, Maryland, the Company entered into a loan agreement for \$7.0 million with PNC to finance the remaining portion of the purchase price. The borrowing accrued interest at 6.625% per annum through October 2006. The Company was required to make interest only payments through that date. Beginning in November 2006, the Company began to make monthly payments of \$62,000, based upon a 15 year amortization schedule. In November 2009 and thereafter, the annual interest rate was fixed at 4.075%. In October 2011, the Company modified the agreement to extend the maturity date to October 2013, reduce the fixed annual interest rate to 3.48% and increase the monthly payment to \$64,000. All unpaid principal and interest is due in full in October 2013. The Company has determined that the modified agreement is not a substantial modification of the original loan agreement.

## 7. Accounting for stock-based compensation plans

As of September 30, 2011, the Company has two stock-based employee compensation plans, the Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan") and the Emergent BioSolutions Employee Stock Option Plan (the "2004 Plan" and together with the 2006 Plan, 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.

The Company determines the fair value of restricted stock units using the closing market price of the Company's common stock on the day prior to the date of grant. The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. The fair value of each option is estimated on the date of grant. Set forth below are the assumptions used in valuing the stock options granted and a discussion of the Company's methodology for developing each of the assumptions used:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Expected dividend yield	0%	0%	0%	0%
Expected volatility	60%	55%	60%	55%
Risk-free interest rate	0.35%	1.72%	0.35%-1.04%	0.82%-1.46%
Expected average life of options	3.0 years	3.0 years	3.4 years	3.4 years

- Expected dividend yield — the Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.
- Expected volatility — a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (implied volatility) during a period. The Company analyzed its own historical volatility to estimate expected volatility over the same period as the expected average life of the options.
- Risk-free interest rate — the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date on which the option is granted.
- Expected average life of options — the period of time that options granted are expected to remain outstanding, based primarily on the Company's expectation of optionee exercise behavior subsequent to vesting of options.

As of September 30, 2011, an aggregate of 8,678,826 shares of common stock are authorized for issuance under the 2006 Plan, of which a total of 2,152,513 shares of common stock remain available for future awards to be made to plan participants. Awards of restricted stock units are counted against the maximum aggregate number of shares of common stock available for issuance under the 2006 Plan as one and one-half (1.5) shares of common stock for every one restricted stock unit granted. The maximum number of shares subject to awards that may be granted per year under the 2006 Plan to a single participant is 287,700. The exercise price of each option must be not less than 100% of the fair market value of the shares underlying such option on the date of grant. Awards granted under the 2006 Plan have a contractual life of no more than 10 years. The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Emergent Plans are determined by the Company's compensation committee, which administers the Emergent Plans. Each equity award granted under the Emergent Plans vests as specified in the relevant agreement and no stock 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		Aggregate Intrinsic Value
	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price	
Outstanding at December 31, 2010	3,397,915	\$ 14.31	67,541	\$ 9.80	\$ 32,023,466
Granted	826,227	23.77	-	-	
Exercised	(756,099)	11.59	(14,385)	13.26	
Forfeited	(218,531)	18.73	-	-	
Outstanding at September 30, 2011	3,249,512	\$ 17.08	53,156	\$ 8.86	\$ 5,413,569
Exercisable at September 30, 2011	1,583,683	\$ 13.84	53,156	\$ 8.86	\$ 5,261,857

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, 2010	395,555	\$ 16.09	\$ 9,279,720
Granted	433,123	23.70	
Vested	(124,863)	16.02	
Forfeited	(63,362)	19.57	
Outstanding at September 30, 2011	640,453	\$ 20.91	\$ 9,882,190

## 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 in the advancement of 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. The Company has evaluated its variable interests in OETC and has determined that it is the primary beneficiary as it has the ability to direct the activities of OETC and will absorb the majority of expected losses. Accordingly, the Company consolidates the entity. As of September 30, 2011 and 2010, respectively, assets of \$408,000 and \$229,000 and liabilities of \$532,000 and \$389,000 related to OETC are included within the Company’s consolidated balance sheet. During the three and nine months ended September 30, 2011, OETC incurred net losses of \$3.1 million and \$9.9 million, respectively, of which \$1.6 million and \$5.0 million, respectively, is included in the Company’s consolidated statement of operations. During the three and nine months ended September 30, 2010, OETC incurred net losses of \$2.4 million and \$4.4 million, respectively, of which \$1.2 million and \$2.2 million, respectively, is included in the Company’s consolidated statement of operations.

In July 2011, the Company entered into an intercompany loan agreement with OETC, under which the Company would provide OETC with a loan of up to \$14.0 million to fund future 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 an interest rate of 8% per annum. Principal and interest on the outstanding balance shall 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.

In conjunction with the establishment of OETC, the Company granted a put option to Oxford and the Oxford researchers whereby the Company may be required to acquire all of the OETC shares held by Oxford and the Oxford researchers at 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 has a de minimis fair value as of September 30, 2011.

In July 2010, the Company entered into a collaboration with Temasek Life Sciences Ventures Pte Limited to advance the development of monoclonal products for worldwide prophylaxis or treatment of infection caused by existing or anticipated future pandemic influenza strains via a hemagglutinin-based medical countermeasure, resulting in the formation of EPIC Bio Pte Limited (“EPIC”). The Company has a 60% equity interest in EPIC and controls the EPIC Board of Directors. The Company has evaluated its variable interests in EPIC and has determined that it is the primary beneficiary as it has the ability to direct the activities of EPIC and will absorb the majority of expected losses. Accordingly, the Company consolidates the entity. As of September 30, 2011, assets of \$1.6 million and liabilities of \$830,000 related to EPIC are included within the Company’s consolidated balance sheet. As of September 30, 2010, assets of \$1.3 million are included within the Company’s consolidated balance sheet. There were no liabilities at September 30, 2010. During the three and nine months ended September 30, 2011, EPIC incurred net losses of \$407,000 and \$783,000, respectively, of which \$244,000 and \$470,000, respectively, is included in the Company’s consolidated statement of operations. For each of the three and nine months ended September 30, 2010, EPIC did not incur net income or losses.

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, 2010	\$ 369,464	\$ 4,097	\$ 373,561
Non-cash development expenses from variable interest entities	-	4,263	4,263
Net loss	(5,638)	(5,149)	(10,787)
Other	17,466	-	17,466
Stockholders' equity at September 30, 2011	<u>\$ 381,292</u>	<u>\$ 3,211</u>	<u>\$ 384,503</u>

## 9. Comprehensive income (loss)

Comprehensive income (loss) is comprised of net income (loss) attributable to Emergent BioSolutions Inc. and other changes in equity that are excluded from net income (loss) attributable to Emergent BioSolutions Inc. The Company includes gains and losses on intercompany transactions with foreign subsidiaries that are considered to be long-term investments and translation gains and losses incurred when converting its subsidiaries’ financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income (loss). Comprehensive income for the three months ended September 30, 2011 was \$1.4 million. Comprehensive loss for the nine months ended September 30, 2011 was \$6.4 million. Comprehensive income for the three and nine months ended September 30, 2010 was \$12.6 million and \$24.8 million, respectively.

## 10. Restructuring

In November 2010, the Company adopted a plan to restructure and reprioritize the operations of Emergent Product Development UK Limited (“EPDU”). Severance and other related costs and asset-related charges are reflected within the Company’s consolidated statement of income as a component of selling, general and administrative expense within the Company’s biosciences segment.

The Company has completed this restructuring. The costs of the restructuring as of September 30, 2011 are detailed below:

(in thousands)	Incurred in 2011	Inception to Date Costs Incurred	Total Expected to be Incurred
Termination benefits	\$ 475	\$ 2,893	\$ 2,893
Contract termination costs	1,877	2,295	2,295
Other costs	136	396	396
Total	<u>\$ 2,488</u>	<u>\$ 5,584</u>	<u>\$ 5,584</u>

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

(in thousands)	Termination Benefits	Lease Termination Costs	Total
Balance at December 31, 2010	\$ 2,418	\$ 650	\$ 3,068
Expenses incurred	475	1,877	2,352
Amount paid	(2,893)	(2,311)	(5,204)
Other adjustments	-	(216)	(216)
Balance at September 30, 2011	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

## 11. Earnings per share

Basic net income (loss) per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income (loss) by the weighted average number of shares outstanding for the period. Diluted net income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock.

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

(in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Numerator:				
Net income (loss)	\$ 1,549	\$ 13,120	\$ (5,638)	\$ 25,451
Denominator:				
Weighted-average number of shares—basic	35,855,217	31,301,796	35,552,900	31,094,616
Dilutive securities—equity awards	592,716	811,517	-	722,284
Weighted-average number of shares—diluted	36,447,933	32,113,313	35,552,900	31,816,900
Earnings per share-basic	\$ 0.04	\$ 0.42	\$ (0.16)	\$ 0.82
Earnings per share-diluted	\$ 0.04	\$ 0.41	\$ (0.16)	\$ 0.80

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 September 30, 2011 and 2010, approximately 1.7 million and 1.3 million stock options, respectively, and 1.8 million stock options for the nine month period ended September 30, 2010 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 nine month period ended September 30, 2011, approximately 3.9 million shares 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. Litigation

*Class-action litigation related to Trubion Pharmaceuticals acquisition.* On August 17, 2010, two class action lawsuits were filed in the Superior Court of Washington, King County (the “State Court”), against Trubion Pharmaceuticals, Inc. (“Trubion”), its board of directors, and the Company (collectively, the “Defendants”), alleging in summary that, in connection with the merger of Trubion with a subsidiary of the Company (the “Acquisition”), members of the Trubion board of directors breached their fiduciary duties by conducting an unfair sale process and agreeing to an unfair price. Both complaints also claimed that Trubion and the Company aided and abetted the Trubion board of directors in its breach of fiduciary duties. On September 9, 2010, the actions were consolidated (the “State Action”). On October 1, 2010, the plaintiffs in the State Action served on the Defendants a consolidated amended class action complaint (the “Amended Complaint”). The Amended Complaint alleged, among other things and in addition to the matters alleged in the initial complaints, that the Defendants omitted material information from the Proxy Statement/Prospectus relating to the Acquisition.

On October 4, 2010, a class action lawsuit was filed in the U.S. District Court for the Western District of Washington against the Defendants (the “Federal Action” and, collectively with the State Action, the “Actions”), which made allegations related to the Acquisition that were substantially similar to those matters alleged in the Amended Complaint and included additional allegations regarding purported violations of the federal securities laws and sought substantially similar relief.

On October 8, 2010, the Defendants reached agreement in principle with the plaintiffs in the Actions regarding the settlement of the Actions. The terms of the settlement contemplated by that agreement in principle required Trubion and the Company to make certain additional disclosures related to the Acquisition, as set forth in the Company’s Current Report on Form 8-K filed on October 8, 2010. The parties also agreed that the plaintiffs in the Actions could seek attorneys’ fees and costs in an aggregate amount up to \$475,000, to be paid by Trubion if such fees and costs were approved by the State Court. There will be no other payment by Trubion, any of the members of the Trubion board of directors or the Company to the plaintiffs or their respective counsels in connection with the settlement and dismissal of the Actions. The agreement in principle further contemplated that the parties would enter into a stipulation of settlement, which would be subject to customary conditions, including State Court approval following notice to Trubion’s shareholders. The Actions were stayed pending approval of the settlement of the State Action by the State Court, after which the State Action and all claims asserted therein would be dismissed with prejudice and counsel for the plaintiff in the Federal Action would take all necessary steps to dismiss the Federal Action and all claims asserted therein with prejudice. On April 26, 2011, the State Court entered an order granting preliminary approval of the settlement and requiring that notice of the settlement and preliminary approval be mailed to class members by May 17, 2011. The order also provided that all class members wishing to be excluded from the settlement of the Actions were required to give notice by June 21, 2011. At a hearing on July 29, 2011, the State Court determined that the settlement was fair, reasonable and adequate to the class members and approved the settlement in all aspects. On September 12, 2011 the Federal Action was dismissed and the Company has since made a payment in the amount of \$475,000 for attorneys’ fees and costs.

*Other.* From time to time, the Company is involved in product liability claims and other litigation considered normal in the nature of its business. The Company does not believe that any such proceedings would have a material adverse effect on the results of its operations.

## 13. Related party transactions

The Company entered into an agreement in February 2009 with an entity controlled by family members of the Company’s Chief Executive Officer to market and sell BioThrax. The agreement was effective as of November 2008 and requires payment based on a percentage of net sales of biodefense products of 17.5% in Saudi Arabia and 15% in Qatar and United Arab Emirates, and reimbursement of certain expenses. No expenses were incurred under this agreement during the nine months ended September 30, 2011.

The Company entered into a consulting agreement in September 2010 with an entity controlled by the Company’s former Senior Vice President Corporate Affairs, who is also a family member of the Company’s Chief Executive Officer. The agreement, which terminated in August 2011, provided for consulting services in connection with special projects as assigned by the Company’s President. During the nine months ended September 30, 2011 and 2010, the Company incurred approximately \$40,000 and \$5,000, respectively, for services rendered under this agreement, of which \$5,000 remained in accounts payable at September 30, 2011.

The Company had a consulting agreement with a member of the Company’s Board of Directors. For each of the nine month periods ended September 30, 2011 and 2010, the Company incurred approximately \$135,000 under this agreement for strategic consultation and project support for the Company’s marketing and communications group, of which no balance remained unpaid in accounts payable at September 30, 2011. In October 2011, this director resigned from the Company’s Board of Directors, and the consulting agreement was terminated in November 2011.

## 14. Segment information

For financial reporting purposes, the Company reports financial information for two business segments: biodefense and biosciences. In the biodefense segment, the Company develops, manufactures and commercializes vaccines and antibody therapies for use against biological agents that are potential weapons of bioterrorism or biowarfare. Revenues in this segment relate primarily to the Company's FDA-licensed product, BioThrax® (Anthrax Vaccine Adsorbed). In the biosciences segment, 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 "All Other" segment relates to the general operating costs of the Company and includes costs of the centralized services departments, which are not allocated to the other segments, as well as spending on product candidates or activities that are not classified as biodefense or biosciences. The assets in this segment consist primarily of cash. For the three and nine months ended September 30, 2010, the Company reclassified its business segments to conform with the current period presentation.

(in thousands)	Reportable Segments			
	Biodefense	Biosciences	All Other	Total
<b>Three Months Ended September 30, 2011</b>				
External revenue	\$ 56,679	\$ 2,083	\$ -	\$ 58,762
Net income (loss) attributable to Emergent BioSolutions Inc.	18,304	(15,237)	(1,518)	1,549
Assets	229,351	134,381	149,230	512,962
<b>Three Months Ended September 30, 2010</b>				
External revenue	\$ 73,986	\$ -	\$ -	\$ 73,986
Net income (loss) attributable to Emergent BioSolutions Inc.	29,909	(14,421)	(2,368)	13,120
Assets	173,720	43,790	148,727	366,237

(in thousands)	Reportable Segments			
	Biodefense	Biosciences	All Other	Total
<b>Nine Months Ended September 30, 2011</b>				
External revenue	\$ 155,864	\$ 9,572	\$ -	\$ 165,436
Net income (loss) attributable to Emergent BioSolutions Inc.	49,114	(50,942)	(3,810)	(5,638)
Assets	229,351	134,381	149,230	512,962
<b>Nine Months Ended September 30, 2010</b>				
External revenue	\$ 182,924	\$ -	\$ -	\$ 182,924
Net income (loss) attributable to Emergent BioSolutions Inc.	65,818	(34,985)	(5,382)	25,451
Assets	173,720	43,790	148,727	366,237

## 15. Asset Purchase Agreement

In May 2011, the Company and TenX BioPharma, Inc. ("TenX") entered into an asset purchase agreement in which the Company acquired all assets and rights related to the Zanolimumab product candidate and related technology from TenX. The Company paid approximately \$3.1 million in conjunction with the closing of this acquisition and has recorded this amount in the Company's statement of operations as research and development expense in the biosciences segment. The asset purchase agreement also contemplates additional payments by the Company for future milestones and specified percentages of future net sales.

## 16. Subsequent events

The Company has evaluated subsequent events through the time of filing these financial statements.

## 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 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 protein 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 focuses on vaccines and antibody therapies for use against biological agents that are potential weapons of bioterrorism or biowarfare. Our products and product candidates in this segment are focused on anthrax. We manufacture and market BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. In addition to BioThrax, we are developing PreviThrax™ (Recombinant Protective Antigen Anthrax Vaccine, Purified), Anthravig™ (Human Anthrax Immunoglobulin), Thravixa™ (Fully Human Anthrax Monoclonal Antibody) and NuThrax™ (Anthrax Vaccine Adsorbed with CPG 7909 Adjuvant). Operations in this segment include biologics manufacturing, regulatory and quality affairs, marketing and sales in support of BioThrax and product development of our investigational product candidates.

Our biosciences segment is directed to commercial opportunities. Our programs in this segment target oncology, including B-cell malignancies of chronic lymphocytic leukemia, or CLL, and non-Hodgkin's lymphoma, or NHL; autoimmune and inflammatory disorders, or AIID, including rheumatoid arthritis, or RA, and systemic lupus erythematosus, or SLE; as well as infectious diseases such as tuberculosis and influenza. Additionally, through our recent acquisition of certain assets of TenX BioPharma, Inc., or TenX, we acquired a clinical stage product candidate targeted at cutaneous T-cell lymphoma, or CTCL, and peripheral T-cell lymphoma, or PTCL. Our programs in this segment include clinical and preclinical stage investigational product candidates. 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 U.S. Department of Health and Human Services, or HHS, to supply doses of BioThrax for placement into the Strategic National Stockpile, or SNS. 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 \$120.7 million and \$162.0 million, respectively, for the nine months ended September 30, 2011 and 2010. 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.

On September 30, 2011, we received a notice of award from the Centers for Disease Control and Prevention, or CDC, to supply up to 44.75 million doses of BioThrax to the CDC over a five-year period. We anticipate that delivery of doses under the award will commence in December 2011, immediately following the completion of deliveries under our current supply contract.

## 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 for the following development programs:

- BioThrax post-exposure prophylaxis;
- NuThrax;
- Large-scale manufacturing for BioThrax;
- PreviThrax;
- Anthravig;
- Thravixa;
- Double mutant recombinant protective antigen anthrax vaccine; and
- Recombinant botulinum vaccine.

Additionally, our tuberculosis vaccine product candidate is indirectly supported by grant funding provided to the University of Oxford by the Wellcome Trust and Aeras Global Tuberculosis Vaccine Foundation. Our TRU-016 product candidate is being funded via our collaboration with Abbott Laboratories, or Abbott, in which we and Abbott share all funding responsibilities equally. Our SBI-087 product candidate is substantially funded by Pfizer Inc., or Pfizer.

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

## Manufacturing Infrastructure

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

In November 2009, we purchased a building in Baltimore, Maryland for product development and manufacturing purposes, and have begun renovation, improvement and equipment acquisitions at this facility. We have entered into two loan agreements with PNC Bank totaling up to \$42.0 million to fund these renovations, improvements and equipment acquisitions. Our specific plans for this facility will be contingent on the progress of our existing development programs and the outcome of our efforts to acquire new product candidates.

## Critical Accounting Policies and Estimates

There have been no significant changes to our Critical Accounting Policies and Estimates during the nine months ended September 30, 2011. Refer to the Critical Accounting Policies and Estimates section in our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the Securities and Exchange Commission.

## Financial Operations Overview

### Revenues

On September 30, 2008, we entered into an agreement with HHS to supply up to 14.5 million doses of BioThrax for placement into the SNS. In April 2011, we entered into a modification to this contract to supply an additional 3.4 million doses at a value of up to \$101 million. The term of the modified agreement was from September 30, 2008 through September 30, 2011. On September 28, 2011 we entered into a further modification of this contract that extends the period of performance of the contract at no additional cost, from September 30, 2011 to December 31, 2011. The total purchase price of the modified contract for 17.9 million doses is approximately \$500 million. Through September 30, 2011, we have delivered approximately 15.8 million doses under this agreement. We have agreed to provide all shipping services related to delivery of doses into the SNS over the term of the agreement, for which HHS has agreed to pay us approximately \$2.3 million. We recognize revenue under the agreement upon acceptance of each delivery of BioThrax doses to the SNS.

On September 30, 2011, we received a notice of award from 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 award is up to \$1.25 billion. The period of performance under the award is from September 30, 2011 through September 29, 2016. We anticipate delivery of doses under the award will commence in December 2011, immediately following the completion of deliveries under our current supply 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:

Product Candidate/Manufacturing	Funding Source	Award Date	Amount (Up to)	Performance Period
Anthravig	NIAID	8/2006	\$3.7 million	8/2006 — 12/2011
Anthravig	NIAID	9/2007	\$11.4 million	9/2007 — 12/2011
Recombinant botulinum vaccine	NIAID	6/2008	\$1.8 million	6/2008 — 5/2012
NuThrax	NIAID	7/2008	\$2.8 million	7/2008 — 6/2013
Thravixa	NIAID/BARDA	9/2008	\$16.7 million	9/2008 — 8/2012
NuThrax	NIAID/BARDA	9/2008	\$24.4 million	9/2008 — 7/2012

Double mutant recombinant protective antigen anthrax vaccine	NIAID	9/2009	\$4.9 million	9/2009 — 8/2012
Large-scale manufacturing for BioThrax	BARDA	7/2010	\$107.5 million	7/2010 — 7/2015
NuThrax	NIAID	7/2010	\$28.7 million	8/2010 — 8/2014
PreviThrax	BARDA	9/2010	\$186.6 million	9/2010 — 9/2015

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

#### ***Cost of Product Sales***

The primary expense that we incur to deliver BioThrax to our customers is manufacturing cost, which consist of primarily 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, continued participation of our third-party collaborators, number of product candidates under development, the size, structure and duration of any follow-on clinical programs that we may initiate, costs associated with manufacturing our product candidates on a large-scale basis for later-stage clinical trials, and our ability to use or rely on data generated by government agencies, such as studies with BioThrax conducted by the CDC.

#### ***Selling, General and Administrative Expenses***

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

### **Results of Operations**

#### ***Quarter Ended September 30, 2011 Compared to Quarter Ended September 30, 2010***

##### ***Revenues***

Product sales revenues decreased by \$23.6 million, or 35%, to \$43.7 million for the three months ended September 30, 2011 from \$67.3 million for the three months ended September 30, 2010. This decrease in product sales revenues was due to a 38% decrease in the number of doses of BioThrax delivered, due primarily to lower production yields in the period in which the doses were produced. Product sales revenues for the three months ended September 30, 2011 consisted of BioThrax sales to HHS of \$43.6 million and aggregate international and other sales of \$85,000. Product sales revenues for the three months ended September 30, 2010 consisted of BioThrax sales to HHS of \$67.2 million and aggregate other sales of \$39,000.

Contracts and grants revenues increased by \$8.4 million, or 125%, to \$15.1 million for the three months ended September 30, 2011 from \$6.7 million for the three months ended September 30, 2010. The increase in contracts and grants revenue was primarily due to increased revenue from our development contracts with BARDA for PreviThrax and large-scale manufacturing for BioThrax, along with our collaborations with Abbott and Pfizer. Contracts and grants revenues for the three months ended September 30, 2011 consisted of \$13.0 million in development contract and grant revenue from NIAID and BARDA and \$2.1 million from Abbott and Pfizer. All contracts and grants revenues for the three months ended September 30, 2010 were from NIAID and BARDA.

##### ***Cost of Product Sales***

Cost of product sales decreased by \$826,000, or 7%, to \$10.7 million for the three months ended September 30, 2011 from \$11.5 million for the three months ended September 30, 2010. This decrease was attributable to the 38% decrease in the number of BioThrax doses sold, largely offset by an increase in the cost per dose sold associated with decreased production yield in the period in which the doses were produced.

##### ***Research and Development Expenses***

Research and development expenses increased by \$8.1 million, or 38%, to \$29.2 million for the three months ended September 30, 2011 from \$21.2 million for the three months ended September 30, 2010. This increase primarily reflects higher contract service and personnel-related costs, and includes increased expenses of \$4.5 million for product candidates and technology platform development activities that are categorized in the biosciences segment, increased expenses of \$2.0 million for product candidates that are categorized in the biodefense segment, and increased expenses of \$1.5 million in other research and development, which are in support of central research and development activities. For the three months ended September 30, 2011 and 2010, we incurred research and development expenses net of development contract and grant reimbursements along with the net loss attributable to noncontrolling interests of \$12.4 million and \$13.3 million, respectively.

The 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 spending for NuThrax was due to process characterization and assay development along with the conduct of clinical trial activities. The increase in spending for our large-scale manufacturing for BioThrax program was primarily due to characterization assay development and validation activities. The decrease in spending for BioThrax related programs was related to the timing of clinical and non-clinical studies to support applications for marketing approval of these programs. The increase in spending for PreviThrax was primarily due to formulation development, stability studies and model optimization under the associated development contract awarded in September 2010. The decrease in spending for Anthravig was primarily due to the timing of a clinical trial. The decrease in spending for Thravixa was primarily due to the timing of non-clinical studies. 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 due primarily to reduced funding by the U.S. government for this product candidate. We expect that spending for our double mutant recombinant protective antigen anthrax vaccine will continue to decrease in the future.

The increase in spending on biosciences product candidates, detailed in the table below, was primarily attributable to the timing of development efforts and the acquisition of certain biosciences product candidates. The increase in spending for our tuberculosis vaccine product candidate is related to the costs incurred for the continued conduct of a Phase IIb clinical trial, along with process development and manufacturing activities. The increase in spending for our TRU-016, ES-301 (formerly DRACO) and XI product candidates, acquired as a result of our October 2010 acquisition of Trubion Pharmaceuticals, Inc. or Trubion, and its development programs for product candidates to treat certain autoimmune diseases and oncology, is primarily related to clinical trials, process development and manufacturing costs. The spending for our Zanolimumab product candidate, which was acquired in the May 2011 acquisition of certain assets of TenX, was primarily due to ongoing analysis of clinical study data. The decrease in spending for our influenza vaccine product candidate was due to the timing of process and analytical development. The decrease in spending for Typhella was primarily due to the substantial completion of manufacturing and clinical studies. We have significantly reduced ongoing spending with regard to Typhella while we investigate options to sell or outlicense the related technology, and we expect that future spending will be reduced. The decrease in spending for our other biosciences activities was primarily due to reduced spending associated with development of platform technologies along with preclinical product candidates as a result of our acquisition of Trubion.

The spending for other research and development activities was primarily attributable to central research and development activities.

Our principal research and development expenses for the three months ended September 30, 2011 and 2010 are shown in the following table:

(in thousands)	Three Months Ended September 30,	
	2011	2010
<b>Biodefense:</b>		
NuThrax	\$ 2,596	\$ 2,423
Large-scale manufacturing for BioThrax	3,637	2,607
BioThrax related programs	1,467	2,031
PreviThrax	4,496	840
Anthravig	417	1,104
Thravixa	672	1,295
Other biodefense	398	1,382
<b>Total biodefense</b>	<b>13,683</b>	<b>11,682</b>
<b>Biosciences:</b>		
Tuberculosis vaccine	4,287	3,836
TRU-016	2,395	-
ES-301 (formerly DRACO)	1,900	-
X1	774	-
Zanolimumab	633	-
Influenza vaccine	682	999
Typhella	119	1,194
Other biosciences	2,266	2,503
<b>Total biosciences</b>	<b>13,056</b>	<b>8,532</b>
Other	2,477	942
<b>Total</b>	<b>\$ 29,216</b>	<b>\$ 21,156</b>

#### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses decreased by \$3.3 million, or 16%, to \$17.4 million for the three months ended September 30, 2011 from \$20.7 million for the three months ended September 30, 2010. This decrease is primarily due to decreased professional services, including legal and other fees incurred in 2010 related to the Trubion acquisition. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses decreased by \$1.5 million, or 11%, to \$12.0 million for the three months ended September 30, 2011 from \$13.5 million for the three months ended September 30, 2010. Selling, general and administrative expenses related to our biosciences segment decreased by \$1.7 million, or 24%, to \$5.5 million for the three months ended September 30, 2011 from \$7.2 million for the three months ended September 30, 2010.

#### *Total Other Income (Expense)*

Total other income (expense) increased by \$1.0 million to net other income of \$59,000 for the three months ended September 30, 2011 from net other expense of \$965,000 for the three months ended September 30, 2010. The increase was due primarily to a charge to reduce previously recorded accrued interest income related to the settlement with Protein Sciences Corporation, or PSC, in October 2010.

#### *Income Taxes*

Provision for income taxes decreased by \$6.1 million, or 79%, to \$1.6 million for the three months ended September 30, 2011 from \$7.7 million for the three months ended September 30, 2010. The estimated effective tax rate before discrete items for the three months ended September 30, 2011 and 2010 was 34% and 37%, respectively. The decrease in the provision for income taxes was primarily due to the decrease in our income before provision for income taxes plus the loss attributable to noncontrolling interest of \$17.7 million.

#### *Net Loss Attributable to Noncontrolling Interests*

Net loss attributable to noncontrolling interests increased by \$510,000, or 43%, to \$1.7 million for the three months ended September 30, 2011 from \$1.2 million for the three months ended September 30, 2010. The loss was primarily a result of clinical and development activities and related expenses incurred by our joint ventures. These amounts primarily represent the portion of the losses incurred by the joint ventures for the three months ended September 30, 2011 and 2010, respectively, that is attributable to our joint venture partners.

#### *Nine Months Ended September 30, 2011 Compared to Nine Months Ended September 30, 2010*



## Revenues

Product sales revenues decreased by \$41.3 million, or 25%, to \$120.7 million for the nine months ended September 30, 2010 from \$162.0 million for the nine months ended September 30, 2011. This decrease in product sales revenues was primarily due to a 29% decrease in the number of doses of BioThrax delivered due to the redeployment of our potency testing capacity from BioThrax release testing to qualification of replacement reference standards and other development testing during the first quarter 2011 coupled with lower production yields in the period in which the doses were produced. Product sales revenues for the nine months ended September 30, 2011 consisted of BioThrax sales to HHS of \$119.4 million and aggregate international and other sales of \$1.4 million. Product sales revenues for the nine months ended September 30, 2010 consisted of BioThrax sales to HHS of \$159.6 million and aggregate international and other sales of \$2.4 million.

Contracts and grants revenues increased by \$23.8 million, or 114%, to \$44.7 million for the nine months ended September 30, 2011 from \$20.9 million for the nine months ended September 30, 2010. The increase in contracts and grants revenues was primarily due to revenues from our contract with BARDA for large-scale manufacturing for BioThrax and our collaborations with Abbott and Pfizer, along with increased activity and associated revenue from our development contracts with NIAID and BARDA for NuThrax and PreviThrax. Contracts and grants revenues for the nine months ended September 30, 2011 consisted of \$35.1 million in development contract and grant revenue from NIAID and BARDA and \$9.6 million from Abbott and Pfizer. Contracts and grants revenues for the nine months ended September 30, 2010 consisted of \$20.2 million in development contract and grant revenue from NIAID and BARDA and \$750,000 from a milestone payment related to the 2008 sale of technology rights and related materials and documentation pertaining to our Pertussis technology.

## Cost of Product Sales

Cost of product sales decreased by \$2.3 million, or 8%, to \$27.8 million for the nine months ended September 30, 2011 from \$30.1 million for the nine months ended September 30, 2010. This decrease was attributable to a 29% decrease in the number of doses of BioThrax delivered, largely offset by an increase in the cost per dose sold associated with decreased production yield in the period in which the doses were produced.

## Research and Development Expenses

Research and development expenses increased by \$35.8 million, or 60%, to \$95.5 million for the nine months ended September 30, 2011 from \$59.7 million for the nine months ended September 30, 2010. This increase primarily reflects higher contract service and personnel-related costs, and includes increased expenses of \$30.8 million for product candidates and technology platform development activities that are categorized in the biosciences segment, increased expenses of \$3.1 million for product candidates categorized in the biodefense segment, and increased expenses of \$1.9 million in other research and development, which are in support of central research and development activities. For the nine months ended September 30, 2011 and 2010, we incurred research and development expenses net of development contract and grant reimbursements along with the net loss attributable to noncontrolling interests of \$45.6 million and \$36.6 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 increase in spending for NuThrax was due to manufacturing, process characterization, assay validation and the conduct of clinical trial activities. The increase in spending for our large-scale manufacturing for BioThrax program was primarily due to characterization assay development, validation activities and manufacturing that increased subsequent to the associated development contract award in July 2010. The spending for BioThrax related programs was related to clinical and non-clinical studies to support applications for marketing approval of these programs. The increase in spending for PreviThrax was primarily due to formulation development, stability studies and model optimization subsequent to the associated development contract awarded in September 2010. The decrease in spending for Anthravig was primarily due to the timing of a clinical trial and animal model development. The decrease in spending for Thravixa was primarily due to the timing of process development, non-clinical studies and animal model development. 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 due primarily to reduced funding by the U.S. government for this product candidate. As such, we expect that spending for our double mutant recombinant protective antigen anthrax vaccine will decrease in the future.

The increase in spending on biosciences product candidates, detailed in the table below, was primarily attributable to the timing of development efforts and the acquisition of certain biosciences product candidates. The increase in spending for our tuberculosis vaccine product candidate is related to the costs incurred for the continued conduct of a Phase IIb clinical trial along with process development and manufacturing activities. The increase in spending for our TRU-016, ES-301 and XI product candidates, which is a result of our October 2010 acquisition of Trubion and its development programs for product candidates to treat certain autoimmune diseases and oncology, is primarily related to clinical trials, process development and manufacturing costs. The spending for our Zanolimumab product candidate was primarily for upfront and milestone payments related to the May 2011 acquisition of certain assets of TenX. The decrease in spending for our influenza vaccine product candidate is related to the timing of process and analytical development. The decrease in spending for Typhella was primarily due to the substantial completion of manufacturing and clinical studies. We have significantly reduced ongoing spending with regard to Typhella while we investigate options to sell or outlicense the related technology, and we expect that future spending will be reduced. The increase in spending for our other biosciences activities was primarily due to increased spending associated with development of platform technologies along with preclinical product candidates as a result of our acquisition of Trubion.

Our principal research and development expenses for the nine months ended September 30, 2011 and 2010 are shown in the following table:

(in thousands)	Nine Months Ended September 30,	
	2011	2010
<b>Biodefense:</b>		
NuThrax	\$ 9,317	\$ 6,975
Large-scale manufacturing for BioThrax	9,738	6,022
BioThrax related programs	5,236	5,384
PreviThrax	10,420	2,290
Anthravig	1,422	4,994
Thravixa	2,897	7,118
Other biodefense	1,885	5,065
Total biodefense	40,915	37,848
<b>Biosciences:</b>		
Tuberculosis vaccine	14,123	8,158
TRU-016	10,871	-
ES-301 (formerly DRACO)	5,845	-
XI	2,596	-
Zanolimumab	3,782	-
Influenza vaccine	2,144	2,588
Typhella	1,221	2,432
Other biosciences	8,868	5,469
Total biosciences	49,450	18,647

Other	5,091	3,185
<b>Total</b>	<u>\$ 95,456</u>	<u>\$ 59,680</u>

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased by \$1.5 million, or 3%, to \$56.0 million for the nine months ended September 30, 2011 from \$54.5 million for the nine months ended September 30, 2010. This increase is primarily due to approximately \$2.2 million in restructuring charges related to our UK operations. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses increased by \$811,000, or 2%, to \$39.1 million for the nine months ended September 30, 2011 from \$38.3 million for the nine months ended September 30, 2010. Selling, general and administrative expenses related to our biosciences segment, increased by \$683,000, or 4%, to \$16.9 million for the nine months ended September 30, 2011 from \$16.2 million for the nine months ended September 30, 2010.

### *Total Other Income (Expense)*

Total other income increased by \$282,000 to net other income of \$72,000 for the nine months ended September 30, 2011 from net other expense of \$210,000 for the nine months ended September 30, 2010. The increase was due primarily to a charge to reduce previously accrued interest income related to the settlement with PSC in October 2010.

### *Income Taxes*

Provision for (benefit from) income taxes decreased by \$18.1 million to a benefit from income taxes of \$3.0 million for the nine months ended September 30, 2011 from a provision for income taxes of \$15.1 million for the nine months ended September 30, 2010. The estimated annual effective tax rate before discrete items for the nine months ended September 30, 2011 and 2010 was 41% and 37%, respectively. The decrease in income taxes is primarily due to a \$49.2 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 \$3.0 million to \$5.1 million for the nine months ended September 30, 2011 from \$2.2 million for the nine months ended September 30, 2010. 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 nine months ended September 30, 2011 and 2010, 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 September 30, 2011 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases, development funding from government entities and non-government and philanthropic organizations, 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, 2010.

As of September 30, 2011, we had cash, cash equivalents and investments of \$128.8 million. Additionally, as of September 30, 2011, our accounts receivable balance was \$49.0 million.

#### *Cash Flows*

The following table provides information regarding our cash flows for the nine months ended September 30, 2011 and 2010:

<b>(in thousands)</b>	<b>Nine Months Ended</b>	
	<b>September 30, 2011</b>	<b>2010</b>
Net cash provided by (used in):		
Operating activities(1)	\$ (24,755)	\$ 74,668
Investing activities	(35,623)	(14,042)
Financing activities	16,705	(12,321)
<b>Total net cash provided by (used in)</b>	<u><b>\$ (43,673)</b></u>	<u><b>\$ 48,305</b></u>

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

Net cash used in operating activities of \$24.8 million for the nine months ended September 30, 2011 was principally due to our net loss attributable to Emergent BioSolutions Inc. of \$5.6 million, a \$5.3 million increase in inventory related to the timing of BioThrax shipments, a net decrease in income taxes of \$3.8 million related to timing differences, a decrease in accrued compensation of \$9.2 million primarily due to the payment of the 2010 bonuses and UK restructuring costs, an increase in accounts receivable of \$9.7 million due to the timing of collection of amounts billed primarily to HHS, a decrease in deferred revenue of \$5.1 million primarily due to our Abbott collaboration, partially offset by non-cash charges of \$7.9 million for stock-based compensation, \$6.9 million for depreciation and amortization, and \$4.3 million for development expenses primarily from our joint venture with the University of Oxford.

Net cash provided by operating activities of \$74.7 million for the nine months ended September 30, 2010 was due principally to net income attributable to Emergent BioSolutions Inc. of \$25.5 million, a decrease in accounts receivable of \$46.9 million due to the collection of amounts billed primarily to HHS, and non-cash charges of \$5.2 million for stock-based compensation, \$4.0 million for depreciation and amortization and \$2.2 million for development expenses from our joint venture, partially offset by a decrease in income taxes of \$10.6 million due to federal and state tax payments.

Net cash used in investing activities for the nine months ended September 30, 2011 was \$35.6 million, primarily due to capital expenditures of \$34.2 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 \$5.2 million, partially offset by proceeds from the maturity of U.S. Treasury securities of \$3.8 million.

Net cash used in investing activities for the nine months ended September 30, 2010 of \$14.0 million, resulted principally from construction and related costs for Building 55, our large-scale manufacturing facility in Lansing, Michigan, and infrastructure investments and other equipment.

Net cash provided by financing activities of \$16.7 million for the nine months ended September 30, 2011 resulted primarily from \$21.3 million in advances under our construction loan with PNC Bank, or PNC, related to the renovation and improvement of our Baltimore facility, \$8.8 million in proceeds from stock option exercises and \$1.5 million related to excess tax benefits from the exercise of stock options, partially offset by \$14.9 million in principal payments on indebtedness.

Net cash used in financing activities of \$12.3 million for the nine months ended September 30, 2010 resulted primarily from \$32.5 million in principal payments on indebtedness, including \$30.0 million in payments on a revolving line of credit with Fifth Third Bank, partially offset by \$15.0 million in proceeds from borrowings under the revolving line of credit with Fifth Third Bank, \$4.1 million in proceeds from stock option exercises and \$1.1 million related to excess tax benefits from the exercise of stock options.

### ***Debt Financing***

As of September 30, 2011, we had \$53.8 million principal amount of debt outstanding, comprised primarily of the following:

- \$2.5 million outstanding under a loan from the Department of Business and Economic Development of the State of Maryland used to finance eligible costs incurred to purchase our first facility in Frederick, Maryland;
- \$5.3 million outstanding under a mortgage loan from PNC used to finance the remaining portion of the purchase price for our first Frederick facility;
- \$20.1 million outstanding under a term loan from HSBC Realty Credit Corporation used to finance a portion of the costs of our facility expansion in Lansing, Michigan;
- \$4.6 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; and
- \$21.3 million outstanding under a construction loan from PNC used to fund the ongoing renovation of our Baltimore, Maryland facility.

In April 2011, we repaid the remaining \$6.5 million due under the mortgage loan from HSBC Realty Credit Corporation that was used to finance a portion of the purchase price for our second facility at the Frederick site.

In July 2011, we entered into a loan agreement and related agreements with PNC, under which PNC provided us with a construction loan of up to \$30.0 million primarily to fund the ongoing renovation of the our Baltimore facility. A portion of the loan was also used to repay our loan with HSBC Bank, which we used to finance a portion of the purchase price of the facility. Under the loan agreement, PNC agreed to make advances to us of up to \$30.0 million through July 2012 based on periodic requests from us.

In August 2011, we entered into a separate loan agreement with PNC to provide us with an equipment loan of up to \$12.0 million to fund equipment purchases at the Baltimore facility. Under the equipment loan agreement, PNC agreed to make advances to us of up to \$12.0 million through August 2012 based on periodic requests from us. As of September 30, 2011, we had not requested an advance on this loan.

In October 2011, we modified our agreement with PNC related to the first Frederick facility to extend the maturity date to October 2013, reduce the fixed annual interest rate to 3.48% and increase the monthly payment to \$64,000. All unpaid principal and interest is due in full in October 2013.

### ***Funding Requirements***

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

- the level and timing of BioThrax product sales and cost of product sales;
- our ability to obtain funding from government entities and non-government and philanthropic organizations for our development programs;
- the level of participation of collaborative partners in our development programs;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to Building 55, our large-scale manufacturing facility in Lansing, Michigan, the build out of our new facility in Baltimore, Maryland, and any other new facilities;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, other product candidates that we may pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the market acceptance and sales growth of any of our products and product candidates upon regulatory approval;
- the extent to which our growth generates increased administrative costs;
- the extent to which we lend money to, and are able to obtain repayment from, third parties;
- 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 and technologies;
- the effect of competing technological and market developments; and
- the extent to which we become obligated to make cash payments related to the contingent value rights issued to former holders of Trubion common stock in connection with our acquisition of Trubion that are not offset by corresponding cash inflows from our collaborative partners.

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

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

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

Our exposure to market risk is currently confined to our cash and cash equivalents and restricted cash that have maturities of less than three months, our investments, 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 and the small amount of our non-cash investments of

\$3.5 million as of September 30, 2011, we do not believe that an increase in market rates would likely not have a significant impact on the realized value of our investments, but any increase in market rates would likely increase the interest expense associated with our debt.

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2011. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2011, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

##### **Changes in Internal Control Over Financial Reporting**

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the quarter ended September 30, 2011 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**

*Class-action litigation related to Trubion Pharmaceuticals acquisition.* On August 17, 2010, two class action lawsuits were filed in the Superior Court of Washington, King County, or State Court, against Trubion Pharmaceuticals, Inc., or Trubion, its board of directors, and us, or the Defendants, alleging in summary that, in connection with the merger of Trubion with our subsidiary, or the Acquisition, the members of the Trubion board of directors breached their fiduciary duties by conducting an unfair sale process and agreeing to an unfair price. Both complaints also claimed that Trubion and we aided and abetted the Trubion board of directors in its breach of fiduciary duties. On September 9, 2010, the actions were consolidated into one action, or the State Action. On October 1, 2010, the plaintiffs in the State Action served on the Defendants a consolidated amended class action complaint, or the Amended Complaint. The Amended Complaint alleged, among other things and in addition to the matters alleged in the initial complaints, that the Defendants omitted material information from the Proxy Statement/Prospectus relating to the Acquisition.

On October 4, 2010, a class action lawsuit was filed in the U.S. District Court for the Western District of Washington against the Defendants, or the Federal Action, and, collectively with the State Action, the Actions, which made allegations related to the Acquisition that were substantially similar to those matters alleged in the Amended Complaint and included additional allegations regarding purported violations of the federal securities laws and sought substantially similar relief.

On October 8, 2010, the Defendants reached agreement in principle with the plaintiffs in the Actions regarding the settlement of the Actions. The terms of the settlement contemplated by that agreement in principle required that Trubion and we make certain additional disclosures related to the Acquisition, as set forth in our Current Report on Form 8-K filed on October 8, 2010. The parties also agreed that the plaintiffs in the Actions could seek attorneys’ fees and costs in an aggregate amount up to \$475,000, to be paid by Trubion if such fees and costs are approved by the State Court. There would be no other payment by Trubion, any of the members of the Trubion board of directors or us to the plaintiffs or their respective counsels in connection with the settlement and dismissal of the Actions. The agreement in principle further contemplated that the parties would enter into a stipulation of settlement, which would be subject to customary conditions, including State Court approval following notice to Trubion’s shareholders. The Actions were stayed pending approval of the settlement of the State Action by the State Court, after which the State Action and all claims asserted therein would be dismissed with prejudice and counsel for the plaintiff in the Federal Action would take all necessary steps to dismiss the Federal Action and all claims asserted therein with prejudice. On April 26, 2011, the State Court entered an order granting preliminary approval of the settlement and requiring that notice of the settlement and preliminary approval be mailed to class members by May 17, 2011. The order also provided that all class members wishing to be excluded from the settlement of the Actions were required to give notice by June 21, 2011. At a hearing on July 29, 2011, the State Court determined that the settlement was fair, reasonable and adequate to the class members and approved the settlement in all aspects. On September 12, 2011 the Federal Action was dismissed and we have since made a payment in the amount of \$475,000 for attorneys’ fees and costs.

*Other.* From time to time, we are involved in product liability claims and other litigation considered normal in the nature of our business. We do not believe that any such proceedings would have a material adverse effect on the results of our operations.

##### **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 U.S. government demand for BioThrax is reduced, our business, financial condition and operating results could be materially harmed.***

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales to the U.S. government of BioThrax, our FDA-approved anthrax vaccine and only marketed product. We are currently party to a contract with the Centers for Disease Control and Prevention, or CDC, a U.S. federal agency under the U.S. Department of Health and Human Services, or HHS, to supply doses of BioThrax for placement into the Strategic National Stockpile, or SNS. If the SNS priorities change, or if the Department of Defense, or DoD, dose requirements from the SNS are reduced, our revenues could be substantially reduced.

Our existing contract expires in December 2011. In September 2011, we received an award from the CDC for the supply of 44.75 million doses of BioThrax for placement into the SNS over a five-year period, and we are currently working with CDC to finalize a related contract necessary to document the award. The procurement of doses of BioThrax by the CDC is subject to availability of funding. However, our existing and prior contracts with HHS and the DoD do not necessarily increase the likelihood that funding for the procurement of doses will be available. If we are unable to successfully come to an agreement with the CDC on the final terms of this contract, or if funding to procure doses of BioThrax is not available, our business, financial condition and operating results could be materially harmed. The success of our business and our operating results for the foreseeable future are substantially dependent on the terms of our BioThrax sales to the U.S. government, including price per dose, the number of doses and the timing of deliveries.

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

We expect that a significant portion of our near-term business will be under government contracts or subcontracts awarded through competitive bidding. Competitive bidding for government contracts presents a number of risks or requirements that are not typically present in the commercial contracting process, including:

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

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

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

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

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

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

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

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

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

Our existing and prior contracts for the supply of BioThrax with HHS and the DoD, as well as our current award for the procurement of 44.75 million doses of BioThrax from the CDC, are fixed price contracts. We expect that our future contracts with the U.S. government for BioThrax, as well as contracts for biodefense product candidates that we successfully develop, 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 government substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the government to:

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including by imposing equitable price adjustments;
- cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- decline to exercise an option to renew a contract;
- exercise an option to purchase only the minimum amount, if any, specified in a contract;
- decline to exercise an option to purchase the maximum amount, if any, specified in a contract;
- claim rights to products, including intellectual property, developed under the contract;
- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- suspend or debar the contractor from doing business with the government or a specific government agency;
- pursue criminal or civil remedies under the False Claims Act and False Statements Act; and

- control or prohibit the export of products.

Generally, government contracts, including our HHS contracts for BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the government's convenience. Under general principles of government contracting law, if the 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 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 government contracts grant the 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 government.

***Legal proceedings challenging the U.S. government's use of BioThrax may be costly to defend and could limit future purchases of BioThrax by the U.S. government.***

Legal proceedings could be costly to defend, and the results could reduce demand for BioThrax by the U.S. government. For example, a group of unnamed military personnel filed a lawsuit in 2003 seeking to enjoin the DoD from administering BioThrax on a mandatory basis without informed consent of the recipient or a Presidential waiver, and a federal court issued the requested injunction in 2004. In 2005, the Food and Drug Administration, or FDA, issued an order affirming the BioThrax license and, as a result, an appellate court ruled in February 2006 that the injunction was dissolved.

In October 2006, the DoD announced that it was resuming a mandatory vaccination program for BioThrax for designated personnel and contractors. In December 2006, the same counsel who brought the prior lawsuit filed a new lawsuit contending that the FDA's 2005 Final Order should be set aside and that BioThrax is not properly approved for use in the DoD's vaccination program. In February 2008, the federal district court in which that case was pending dismissed the action, concluding that the FDA did not make a clear error of judgment in reaffirming the safety and efficacy of BioThrax. On September 29, 2009, the United States Court of Appeals for the District of Columbia Circuit issued its opinion in *Rempfer v. Torti*, affirming the February 29, 2008 finding of the District Court that the FDA did not violate the Administrative Procedure Act in connection with its December 19, 2005 Final Order classifying BioThrax as safe and effective. The plaintiffs' petition for writ of certiorari in the United States Supreme Court was denied on March 1, 2010.

Although we are not a party to any lawsuits challenging the DoD's mandatory use of BioThrax, if a court were to again enjoin the DoD's use of BioThrax on a mandatory basis, the amount of future purchases of BioThrax by the U.S. government could be affected. Furthermore, contractual indemnification provisions and statutory liability protections may not fully protect us from all related liabilities, and statutory liability protections could be revoked or amended to reduce the scope of liability protection. For example, we have invoiced the DoD for reimbursement of our costs incurred with respect to the lawsuits filed against us by current and former members of the U.S. military claiming damages as the result of personal injuries allegedly suffered from vaccination with BioThrax, and we are continuing our efforts to negotiate with the DoD for a satisfactory resolution of that claim. In addition, lawsuits brought directly against us by third parties, even if not successful, would require us to spend time and money defending the related litigation that may not be reimbursed by insurance carriers or covered by indemnification under existing contracts.

#### **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 of \$5.6 million for the period of 2011 covered by this quarterly report. 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 fulfilling 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 September 30, 2011, we had \$53.8 million principal amount of debt outstanding. We may seek to raise substantial external debt financing to provide additional financial flexibility. The assumption of debt could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of any cash flow from operations to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- increasing the amount of interest that we have to pay on debt with variable interest rates if market rates of interest increase;
- increasing our vulnerability to general adverse economic and industry conditions;
- obligating us to restrictive covenant that may reduce our ability to 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 expect to 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 September 30, 2011, we had \$128.8 million of cash, cash equivalents and investments. Our future capital requirements will depend on many factors, including:

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

- the level of participation of collaborative partners in our development programs, including Pfizer Inc., or Pfizer, with respect to SBI-087, and Abbott Laboratories, or Abbott, with respect to TRU-016;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to Building 55, our large-scale manufacturing facility in Lansing, Michigan, the build out of our new facility in Baltimore, Maryland, and any other new facilities;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, other product candidates that we may pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the market acceptance and sales growth of any of our products or product candidates upon regulatory approval;
- the extent to which our growth generates increased administrative costs;
- the extent to which we lend money to, and are able to obtain repayment from, third parties;
- 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;
- the effect of competing technological and market developments; and
- the extent to which we become obligated to make cash payments related to the contingent value rights issued to former holders of common stock of Trubion Pharmaceuticals, Inc., or Trubion, in connection with our acquisition of Trubion that are not offset by corresponding cash inflows from our collaborative partners.

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

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

Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

#### **Risks Related to Manufacturing and Manufacturing Facilities**

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

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

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

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

BioThrax and all our product candidates are biologics. Manufacturing biologic products, especially in large quantities, is complex. The products must be made consistently and in compliance with a clearly defined manufacturing process. Accordingly, it is essential to be able to validate and control the manufacturing process to assure that it is reproducible. Slight deviations anywhere in the manufacturing process, including maintaining master seed or cell banks and preventing drift, obtaining materials, seed or cell growth, fermentation, filtration, filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures or manufacturing shut-down, delays in the release of lots, product recalls, spoilage or regulatory action. Success rates can vary dramatically at different stages of the manufacturing process, which can reduce yields and increase costs. From time to time we may experience deviations in the manufacturing process that may take significant time and resources to resolve and if unresolved may affect manufacturing output and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation or regulatory action against us or cause the FDA to cease releasing product until the deviations are explained and corrected, any of which could be costly to us and negatively impact our business.

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

Additionally, potency testing of each lot of BioThrax is performed against a qualified reference lot that we maintain. We continually monitor the status of our reference lot and periodically produce and qualify a new reference lot to replace the existing reference lot. For example, we prepared and qualified a new reference lot during the second quarter of 2011 to replace our prior, qualified reference lot. If we are not able to satisfy the FDA's requirements for release of BioThrax, our ability to sell BioThrax would be impaired until such time as we become able to meet such requirements, which would significantly impact our revenues, require us to utilize our cash balances to help fund our ongoing operations and otherwise harm our business.

In addition, we are contractually required to ship BioThrax at a prescribed temperature range during shipping, and variations from that temperature range could result in loss of product and could adversely affect our profitability. Delays, lot failures, shipping deviations, spoilage or other loss during shipping could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

***Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture BioThrax, which would harm our business, financial condition and operating results.***

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

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

As our equipment ages, it will need to be replaced. Replacement of equipment has the potential to introduce variations in the manufacturing process that may result in lot failures or manufacturing shut-down, delay in the release of lots, product recalls, spoilage or regulatory action.

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

***If the company on which we rely for filling BioThrax vials is unable to perform these services for us, our business may suffer.***

We have outsourced the operation for filling BioThrax into vials to a single company. If this filler were unable to perform filling services for us, we would need to engage, qualify and license an alternative filling company or develop our own filling capabilities, all of which could involve significant time and cost. Any new contract filling company or filling capabilities that we acquire or develop will need to be approved by the FDA. We have identified and contracted with an additional provider that we believe can handle our filling needs. Before this additional provider can perform filling services for us, it must be qualified and licensed by the FDA. Such qualification and licensure may be time consuming and costly, and may not result in FDA approval.

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

The timing and amount of customer demand is difficult to predict. We may not be able to scale-up our production quickly enough to fill any new customer orders on a timely basis. This could cause us to lose new business and possibly existing business. For example, we, or third party manufacturers with whom we may contract, may not be able to scale-up manufacturing processes for our product candidates to allow production of commercial quantities at a reasonable cost or at all. Furthermore, if we overestimate customer demand, or choose to commercialize products for which the market is smaller than we anticipate, we could incur significant unrecoverable costs from creating excess capacity. In addition, if we do not successfully develop and commercialize any of our product candidates, we may never utilize the production capacity that we expect to have available.

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

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

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

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

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

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

If alternative suppliers are not available or are delayed in fulfilling our requirements, or if we are unsuccessful in developing our own manufacturing capabilities, we may not be able to obtain adequate supplies of our product candidates on a timely basis. A change of manufacturers would require review and



approval by the FDA and the applicable foreign regulatory agencies. This review and approval may be costly and time consuming. There are a limited number of manufacturers that operate under cGMP requirements and that are both capable of manufacturing for us and willing to do so. We may not be able to reach agreement on reasonable terms, if at all, with these manufacturers.

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

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

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

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

We also depend on certain single-source suppliers for materials and services necessary for the manufacture of BioThrax and our product candidates. A disruption in the availability of such materials or services from these suppliers could require us to qualify and validate alternative suppliers. If we are unable to locate or establish alternative suppliers, our ability to manufacture our products could be adversely affected and also could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

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

Our research and development and manufacturing processes involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we, the third parties that conduct clinical trials on our behalf, and the third parties that manufacture our product candidates are subject to federal, state, local and foreign laws and regulations governing the use, manufacture, distribution, storage, handling, disposal and recordkeeping of these materials. We are also subject to a variety of environmental laws in Michigan, including those regarding underground storage tanks. One such tank on our Lansing, Michigan campus has leaked in the past. The State of Michigan removed the tank, continues to monitor the situation and has agreed to indemnify us for any resulting liabilities. In the event that the State of Michigan does not indemnify us, or if our insurance does not cover the exposure of any remediation that may be necessary, we may be required to spend significant amounts on remediation efforts. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS and the DoD.

The Public Health Security and Bioterrorism Preparedness and Response Act and the Agricultural Protection Act require us to register with the CDC and U.S. Department of Agriculture our possession, use or transfer of select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires increased safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel and establishes a comprehensive national database of registered entities.

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

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

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

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

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

**Risks Related to Product Development**

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

We have invested a significant portion of our efforts and financial resources in the development of our vaccines and therapeutic product candidates and the acquisition of additional product candidates. In addition to BioThrax sales, our ability to generate near term revenue is dependent on the success of our development programs and collaboration programs, on the U.S. government's interest in providing development funding for or procuring certain of our

product candidates, on the interest of non-governmental organizations in providing grant funding for development of certain of our product candidates and on the commercial viability of our product candidates. The commercial success of our product candidates will depend on many factors, including accomplishing the following in an economical manner:

- successful development, formulation and cGMP scale-up of biological manufacturing that meets FDA requirements;
- successful development of animal models;
- successful completion of non-clinical development, including studies in approved animal models;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- successful completion of clinical trials;
- receipt of marketing approvals from the FDA and equivalent foreign regulatory authorities;
- procurement of our biodefense product candidates prior to FDA approval;
- establishing commercial manufacturing processes of our own or arrangements with contract manufacturers;
- manufacturing stable commercial supplies of product candidates, including materials based on recombinant technology;
- launching commercial sales of the product candidate, whether alone or in collaboration with others; and
- acceptance of the product candidate by potential government customers, physicians, patients, healthcare payors and others in the medical community.

If we are prevented from developing and commercializing a product candidate in an economically acceptable manner, that product program may be adversely affected and the commercial success of the product candidate may be harmed. For example, we recently agreed with one of our contract manufacturers to extend the commencement date of the commercial term for manufacture of Anthravig. We are currently in negotiations with that contract manufacturer for a longer-term resolution regarding commercial production; however, in the event that we are not able to negotiate a satisfactory resolution we may be required to explore other options for Anthravig, which could result in less favorable commercial success for this product candidate, or no commercial success at all.

***We depend on our collaborative relationships with Pfizer and Abbott to develop, manufacture and commercialize certain of our recently acquired product candidates.***

We are party to collaboration agreements with each of Pfizer and Abbott. Under the terms of our agreement with Pfizer, Pfizer is responsible for regulatory approval of and any subsequent commercialization of SBI-087. Under the Abbott collaboration for the development and commercialization of TRU-016, we and Abbott must jointly agree to all development and commercialization plans and timelines for TRU-016. If either Pfizer or Abbott were to terminate its agreement with us or otherwise curtail or fail to fulfill its obligations, we would need to obtain the capital necessary to fully fund the development and commercialization of the related product candidates or enter into alternative arrangements with a third party. We could also become involved in disputes with either of these partners, which could lead to delays in or termination of certain of our development and commercialization programs and time-consuming and expensive litigation or arbitration. If either Pfizer or Abbott terminates or breaches its agreement with us, or otherwise fails to complete its obligations in a timely manner, certain of our product development programs would be substantially delayed and the chances of successfully developing or commercializing the impacted product candidate(s) would be materially and adversely affected.

Our collaboration with Pfizer initially also included TRU-015, an investigational drug in Phase II evaluation for the treatment of Rheumatoid Arthritis, or RA. In June 2010, Pfizer decided to discontinue development of TRU-015 based on preliminary results from the Phase II study, which, although consistent with previous studies and similar to other B-cell-depleting therapies, did not meet the internally predefined primary endpoint of the Phase II study. In April 2011, Pfizer also determined to not pursue development of certain other product candidates directed to targets other than CD20 that had been established pursuant to our agreement with Pfizer. Additionally, in May 2011, we and Pfizer agreed to remove certain exclusivity restrictions on Pfizer's ability to develop and commercialize certain anti-CD20 product candidates that are part of our collaboration. We cannot predict how or whether Pfizer will proceed with the development of the remaining product candidates covered by our agreement, including SBI-087 and other therapeutics directed to CD20. Our ability to receive any significant revenue from our product candidates covered by the agreement depends on the efforts of Pfizer and on our ability to collaborate effectively. Any future payments, including royalties to us, will depend on the extent to which Pfizer advances product candidates through development and commercialization. Pfizer may terminate our relationship with them, in whole or in part, without cause, by giving us 90 days' written notice. Pfizer also has the right to terminate the agreement, on a target-by-target basis, upon 60 days' written notice, if any safety or regulatory issue arises that would have a material adverse effect on Pfizer's ability to develop, manufacture or commercialize one or more product candidates. With respect to control over decisions and responsibilities, our agreement with Pfizer provides for a CD20-directed therapy development committee consisting of representatives of Pfizer and us. Ultimate decision-making authority as to most matters within the collaboration, including development plans and timelines, however, is vested in Pfizer.

In August 2009, Trubion entered into a collaboration agreement with Facet Biotech Corporation, or Facet, for the joint worldwide development and commercialization of TRU-016, a product candidate in Phase I clinical development for chronic lymphocytic leukemia, or CLL, and other CD37-directed protein therapeutics. Facet became a wholly-owned subsidiary of Abbott in April 2010. Under the terms of the collaboration agreement, neither we nor Abbott have the right to develop or commercialize protein therapeutics directed to CD37 outside of the collaboration, and development and commercialization expenses incurred by both companies in the development and commercialization of TRU-016 are shared equally. Our ability to receive funding for TRU-016 under the collaboration depends on our ability to collaborate effectively with Abbott. Any future payments, including milestones payable to us, will depend on the extent to which we and Abbott advance TRU-016 through development and commercialization. With respect to control over decisions and responsibilities, the collaboration agreement provides for a joint steering committee that must make decisions by consensus. Failure to reach consensus on material aspects of the development or commercialization of TRU-016 would lead to dispute resolution by our respective designated officers, and potentially arbitration, any of which could delay the development of TRU-016, which may harm our business. Additionally, Abbott may terminate the collaboration agreement without cause, and would not be obligated to pay us a termination fee. Abbott also has the right upon 90 days' written notice to terminate the agreement for any uncured material breach by us. Under certain circumstances, the parties have the right to opt out of the collaboration or may be deemed to have opted out of the collaboration with respect to the product. If Abbott opts out of the collaboration with respect to a product, then we would become responsible for all development and commercialization costs for that product and be obligated to pay Abbott certain royalty payments upon the sale of that product. We are currently the lead manufacturing party for TRU-016. If we opt out of the collaboration and are the lead TRU-016 manufacturing party at that time, we would be obligated to continue to supply TRU-016 to Abbott for up to 18 months.

While SBI-087 or TRU-016 may never be successfully developed or commercialized, if either Pfizer or Abbott were to fail to perform its obligations in a timely manner or were to terminate or opt out of its collaboration with us, the development and commercialization of the affected product would be substantially delayed and may be otherwise adversely affected, which could have a material adverse effect on our results of operations.

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

Before obtaining regulatory approval for the sale of our product candidates, we and our collaborative partners must conduct extensive preclinical studies and clinical trials to establish proof of concept, safety and efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and the outcome of such trials is uncertain. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. For example, in December 2008, we and Sanofi Pasteur determined that the joint efforts of our collaboration related to our meningitis B product development program had not identified a viable product candidate, which effectively ended development activities under this collaboration. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials.

We expect to rely on FDA regulations known as the “animal rule” to obtain approval for certain of our product candidates. The animal rule permits the use of animal efficacy studies together with human clinical safety and immunogenicity trials to support an application for marketing approval. These regulations are relatively new, and we have limited experience in the application of these rules to the product candidates that we are developing. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our vaccine and therapeutic product candidates in humans. If we are not successful in completing the development and commercialization of our vaccine and therapeutic product candidates, or if we are significantly delayed in doing so, our business will be materially harmed.

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

- regulators or institutional review boards may not authorize us, or our collaborators, to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;
- regulators may determine that service providers we use in the conduct of a clinical trial are precluded from providing such services;
- we or a collaborative partner may experience delay in beginning the clinical trial;
- we may experience competition in recruiting clinical investigators;
- the cost of our clinical trials could escalate and become cost prohibitive;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- regulatory requirements, policy and guidelines could change;
- we may experience limitations in our ability to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials;
- we or our collaborators may fail to adequately manage the increasing number, size and complexity of our clinical trials;
- any or all of our collaborators, the FDA and foreign regulatory agencies may interpret data differently;
- third parties conducting and overseeing the operations of our clinical trials may fail to perform their contractual or regulatory obligations in a timely fashion;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials or may experience delays in patient enrollment and variability in the number and types of patients available for clinical trials; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

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

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

- be delayed in obtaining marketing approval for our product candidates;
- obtain approval for indications that are not as broad as intended; or
- not be able to obtain marketing approval.

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

Under the Project BioShield Act, the Secretary of HHS, or the Secretary, can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the Secretary to authorize the emergency use of medical products that have not yet been approved by the FDA. However, our biodefense product candidates might not be selected by the Secretary under this authority. Moreover, this authority could result in increased competition for our products and product candidates.

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

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

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

#### **Risks Related to Commercialization**

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

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

The market for sales of BioThrax to customers other than the U.S. government is undeveloped, and we may not be successful in generating meaningful sales of BioThrax to these potential customers. For example, in June 2011 the Singapore Health Sciences Authority approved our product license application for the marketing and sale of BioThrax in Singapore. Although our product license application has been approved, we have not secured a contract for the sale of BioThrax to the Singapore government. To date, we have supplied only small amounts of BioThrax directly to foreign governments and our sales of BioThrax to customers other than the U.S. government has represented a small portion of our revenue. If we fail to significantly increase our sales of BioThrax to these customers, our business and opportunities for growth could be materially harmed.

Government regulations may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, many foreign governments require licensure of BioThrax in their jurisdiction before they will consider procuring doses. Additionally, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of BioThrax and related technology, the U.S. government may decide, particularly in the current environment of elevated concerns about global terrorism, to increase the scope of export prohibitions. These prohibitions could limit our sales of BioThrax to foreign governments and other foreign customers. In addition, U.S. government demand for an anthrax vaccine may limit supplies of BioThrax available for sale to non-U.S. government customers. For example, our efforts to develop domestic commercial and international sales may be impeded by the DoD's right under the Defense Production Act to require us to deliver more doses than we currently anticipate. Furthermore, the DoD's sale of BioThrax to foreign governments under the Foreign Military Sales program has had and may continue to have an adverse effect on our ability to sell BioThrax internationally.

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

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

As we continue to expand our operations outside of the United States, we must comply with numerous laws and regulations relating to international business operations. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

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

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

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

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

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

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

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

In addition, notwithstanding favorable findings regarding the safety and efficacy of BioThrax by the FDA in its final ruling in December 2005, the Government Accountability Office reiterated concerns regarding BioThrax in Congressional testimony in May 2006 that it had previously identified beginning in 1999. These concerns include the then-licensed six-dose regimen and annual booster doses, questions about the long-term and short-term safety of the vaccine, including how safety is affected by gender differences, and uncertainty about the vaccine's efficacy against inhalational anthrax. Continued reiteration of these concerns could have a detrimental effect on the market's acceptance of BioThrax.

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

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

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

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

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

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

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

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

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

To achieve commercial success for any approved product, we must either develop our own sales and marketing capabilities, enter into collaborations with third parties able to perform these services or outsource these functions to third parties.

We currently market and sell BioThrax through a small, targeted sales and marketing group. We plan to continue to do so and expect that we will use a similar approach for sales to the U.S. government of any other biodefense product candidates that we successfully develop.

In addition, we are a party to a collaboration agreement with Pfizer to develop and commercialize therapeutics directed to CD20 and to a collaboration agreement with Abbott to develop and commercialize therapeutics directed to CD37.

To increase our sales of BioThrax to state and local governments and foreign governments and create an infrastructure for future sales of other biodefense products to these customers, we plan to expand our sales and marketing organization. In addition, if we do not enter into collaborative agreements with respect to product candidates not covered by the Pfizer or Abbott collaborations, or if any of our product candidates are the subject of collaborative agreements with third parties that are not covered by commercialize such product candidates, we may need to further expand our sales, marketing and distribution infrastructure to effectively commercialize these product candidates.

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

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

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

***We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.***

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid technological advances. We may face future competition with respect to BioThrax, our current product candidates and any products we may seek to develop or commercialize in the future from pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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

We believe that our most significant competitors in the area of vaccine and therapeutics are a number of pharmaceutical companies that have vaccine programs, including Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Pfizer, and Novartis, as well as smaller more focused companies engaged in vaccine and therapeutic development, such as Aeras, Crucell, Cangene, Human Genome Sciences, Soligenix, Dynport Vaccine Company, Elusys, Bavarian Nordic and PharmAthene. Specifically with respect to oncology and autoimmune disease, our competitors include Amgen, Pfizer, Takeda, Centocor Ortho Biotech, Merck, Mitsubishi Tanabe, Abbott, Eisai, Celgene, Bristol-Myers Squibb, UCB, Otsuka, Roche, Chugai, Genentech, Biogen Idec, Spectrum Pharmaceuticals, Inc., Bayer Schering AG, GSK, Genzyme, Cephalon Oncology, Genmab, Allos Therapeutics, AstraZeneca, Boehringer Ingelheim and ImmunoGen, Inc.

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

Numerous companies have products or product candidates in development that would compete with the commercial product candidates for which we are seeking to obtain marketing approval. If approved for the treatment of RA, we anticipate that some of our commercial product candidates would compete with other marketed protein therapeutics for the treatment of RA, including: Enbrel® (Amgen, Pfizer and Takeda), Remicade® (Centocor Ortho Biotech, Merck and Mitsubishi Tanabe), Humira® (Abbott and Eisai), Orenicia® (BMS), Cimzia® (UCB and Otsuka), Simponi® (JNJ and Merck), Actemra® (Roche and Chugai) and Rituxan® (Genentech, Roche and Biogen Idec). If approved for the treatment of systemic lupus erythematosus, or SLE, our product candidates will compete with Benlysta (Human Genome Sciences and GSK) and other B cell depleting therapies, including CD20-directed therapeutics.

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

If approved for the treatment of cutaneous T-cell lymphoma, or CTCL, and peripheral T-cell lymphoma, or PTCL, or other T-cell lymphomas, we anticipate that our product candidates would compete with other T-cell therapies and related therapeutics. Therapeutics marketed for the treatment of CTCL or PTCL include Ontak and Targretin (Eisai), Istodax® (Celgene), Zolinza® (Merck), Folutin® (Allos Therapeutics), Campath (Bayer Schering AG), and R788® (AstraZeneca). In addition, TaiMed Biologics, Biogen Idec, Roche, Adeona Pharmaceuticals, Bristol-Myers Squibb, Tolterx and Viral Genetics Inc. are developing therapies directed to CTCL or PTCL.

The Aeras Global Tuberculosis Vaccine Foundation is developing or supporting the development of five tuberculosis vaccine product candidates in addition to ours, any of which could present competitive risks.

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

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

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

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

Under our prior BioThrax contracts with the DoD and HHS, the U.S. government agreed to indemnify us against claims by third parties for death, personal injury and other damages related to BioThrax, including reasonable litigation and settlement costs, to the extent that the claim or loss results from specified risks not covered by insurance or caused by our grossly negligent or criminal behavior. As required under our prior BioThrax contracts, we have notified the DoD of personal injury claims that have been filed against us as a result of the vaccination of U.S. military personnel with BioThrax and are seeking reimbursement from the DoD for uninsured costs incurred in defending these claims. The collection process can be lengthy and complicated, and there is no guarantee that we will be able to recover these amounts from the U.S. government.

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

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

We face an inherent risk of product liability exposure related to the sale of BioThrax and any other products that we successfully develop and the testing of our product candidates in clinical trials. For example, we have been a defendant in lawsuits filed on behalf of military personnel who alleged that they were vaccinated with BioThrax by the DoD and claimed damages resulting from personal injuries allegedly suffered because of the vaccinations. The plaintiffs in these lawsuits claimed different injuries and sought varying amounts of damages. Although we successfully defended these lawsuits, we cannot ensure that we will be able to do so in the future.

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

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

We currently have product liability insurance for coverage up to a \$15 million annual aggregate limit with a deductible of \$75,000 per claim up to \$375,000 in aggregate. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Product liability insurance is difficult to obtain and increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. For example, from 2002 through February 2006, we were unable to obtain product liability insurance for sales of BioThrax on commercially reasonable terms. We do not believe that the amount of insurance we have been able to obtain for BioThrax is sufficient to manage the risk associated with the potential large scale deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on statutory protections in addition to insurance to help mitigate our liability exposure for BioThrax.

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

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

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

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

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

Even when a payor determines that a product is covered, the payor may impose limitations that preclude payment for some uses that are approved by the FDA or comparable authorities but are determined by the payor to not be medically reasonable and necessary. Moreover, eligibility for coverage does not imply that any product will be covered in all cases or that reimbursement will be available at a rate that permits the health care provider to cover its costs of using the product.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### **Risks Related to Our Acquisition Strategy**

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

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

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

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

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



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

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

Since our inception we have pursued a strategy of growing our business through licensing and acquisition. We commenced operations in September 1998 through an acquisition of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how, all from the Michigan Biologic Products Institute. We acquired a portion of our pipeline of vaccine and therapeutic product candidates through our acquisition of Microscience Limited in a share exchange in 2005, our acquisition of substantially all of the assets, for cash, of ViVacs GmbH in 2006, our acquisition of Trubion in October 2010 and our acquisition of certain assets of TenX BioPharma, Inc. in May 2011.

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

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

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

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

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

**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 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.

***We rely on property and equipment owned by the U.S. government in the manufacturing process for BioThrax.***

We have the right to use certain property and equipment that is owned by the U.S. government, referred to as government furnished equipment, or GFE, at our Lansing, Michigan site in the manufacture of BioThrax. We have the option to purchase all or part of the existing GFE from the U.S. government on terms to be negotiated with the U.S. government. If the U.S. government modifies the terms under which we use the GFE in a manner that is unfavorable to us or we are unable to reach an agreement with the U.S. government concerning the terms of the purchase of that part of the GFE necessary for our business, our business could be harmed. If the U.S. government were to terminate or fail to extend all BioThrax supply contracts with us, we potentially could be required to rent or purchase that part of the GFE necessary for the continued production of BioThrax in our current manufacturing facility.

### **Risks Related to Regulatory Approvals**

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

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

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

In the United States, BioThrax and our product candidates are regulated by the FDA as biologics. To obtain approval from the FDA to market our product candidates, we will be required to submit a biologics license application, or BLA, to the FDA. Ordinarily, the FDA requires a sponsor to support a BLA with substantial evidence of the product's safety and effectiveness in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted. For example, this will be the case with respect to any BLA that we may file in the future with respect to our oncology and auto-immune disease product candidates. However, our biodefense product candidates require slightly different treatment. Specifically, because humans are rarely exposed to anthrax toxins under natural conditions, and cannot be intentionally exposed, statistically significant effectiveness of our biodefense product candidates cannot be demonstrated in humans, but instead must be demonstrated, in part, by utilizing animal models before they can be approved for marketing. This is known as the FDA's "animal rule".

We intend to use the animal rule in pursuit of FDA approval for BioThrax as a post-exposure prophylaxis, Anthravig, PreviThrax, Thravixa, and NuThrax. We cannot guarantee that the FDA will permit us to proceed with licensure of any of our BioThrax related programs or our other product candidates under the animal rule. Even if we are able to proceed pursuant to the animal rule, the FDA may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review for a submitted product application, may cause delays in the approval or rejection of an application.

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

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

Any vaccine and therapeutic product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies. As an approved product, BioThrax is subject to these requirements and ongoing review.

These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents and recordkeeping. The FDA enforces its cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect manufacturing facilities without a warrant or prior notice at reasonable times and in a reasonable manner.

The FDA conducted routine, biannual inspections of our Lansing facilities in September 2002, May 2004, May 2006, March 2008, December 2009 and August 2011. Following each of these inspections, the FDA issued inspectional observations on Form FDA 483, some of which were significant. We responded to the FDA regarding the inspectional observations relating to each inspection and, where necessary, implemented corrective action. All observations from the 2002, 2004, 2006, 2008 and 2009 inspections have been successfully closed out. We are in the process of implementing corrective action where necessary in response to the FDA observations during the August 2011 inspection and we anticipate that all observations from the 2011 inspection will also be successfully closed out. In December 2005, the FDA stated in its final order on BioThrax that at that time we were in substantial compliance with all regulatory requirements related to the manufacture of BioThrax and that the FDA would continue to evaluate the production of BioThrax to assure compliance with federal standards and regulations. If in connection with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, or if the FDA is not satisfied with the corrective actions we take in connection with any such inspection, the FDA may undertake enforcement action against us.

Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products or manufacturing processes, or failure to comply with regulatory requirements, may result in:

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

- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

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

The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval, or may include different or additional risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in another jurisdiction, including approval by the FDA. For example, in 2010 the United Kingdom Medicines and Healthcare products Regulatory Authority, or MHRA, informed us that a provision of the European Pharmacopoeia may prevent licensure of our Tuberculosis vaccine product candidate in the European Union unless such provision can be interpreted in a manner consistent with our product candidate's manufacturing process, despite the fact that the FDA had provided recent guidance to the contrary. We are continuing to work with the MHRA and outside advisors to clarify the provision but we cannot be certain that our efforts will be successful, which could preclude our ability to commercialize this product candidate in the European Union. We and our collaborators may not be able to obtain regulatory approvals to commercialize our products in any market. The failure to obtain regulatory approval in foreign jurisdictions could materially harm our business.

#### **Risks Related to Our Dependence on Third Parties**

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

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

If we are unable to reach agreements with suitable collaborators, we may fail to meet our business objectives for the affected product or program. We face, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements, or the arrangements that we establish may not turn out to be productive or beneficial for us. The terms of any collaboration or other arrangements that we establish may not be favorable to us.

Any collaboration that we enter into may not be successful. For example, in June 2010 Pfizer decided to discontinue development of TRU-015 based on preliminary results from a Phase II study. Even though these results were consistent with previous studies and similar to other B-cell-depleting therapies, they did not meet the internally predefined endpoint of the study. Additionally, the success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. It is likely that our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations.

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

- we may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of product candidates;
- our collaborators may delay clinical trials, design clinical trials in a manner with which we do not agree, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new version of a product candidate for clinical testing;
- our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach by us;
- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not do so, our ability to maintain and defend our intellectual property rights may be compromised by our collaborators' acts or omissions;
- our collaborators may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;

- our collaborators may decide not to pursue further development and commercialization of products and product candidates resulting from the collaboration, or may elect to discontinue research and development programs, which could delay development and increase the cost of developing our product candidates;
- our collaborators may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;
- we may experience difficulties in the day-to-day activities required by collaboration including close and frequent communications between several different teams, technology transfer and a collaborative sharing of responsibilities;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- our collaborators may experience financial difficulties;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations; and
- our collaborators could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

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

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

We do not have the ability to independently conduct the clinical or non-clinical trials required to obtain regulatory approval for our products. We depend on third parties, such as independent clinical investigators, contract research organizations and other third party service providers, to conduct the clinical and non-clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical and non-clinical trials, but do not exercise day-to-day control over their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

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

In addition, in certain cases, we encourage government entities and non-government organizations to conduct studies of, and pursue other development efforts for, our product candidates. For example, we expect to rely on data from clinical trials conducted by third parties seeking marketing approval for certain of our product candidates, including our BLA supplement for a label expansion of BioThrax for a regimen of fewer doses is based on the results of a clinical trial conducted by the CDC. These government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. In addition, government entities depend on annual Congressional appropriations to fund these development efforts.

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

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

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

### **Risks Related to Our Intellectual Property**

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

Our success, particularly with respect to our biosciences business, will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property covering or incorporated into our technology, products and product candidates, including those which are the subject of collaborations. This protection is very costly. The patentability of technology in the field of vaccine and therapeutic development and other pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions.

We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the duration of patent protection we may have for our products. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, or result in costly defense measures.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, we know that other entities have filed patent applications in various jurisdictions that relate to several areas in which we are developing

products. Some of these patent applications have already resulted in patents and some are still pending. If use of technology incorporated into or used to produce our product candidates is challenged, or if our processes or product candidates conflict with patent rights of others, third parties could bring legal actions against us in Europe, the U.S. and elsewhere claiming damages and seeking to enjoin manufacturing and marketing of the affected products. Further, patents generally expire, regardless of their date of issue, 20 years from the earliest claimed non-provisional filing date. As a result, the time required to obtain regulatory approval for a product candidate may consume part or all of the patent term. We are not able to accurately predict the remaining length of the applicable patent term following regulatory approval of any of our product candidates.

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

The cost of litigation to uphold the validity of patents to prevent infringement or to otherwise protect our proprietary rights could be substantial. Some of our competitors may be better able to sustain the costs of complex patent litigation because they may have substantially greater resources. Intellectual property lawsuits are expensive and unpredictable and would consume time and other resources, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also a risk that, even if the validity of a patent were upheld, a court would refuse to stop the other party from using the invention(s), including on the grounds that its activities do not infringe the patent. If any of these events were to occur, our business, financial condition and operating results could be materially adversely affected.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not do so, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties. For example, we licensed an oligonucleotide adjuvant, CpG 7909, for use in our double mutant recombinant protective antigen product candidate and NuThrax from Coley Pharmaceutical Group, Inc., or Coley. Coley, which was subsequently acquired by Pfizer is responsible for prosecuting, maintaining and defending these licensed patent rights. Coley notified us that a patent interference had been declared in the U.S. Patent and Trademark Office between our licensed patent and a third party patent application, which could result in revocation of the patent we have licensed. We may not know the outcome for a considerable period of time.

We also will rely on current and future trademarks to establish and maintain recognized brands. If we fail to acquire and protect such trademarks, our ability to market and sell our products, and therefore our business, financial condition and operating results, could be materially and adversely affected.

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

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

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

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. For example, we consider our license from the Oxford-Emergent Tuberculosis Consortium for our tuberculosis vaccine product candidate to be material to our business. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

***If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.***

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for BioThrax or the label expansions and improvements that we are pursuing for BioThrax, our only intellectual property protection for BioThrax, other than the BioThrax trademark, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and biological starting materials. However, these types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, with agreements with our employees, consultants and third parties.

These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

***If we infringe or are alleged to infringe intellectual property rights of third parties, it may adversely affect our business.***

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents and other intellectual property rights of third parties under which we do not hold licenses or other rights. Additionally, third parties may be successful in obtaining patent protection for technologies that cover development and commercialization activities in which we are already engaged. Third parties may own or control these patents and intellectual property rights in the U.S. and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement or other similar suit were brought against us or our collaborators, we or they could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit.

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

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology and pharmaceutical industries. For example, modified vaccinia Ankara, or MVA,-based vaccines have been the subject of significant intellectual property litigation. Specifically, Bavarian Nordic sued Acambis for patent infringement and other claims arising out of Acambis' importation of an MVA-based

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

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

### **Risks Related to Our Common Stock**

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

Mr. El-Hibri has the ability to control the election of the members of our Board of Directors through his ownership interests in our significant stockholders. As of October 28, 2011, Mr. El-Hibri was the beneficial owner of approximately 27% of our outstanding common stock. Because Mr. El-Hibri has significant influence over the election of the members of our board, and because of his substantial control of our capital stock, Mr. El-Hibri will likely have the ability to delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

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

Provisions of our certificate of incorporation and by-laws may discourage, delay or prevent a merger, acquisition or other changes in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management.

These provisions include:

- the classification of our directors;
- limitations on changing the number of directors then in office;
- limitations on the removal of directors;
- limitations on filling vacancies on the board;
- limitations on the removal and appointment of the chairman of our Board of Directors;
- advance notice requirements for stockholder nominations for election of directors and other proposals;
- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval.

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

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

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

Under a rights agreement that establishes our stockholder rights plan, we issue to each of our stockholders one preferred stock purchase right for each outstanding share of our common stock. Each right, when exercisable, will entitle its holder to purchase from us a unit consisting of one one-thousandth of a share of series A junior participating preferred stock at a purchase price of \$150 in cash, subject to adjustments.

Our stockholder rights plan is intended to protect stockholders in the event of an unfair or coercive offer to acquire us and to provide our Board of Directors with adequate time to evaluate unsolicited offers. The rights plan may have anti-takeover effects. The rights plan will cause substantial dilution to a person or group that attempts to acquire us on terms that our Board of Directors does not believe are in our best interests and those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

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

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through October 28, 2011 our common stock has traded as high as \$27.00 per share and as low as \$4.40 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors and success in our research and development programs;
- decisions and procurement policies by the U.S. government affecting BioThrax and our biodefense product candidates;
- regulatory developments in the U.S. and foreign countries;
- public concern as to the safety of drugs developed by us or others;
- announcements of issuances of common stock or acquisitions by us;

- the announcement and timing of new product introductions by us or others;
- termination or delay of development program(s) by our collaborative partners, or delay in achievement of collaboration milestones;
- announcements of technological innovations or new therapeutic products or methods by us or others;
- acts or omissions of our licensees, collaborators and suppliers;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions or other external factors, such as disaster or crisis; and
- the other factors described in this "Risk Factors" section.

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

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

We currently intend to retain our future earnings, if any, to fund the development and growth of our business. Our current and any future debt agreements that we enter into may limit our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

*A significant portion of our shares may be sold into the market at any time. This could cause the market price of our common stock to drop significantly, even if our business is doing well.*

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. For example, we have filed a registration statement that would permit us to issue up to \$100 million in common stock. Moreover, holders of an aggregate of approximately 8.8 million shares of our common stock outstanding as of October 28, 2011 have the right to require us to register these shares of common stock under specified circumstances.

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

**Recent Sales of Unregistered Securities**

Not applicable.

**Use of Proceeds**

Not applicable.

**Purchases of Equity Securities**

Not applicable.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. REMOVED AND RESERVED**

**ITEM 5. OTHER INFORMATION**

Not applicable.

**ITEM 6. EXHIBITS**

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

## SIGNATURES

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

### **EMERGENT BIOSOLUTIONS INC.**

By: /s/ Fuad El-Hibri  
Fuad El-Hibri  
Chief Executive Officer and  
Chairman of the Board of Directors  
(Principal Executive Officer)

Date: November 3, 2011

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

Date: November 3, 2011

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## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description</b>
10.1#	Construction Loan Agreement, dated July 28, 2011, among Emergent BioSolutions Inc., Emergent Manufacturing Operations Baltimore LLC and PNC Bank, National Association
10.2#	Promissory Note, dated July 28, 2011, from Emergent BioSolutions Inc. to PNC Bank, National Association
10.3#	Loan and Security Agreement, dated August 3, 2011, among Emergent Manufacturing Operations Baltimore LLC, Emergent BioSolutions Inc. and PNC Equipment Finance, LLC
10.4#	Modification No. 14 to Contract No. 200-2009-30162, dated September 29, 2011, between Emergent BioDefense Operations Lansing LLC, formerly known as Emergent BioDefense Operations Lansing Inc., and the Centers for Disease Control and Prevention
10.5#	Modification No. 12 to Contract No. HHS0100200700037C, dated August 24, 2011, between Emergent BioDefense Operations Lansing LLC, formerly known as Emergent BioDefense Operations Lansing Inc., and the Department of Health and Human Services
10.6#†	Notice of Award Letter, dated September 30, 2011, from the Centers for Disease Control and Prevention to Emergent BioDefense Operations Lansing LLC awarding Solicitation 2011-N-13414 for Acquiring Doses of Anthrax Vaccine Absorbed (AVA)
31.1#	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)
31.2#	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)
32.1#	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

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

- (i) Condensed Consolidated Statements of Income for the three and nine months ended September 30, 2011 and September 30, 2010, (ii) Condensed Consolidated Balance Sheets at September 30, 2011 and December 31, 2010, (iii) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2011 and September 30, 2010 and (iv) Notes to Consolidated Financial Statements.

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

# Filed herewith.

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

## Construction Loan Agreement

**THIS CONSTRUCTION LOAN AGREEMENT** is made as of the 29<sup>th</sup> day of July, 2011, by and between **EMERGENT BIOSOLUTIONS INC.**, a Delaware corporation (the “**Borrower**”), **EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC**, a Delaware limited liability company (“**Guarantor**”), and **PNC BANK, NATIONAL ASSOCIATION** (the “**Bank**”).

### RECITALS:

- A. The Borrower has requested that the Bank provide a construction loan to the Borrower in an aggregate amount not to exceed Thirty Million and No/100 Dollars (\$30,000,000.00) (the “**Loan**”). Each initially capitalized term used in these Recitals shall have the meaning set forth in Section 1.1.
- B. The Loan will be used by the Borrower to fund the cost of refinancing the acquisition loan and the construction on the Land of the Improvements in accordance with the Plans (the Land and the Improvements, together with any and all other improvements now or hereafter located or constructed on the Land are sometimes hereinafter referred to collectively as the “**Project**”).
- C. The Bank is willing to provide the Loan upon the terms and conditions hereinafter set forth.

**NOW, THEREFORE**, the parties hereto, in consideration of the mutual covenants and agreements hereinafter set forth and intending to be legally bound hereby, covenant and agree as follows:

### ARTICLE 1 - DEFINITIONS

**1.1. Definitions.** In addition to words and terms defined in the Recitals or elsewhere in this Agreement, the following terms shall have the meanings provided below:

“**Agreement**” means this Construction Loan Agreement, including all schedules and exhibits hereto, as the same may be amended, replaced or supplemented from time to time.

“**Assignment of Rents**” means that certain Assignment of Rents, Leases and Profits of even date herewith, given by Borrower to the Bank with respect to the Property, as the same may be amended, replaced or supplemented from time to time.

“**Closing Date**” means the date of this Agreement.

“**Completion Date**” means the earlier of July 28, 2012, or the date on which the Construction Consultant issues a certificate to the Bank stating that the Improvements have been completed in accordance with the Plans / the date on which an unconditional certificate of occupancy is issued for the Project.

“**Consolidated Group**” means the Borrower and all of its subsidiary and affiliate entities on a consolidated basis.

“**Construction Consultant**” means such person or entity as the Bank may designate from time to time to inspect construction of the Improvements and perform other services with respect thereto on behalf of the Bank.

“**Construction Contract**” means that certain construction contract dated as of September 15, 2010, between Guarantor and the Contractor, and all exhibits and attachments thereto, as the same may be amended from time to time with the Bank’s prior written consent.

“**Contractor**” means Whiting-Turner Contracting Company, Inc. or such other contractor as may be approved by the Bank, and shall include all subcontractors of Contractor as provided in the Construction Contract.

“**Deed of Trust**” means the Indemnity Deed of Trust, Assignment and Security Agreement given by Guarantor to the Bank and securing the Note, as the same may be amended, replaced or supplemented from time to time.

“**Development Documents**” means the Construction Contract, the Plans, all consents, licenses, permits, authorizations and approvals relating to the construction, completion, management, use and occupancy of the Improvements and all other instruments, documents and rights required or in any way relating to the design, construction, renovation, use, occupancy or ownership of the Improvements, whether now existing or hereafter arising, which Development Documents have been assigned to the Bank as security for the Loan pursuant to Article 8 hereof.

“**Equity Contribution**” means the Borrower’s contribution of not less than Ten Million and No/100 Dollars (\$10,000,000.00) towards the cost of the Project.

“**Guaranty**” means that certain Guaranty and Suretyship Agreement (Payment and Completion) given by the Guarantor to the Bank, as the same may be amended, replaced, or supplemented from time to time.

“**Improvements**” means the manufacturing facility and related improvements to be constructed on the Land in accordance with the Plans.

“**Land**” means that certain legally subdivided parcel or parcels of land located in the City of Baltimore, Maryland, as more particularly described on **Exhibit A** to the Deed of Trust.

“**Loan**” means the loan to be made by the Bank pursuant to this Agreement, as evidenced by the Note.

“**Loan Documents**” means this Agreement, the Note, the Deed of Trust, the Assignment of Rents, the Guaranty and all other indemnification agreements, documents, instruments, certificates and agreements now or hereafter executed in connection with the Loan, as the same may be amended, replaced, or supplemented from time to time.

“**Note**” means the promissory note of the Borrower payable to the order of the Bank, as the same may be amended, renewed, replaced, or supplemented from time to time.

“**Plans**” means the plans and specifications for the Improvements prepared by the Borrower, as the same may be amended in accordance with this Agreement.

“**Project Budget**” means the project budget attached as **Exhibit A** hereto, as the same may be amended in accordance with this Agreement.

“**Project Costs**” shall mean the total costs to complete the Improvements, as described in the Project Budget attached as **Exhibit A** hereto (without amendment or revision).

“**Property**” shall have the meaning ascribed to such term in the Deed of Trust.

## **ARTICLE 2 - LOAN; LOAN DOCUMENTS**

**2.1. Loan.** Subject to the terms and conditions hereinafter set forth, the Bank agrees to make the Loan to the Borrower. The Bank and the Borrower acknowledge and agree that the Bank will disburse the proceeds of the Loan only for the payment of or reimbursement for the actual costs, fees and expenses incurred by the Borrower or the Guarantor in connection with (a) the refinancing of the acquisition of the Land, (b) the construction and development of the Improvements as herein set forth, and (c) Loan closing costs and fees, as shown on the Project Budget, with all such disbursements to be made in accordance with the terms and subject to the conditions set forth in this Agreement.

**2.2. Operating Account; Disbursements.** The Borrower will maintain with the Bank throughout the term of the Loan a commercial operating account. The Borrower hereby authorizes the Bank to make disbursements of Loan proceeds by the Bank’s crediting of such disbursements directly into such account, and the Borrower agrees that such disbursements shall constitute an advance under the Note. The Borrower agrees to pay all normal and customary charges of the Bank for maintaining such account.

**2.3. Loan Fee.** The Borrower will pay to the Bank a non-refundable construction loan fee (the “**Loan Fee**”) in the amount of forty (40) basis points (0.40%) of the total aggregate amount drawn under the Loan and the equipment loan made to the Borrower by PNC Equipment Finance, LLC on or about the date hereof. Eighty Four Thousand Dollars (\$84,000.00) of the Loan Fee will be paid to the Bank on or before Closing, and the remainder of the Loan Fee will be paid to the Bank on or before the Completion Date.

## **ARTICLE 3 - REPRESENTATIONS AND WARRANTIES**

Each of the Borrower and the Guarantor hereby represents and warrants to the Bank as follows, which representations and warranties shall be automatically recertified to the Bank with each disbursement request:

**3.1. Existence, Power and Authority.** Each of the Borrower and the Guarantor is duly organized or incorporated, validly existing and in good standing under the laws of the State of its incorporation or organization and has the power and authority to own and operate its assets and to conduct its business as now or proposed to be carried on, and is duly qualified, licensed and in good standing to do business in all jurisdictions where its ownership of property or the nature of its business requires such qualification or licensing. Each of the Borrower and the Guarantor is duly authorized to execute and deliver the Loan Documents executed by it, all necessary action to authorize the execution and delivery of the Loan Documents has been properly taken, and each of the Borrower and the Guarantor is and will continue to be duly authorized to borrow under this Agreement and to perform all of the other terms and provisions of the Loan Documents.

**3.2. Financial Statements.** The Borrower and the Guarantor (on a consolidated basis) have provided or caused to be provided to the Bank its most recent balance sheet, income statement and statement of cash flows (to the extent available) (the “**Historical Financial Statements**”). The Historical Financial Statements are true, complete and accurate in all material respects and fairly present the financial condition, assets and liabilities, whether accrued, absolute, contingent or otherwise and the results of the Borrower’s and the Guarantor’s operations for the period specified therein. The Historical Financial Statements have been prepared in accordance with generally accepted accounting principles consistently applied from period to period subject in the case of interim statements to normal year-end adjustments and to any comments and notes acceptable to the Bank in its sole discretion.

**3.3. No Material Adverse Change.** Except as disclosed on **Exhibit B** attached hereto, since the date of the most recent Historical Financial Statements, neither the Borrower nor the Guarantor has suffered any damage, destruction or loss, and no event or condition has occurred or exists, which has resulted or could result in a material adverse change in its business, assets, operations, condition (financial or otherwise) or results of operation.

**3.4. Binding Obligations.** Each of the Borrower and the Guarantor has full power and authority to enter into the transactions provided for in this Agreement and has been duly authorized to do so by appropriate action of its Board of Directors with respect to the Borrower or of its sole member with regard to the Guarantor, or otherwise as may be required by law, charter, other organizational documents or agreements; and the Loan Documents, when executed and delivered by the Borrower and the Guarantor, will constitute the legal, valid and binding obligations of the Borrower and of the Guarantor enforceable in accordance with their terms.

**3.5. No Defaults or Violations.** There does not exist any Event of Default under this Agreement or any material default or violation by the Borrower or the Guarantor of or under any of the terms, conditions or obligations of: (a) its articles or certificate of incorporation, regulations or bylaws if the Borrower or the Guarantor is a corporation or its other organizational documents as applicable; (b) any indenture, mortgage, deed of trust, franchise, permit, material contract, material agreement, or other instrument to which it is a party or by which it is bound; or (c) any law, ordinance, regulation, ruling, order, injunction, decree, condition or other requirement applicable to or imposed upon it by any law, the action of any court or any governmental authority or agency; and the consummation of this Agreement and the transactions set forth herein will not result in any such default or violation or Event of Default.

**3.6. Litigation.** Except as disclosed in the Borrower’s quarterly report filed with the Securities and Exchange Commission on May 6, 2011, there are no actions, suits, proceedings or governmental investigations pending or, to the knowledge of the Borrower or the Guarantor, threatened against the Borrower or the Guarantor, which could result in a material adverse change in its business, assets, operations, condition (financial or otherwise) or results of operations and there is no basis known to the Borrower or the Guarantor for any action, suit, proceeding or investigation which could result in such a material adverse change.

**3.7. Title; Subdivision; Access.** The Guarantor has clear and marketable fee simple title to the Property, free, clear and unencumbered, of record and in fact, except for and subject only to those matters permitted by the terms of the Deed of Trust. The Guarantor has been granted all easements appropriate for construction of the Improvements. The Land is a separately subdivided parcel or parcels under applicable laws regulating subdivision and land development. All streets necessary for the full utilization of the Land have been completed, and the Land has direct, unfettered access to sewer right-of-ways.

**3.8. Utilities.** All utility services necessary for the construction of the Improvements and the use and operation thereof for their intended purposes, including water, storm and sanitary sewer facilities, electric, gas, and telephone, are available at the boundaries of the Land and shall, by the Completion Date, be installed and operating.

**3.9. Information.** The Guarantor has delivered to the Bank a true and correct copy of the Development Documents and any certificates, consents, amendments, waivers and other documents executed in relation therewith, and there have been no other amendments, waivers or modifications thereof. All

surveys, plat plans and similar documents furnished by the Guarantor to the Bank are accurate and complete in all material respects as of their respective dates.

**3.10. Zoning and Governmental Approvals.** The development, construction, use and occupancy of the Improvements in accordance with the Plans will conform to all applicable laws, all existing governmental approvals and all covenants, conditions and restrictions contained in a deed, lease or other instrument or agreement covering or affecting all or any portion of the Project. All governmental approvals (except to the extent the same are of a nature so as not to be obtainable until a later stage of construction or completion of the Improvements) have been obtained and are valid and in full force and effect, including approval of the Plans.

**3.11. Contracts.** There are no contracts affecting or relating to the management or operation of the Project that have a material impact on such management or operation except the Construction Contract and any other Development Documents heretofore delivered to the Bank.

**3.12. Regulatory Matters.** No part of the proceeds of the Loan will be used for "purchasing" or "carrying" any "margin stock" within the respective meanings of each of the quoted terms under Regulation U of the Board of Governors of the Federal Reserve System as now and from time to time in effect or for any purpose which violates the provisions of the Regulations of such Board of Governors.

**3.13. Solvency.** As of the date hereof and after giving effect to the transactions contemplated by the Loan Documents, (i) the aggregate value of the Consolidated Group's assets will exceed its liabilities (including contingent, subordinated, unmatured and unliquidated liabilities), (ii) the Consolidated Group will have sufficient cash flow to enable it to pay its debts as they become due, and (iii) the Consolidated Group will not have unreasonably small capital for the business in which it is engaged.

**3.14. Disclosure.** None of the Loan Documents contains or will contain any untrue statement of material fact or omits or will omit to state a material fact necessary in order to make the statements contained in this Agreement or the Loan Documents not misleading.

#### **ARTICLE 4 - AFFIRMATIVE COVENANTS OF BORROWER**

The Borrower and the Guarantor covenant and agree that until the Loan is paid in full, the Borrower and the Guarantor shall:

**4.1. Use of Proceeds.** Use the proceeds of the Loan only for the purposes provided for in Section 2.1 hereof.

**4.2. Construction.** Cause the ongoing construction of the Improvements to be carried forward with diligence and continuity for completion by the Completion Date. The Borrower and the Guarantor shall cause the Improvements to be constructed in accordance with the Plans and all applicable zoning, building, and other laws, statutes, codes, ordinances, rules and regulations, and all applicable agreements, covenants and restrictions and utilize only the Contractor to complete the Improvements.

**4.3. Books and Records.** Make available for inspection by a duly authorized representative of the Bank any of the Borrower's or the Guarantor's books and records insofar as they relate to the Project at such times as may be reasonably requested by the Bank; and furnish to the Bank, upon reasonable notice to the Borrower by the Bank, such information regarding its business affairs and financial condition as the Bank may reasonably request.

**4.4. Reimbursement.** Reimburse the Bank promptly for all costs and expenses paid or incurred by the Bank in connection with the Loan, including the cost of title insurance premiums, charges and update fees, reasonable fees and expenses of the Bank's attorneys, survey costs, appraisal costs, flood search costs, environmental consultant fees, all reasonable costs and expenses of the Construction Consultant whether incurred prior to or during construction, lending fees, recording fees and taxes and all other expenses paid in connection with the preparation, closing and administration of the Loan.

**4.5. Compliance with Covenants, Agreements and Laws.** Comply with all applicable laws, covenants and restrictions now of record affecting all or any part of the Property. The Borrower and the Guarantor shall comply with the Development Documents and all other material obligations under other contracts, instruments and agreements to which it is a party or to which any of its properties or assets may be subject.

**4.6. Insurance.** Obtain and keep in full force and effect such insurance as may be required by the Bank from time to time as set forth in the Deed of Trust.

**4.7. Financial Requirements.** Comply with the financial covenants set forth on **Exhibit C** attached hereto and made a part hereof, and shall furnish or cause to be furnished to the Bank such other information as the Bank may reasonably request from time to time.

**4.8. Appraisal.** Reimburse the Bank promptly for all costs and expenses paid or incurred by the Bank in connection with an MAI appraisal of the Property prepared by an MAI appraiser engaged by the Bank, which shall state a fair market value of the Property after completion of the Improvements and be acceptable in form and substance to the Bank. A copy of the appraisal will be shared with the Borrower.

#### **ARTICLE 5 - NEGATIVE COVENANTS OF BORROWER**

The Borrower covenants and agrees that until the Loan is paid in full, the Borrower shall not:

**5.1. Changes; Modifications of Contracts.** To the extent that such action would cause any material change in the total amount of the Project Budget, cause any change in the Plans, modify the terms and conditions of the Construction Contract, modify the terms and conditions of any subcontract or material order or any other contract delivered to and approved by the Bank and relating to the design, operation, use, construction or management of the Improvements, or in the identity of the Contractor without the Bank's prior written consent, which consent shall not be unreasonably withheld.

**5.2. Ownership of Materials and Personal Property.** Without the Bank's prior written consent, which consent shall not be unreasonably withheld, and excluding any government furnished equipment provided to the Borrower or the Guarantor for use at the Property, cause any materials, equipment, personal property or fixtures of any kind to be purchased or acquired for installation or use in or about the Improvements under any conditional sales contract or security agreement or lease agreement. Any such materials, equipment, personal property or fixtures of any kind purchased or acquired for installation or use in or about the Improvements shall be the property of the Borrower or the Guarantor, and shall not be subject to any liens other than those in favor of PNC Equipment Finance, LLC.

**5.3. Publicity.** Erect any sign on the Property or engage in other publicity regarding the financing provided by the Bank without the Bank's prior written approval. Promptly after request by the Bank, the Borrower will erect on the Property up to two (2) financing signs provided by the Borrower to the specifications and satisfaction of the Bank and the Borrower.

**5.4. Transfer of Interests.** Permit the sole member of the Guarantor to sell, assign, give, mortgage, pledge, encumber or otherwise transfer any interest in the Guarantor, without the Bank's prior written consent. The Borrower will not liquidate, merge or consolidate with any person, firm, corporation or other entity, or sell, lease, transfer or otherwise dispose of a material portion of its operating property or assets, whether now owned or hereafter acquired; provided, however, that the foregoing restrictions do not apply to any merger or consolidation where the following conditions are satisfied:

(a) the Borrower or an entity controlled by the Borrower shall be the continuing or surviving entity of such merger or consolidation;

(b) such merger or consolidation shall be non-hostile;

(c) the person, firm, corporation or other entity with which the Borrower will merge or consolidate shall conduct, or have conducted within the last three (3) years, lines of business that are substantially similar or complementary to one or more of the principal businesses of the Borrower in the ordinary course;

(d) such merger or consolidation shall not include or result in any contingent liabilities (other than contingent value rights or similar contingent liabilities dependent upon the success of the business of Borrower's merger or consolidation partner) that could reasonably be expected to have a material adverse effect upon the business, financial condition, operations or prospects of the Borrower, taken as a whole (as reasonably determined in good faith by the Bank);

(e) (i) immediately before and immediately after giving pro forma effect to any such merger or consolidation (including all indebtedness to be incurred in connection therewith), no Event of Default shall have occurred and be continuing and (ii) immediately after giving effect to such merger or consolidation, the Consolidated Group shall be in pro forma compliance with all of the covenants set forth on **Exhibit C**, such compliance to be determined on the basis of the financial information most recently delivered to the Bank as though such merger or consolidation had been consummated as of the first day of the fiscal period covered thereby; and

(f) the Borrower shall have delivered to the Bank, at least five (5) business days prior to the date on which any such merger or consolidation is to be consummated, a certificate of an officer of the Borrower, in form and substance reasonably satisfactory to the Bank, certifying that all of the requirements set forth in this Section 5.4 have been satisfied or will be satisfied on or prior to the consummation of such merger or consolidation.

## **ARTICLE 6 - CONDITIONS FOR DISBURSEMENTS**

**6.1. Conditions for Closing and First Disbursement.** The Bank shall not be obligated to make the first disbursement of the Loan until the Borrower at its expense shall have fulfilled, to the Bank's satisfaction, all provisions of this Agreement applicable thereto and shall have delivered all items set forth on **Exhibit F** attached hereto and the following conditions have been met:

(a) **Transaction Documents.** The Loan Documents and the Development Documents shall have been duly executed and, where applicable, delivered to the Bank. The Deed of Trust and other documents to be placed of record or filed shall have been duly executed and recorded and filed in all appropriate offices and shall constitute a first and prior lien on the Project, subject only to matters approved by the Bank as set forth in the Deed of Trust.

(b) **Inspection Report.** If required by Bank, the Construction Consultant shall have delivered a favorable report as to the detail set forth in the Plans, the quality of construction called for by the Plans and the adequacy of the Construction Contract to provide for completion of the Improvements in accordance with the Plans and as to such other matters as the Bank may request.

(c) **Loan Fee, Costs and Expenses.** The portion of the Loan Fee payable on the Closing Date and all reimbursable costs and expenses pursuant to the Loan Documents shall have been paid.

(d) **No Damage or Taking.** No portion of the Improvements shall have been damaged by fire or other casualty and no condemnation or taking of the Property or the Improvements or any portion thereof shall be pending or threatened.

(e) **License and Permits.** All licenses, permits, consents, approvals and authorizations for the construction of the Improvements shall be in full force and effect and no notices of violation or revocation with respect thereto shall have been received.

(f) **No Default.** No Event of Default shall have occurred and be continuing hereunder or under any of the other Loan Documents.

**6.2. Subsequent Disbursements.** The Bank shall not be obligated to make future disbursements on the Loan (including the final disbursement referred to in Section 6.3) unless the Borrower shall have fulfilled the following conditions:

(a) **Preceding Conditions.** All applicable conditions of the preceding Section 6.1 shall continue to be met.

(b) **Title Policy Endorsement.** The Bank shall have received an endorsement to the title insurance policy (i) indicating that since the last preceding disbursement of the Loan there has been no change in the state of title and no survey exceptions not theretofore approved by the Bank, (ii) increasing the coverage of the policy by an amount equal to the disbursement then being made, so that the total amount insured equals the total amount of the Loan disbursed by the Bank, and (iii) changing the effective date of the policy to the date of disbursement.

**6.3. Final Disbursement.** The Bank shall make the final disbursement of Loan proceeds only upon a fulfillment of the following conditions:

(a) **Preceding Conditions.** All applicable conditions of Section 6.1 and 6.2 shall continue to be met.

(b) **Title Policy Endorsement.** The Bank shall have received an endorsement to the title insurance policy in a form approved by the Bank, insuring that no encroachments exist over any building, zoning, right-of-way or property boundary lines.

(c) **Final Lien Releases.** The Bank shall have received final lien releases from the Contractor and all subcontractors with respect to the work performed in connection with the construction and equipping of the Improvements.

(d) **Miscellaneous.** The Borrower and the Guarantor shall provide the Bank with such other information and documentation reasonably requested by the Bank.

**6.4. Other Conditions and Procedure for Disbursements.** Subject to the terms and conditions hereof, the Bank shall undertake to disburse the proceeds of the Loan from time to time for payment of construction costs of the Improvements and other development costs, all as described in the Project Budget, as such construction is completed and as the other development costs are incurred as the Bank or its Construction Consultant shall determine. The Bank's obligation to make any such disbursement is conditioned upon a request of the Borrower, delivery by the Borrower and the Guarantor and approval by the Bank of the items required pursuant to Sections 6.1, 6.2, and 6.3, satisfaction of all other conditions to disbursements set forth herein, delivery of the items specified below and the performance by each of the Borrower and the Guarantor of all of its covenants, agreements and obligations under this Agreement and the other Loan Documents.

(a) **Requisition.** At closing or at least ten (10) business days prior to the date on which the Borrower desires a disbursement, the Borrower shall submit to the Bank (i) a Request for Disbursement in the form of **Exhibit D** hereto, signed by the Borrower, together with copies of invoices for all costs and expenses reflected in the Request for Disbursement, (ii) a Project Budget showing the total project costs to date, and the allocation of the

Equity Contribution and the balance of each category of construction costs; and (iii) copies of invoices for indirect construction costs, the accuracy of which may at the Bank's option be certified by the Construction Consultant, and such other information and documentation required hereunder. With the exception of closing, the Bank shall not be required to disburse funds until ten (10) days after the last required item is received. The Bank shall not be required to disburse funds for any amounts in excess of one hundred percent (100%) of the amount of the acquisition loan refinanced by the Loan up to a maximum of \$6,300,000, plus seventy-five percent (75%) of Project Costs incurred.

(b) **Timing.** Requests for disbursements shall not be made more often than once a month. Prior to disbursement of any Loan proceeds for any line item shown on the Project Budget, the Borrower shall have expended, for costs approved by the Bank, sums at least equal to the Equity Contribution, if any for such line item. Prior to each disbursement, at the Borrower's expense, the Bank may request that the Construction Consultant inspect the Improvements to verify the accuracy of all other reports, requests or documents submitted by the Borrower.

(c) **Lien Waivers.** If requested by the Bank, the Borrower and the Guarantor shall furnish the Bank with a schedule from the Borrower in the form of **Exhibit E** hereto identifying all contractors or subcontractors who have performed work or furnished materials in connection with the Improvements, together with lien waivers from the Contractor and all subcontractors who have performed work or furnished materials in connection with the Improvements, current through the period covered by such request for funds.

(d) **Limitation on Disbursements.** Anything contained in this Agreement to the contrary notwithstanding, it is expressly understood and agreed that the Bank shall not fund any amounts in excess of one hundred percent (100%) of the amount of the acquisition loan refinanced by the Loan up to a maximum of \$6,300,000, plus seventy-five percent (75%) of Project Costs incurred. If the Bank or the Construction Consultant determine in its sole discretion that the Bank has funded more than one hundred percent (100%) of the amount of the acquisition loan refinanced by the Loan up to a maximum of \$6,300,000, plus seventy-five percent (75%) of Project Costs incurred, the Borrower shall, within ten (10) days after written request by the Bank, deposit the amount by which the total aggregate amount of all previous disbursements exceeds one hundred percent (100%) of the amount of the acquisition loan refinanced by the Loan up to a maximum of \$6,300,000, plus seventy-five percent (75%) of Project Costs incurred with the Bank, which deposit shall first be exhausted before any further disbursement of the Loan proceeds is made. The Bank shall not be obligated to make any Loan disbursements in excess of one hundred percent (100%) of the amount of the acquisition loan refinanced by the Loan up to a maximum of \$6,300,000, plus seventy-five percent (75%) of Project Costs. Whenever the Bank has any such deficiency funds on deposit, such funds, together with any interest thereon, shall be additional security for the Loan and the Borrower hereby grants the Bank a security interest in such funds.

(e) **Material Damage.** Notwithstanding any provision of this Agreement to the contrary, if the Property shall have suffered any material damage or destruction prior to any disbursement, such damaged or destroyed portion shall be restored or replaced in a manner acceptable to the Bank without cost to the Bank prior to any further disbursement from the Bank.

(f) **Mechanics' Liens.** In the event of the filing of any mechanics' or materialmen's lien, the Borrower and the Guarantor shall within ten (10) days after the filing thereof, or if earlier, prior to the next disbursement of Loan proceeds, cause such lien to be removed by bonding or otherwise, or insured over by the title company to the Bank's satisfaction.

(g) **Other Disbursement Contingencies.** The Bank shall not be obligated to make any disbursement hereunder or to take any action hereunder or under the Loan Documents if, on the date of a proposed disbursement or the date of a proposed action, (i) the Borrower is in default of its obligations hereunder or under any of the Loan Documents, or an event has occurred which with the passage of time or the giving of notice or both would constitute an Event of Default hereunder or thereunder, or (ii) any representation or warranty made by the Borrower herein or in any of the other Loan Documents proves to be untrue in any material respect.

(h) **Payment.** The Bank may, at its option, make disbursements (i) to the operating account of the Borrower opened with the Bank, or (ii) directly to persons furnishing labor or material to the Project.

(i) **Access to Property; Right to Stop Work; Correction of Defective Work.** Guarantor will allow the Bank, through the Construction Consultant and the Bank's officers, agents, or employees, at all reasonable times and upon reasonable notice, the right of entry and access to the Property (subject to Guarantor's reasonable safety policies and procedures) and the right to inspect all work done, labor performed and materials furnished or to be furnished in furtherance of the Improvements. If the Bank determines that any work or material does not comply with the Plans or sound building practice or otherwise departs from the requirements of this Agreement or the Construction Contract, then the Bank may require the work to be stopped and may withhold disbursements until the matter is corrected to the Bank's satisfaction. The Bank shall also have the right to require that the work be stopped upon the occurrence of an Event of Default or event which with notice, the lapse of time or both would constitute an Event of Default. If the Project shall require, in the Bank's reasonable judgment, the written consent of any person or entity as to any aspect of the construction of the Improvements, the Bank may require the work to be stopped and may withhold further disbursements of the Loan until all such written consents, in writing shall have been delivered to the Bank. The Borrower and the Guarantor shall promptly correct any non-conforming work or materials. Unless otherwise agreed by the Bank, the Borrower and the Guarantor, no such action by the Bank will affect the Borrower's and the Guarantor's obligation to complete the Improvements on or before the Completion Date. The Bank shall be under no duty to examine, supervise or inspect the Plans or the construction of the Improvements. Any inspection or examination by the Bank or the Construction Consultant is for the sole purpose of protecting the Bank's liens and security interests and preserving its rights hereunder. No default or breach of the Borrower or Guarantor will be waived by any inspection by the Bank, nor shall any such inspections constitute a representation that there has been or will be compliance with the Plans or that the construction is free from defective materials or workmanship. The Construction Consultant's services are for the sole benefit of the Bank and the Bank shall not be liable in any manner for the results of such inspection.

(j) **Indemnification.** The Borrower hereby agrees to defend, indemnify, protect and hold harmless the Bank and its affiliates, directors, officers, employees, agents, successors and assigns, from and against any and all claims, losses, damages, liabilities, costs and expenses (including reasonable attorney's fees and claims arising out of the loss of life, injury to persons, property or business) in connection with any construction, demolition or renovation activities of the Borrower or the Guarantor, including the construction of the Improvements, the making of the Loan pursuant to the terms and conditions of this Agreement or the Loan Documents, except to the extent that the foregoing claims, losses, damages, liabilities, costs and expenses arise from the gross negligence or intentional misconduct of the Bank and its affiliates, directors, officers, employees, agents, successors or assigns.

## **ARTICLE 7 - DEFAULTS AND REMEDIES**

**7.1. Events of Default.** The occurrence of one or more of the following events shall constitute an Event of Default hereunder:

(a) The Borrower or the Guarantor shall fail to comply with any covenant contained in this Agreement or any of the other Loan Documents which calls for the payment of money within seven (7) days after such payment is due.

(b) If the construction of the Improvements is not carried on with reasonable dispatch in accordance with the Plans in the Bank's reasonable judgment, or if construction of the Improvements is abandoned for twenty (20) consecutive days or is not substantially completed in all material respects on or prior to the Completion Date.

(c) If the Borrower or the Guarantor fails to keep, observe or perform any of the other material undertakings, conditions, stipulations, agreements, covenants or obligations of the Borrower or the Guarantor as set forth in this Agreement, which do not have a specified grace or cure period, and

continuance of such failure for twenty (20) days after the earlier of written notice from the Bank to the Borrower or the Borrower has knowledge that such failure has occurred.

(d) If any of the representations or warranties made by the Borrower or the Guarantor under this Agreement or under any of the other Loan Documents shall be untrue in any material respect when made.

(e) If any Event of Default or General Default (after the lapse of the applicable cure period) shall occur under any of the Loan Documents or under any other instruments relating thereto delivered by the Borrower or the Guarantor to the Bank under this Agreement.

Notwithstanding the foregoing, if any default or failure to observe or perform any covenant or other agreement hereunder or under the Loan Documents occurs (a "**General Default**"), such General Default is curable, and no specific cure period otherwise applies to such General Default, the General Default may be cured if the Borrower, after receiving written notice from the Bank demanding cure of such General Default cures the General Default within twenty (20) days.

**7.2. Remedies.** Upon the occurrence of any one or more of the Events of Default, at the Bank's option and following the lapse or expiration of any applicable cure period, all obligations on the Bank's part to make the Loan, or to make any further disbursements hereunder shall cease and terminate, and the Loan and all sums then or thereafter due under any and all of the Loan Documents shall thereupon become immediately due and payable. Upon the occurrence of an Event of Default, the Bank may enforce any or all of its rights hereunder or under any other Loan Documents, or at law or in equity, and in addition, the Bank, at its option, may apply any or all funds not previously disbursed to the payment of outstanding invoices and to the completion of the Improvements, with the right and power in such event to enter upon and take possession of the Property, to make such changes in the Plans or the Development Documents as may seem desirable, and to do all things reasonably necessary in the Bank's opinion to complete or partially complete the Improvements. The Borrower irrevocably appoints the Bank as its attorney-in-fact, with full power of substitution, to complete the Improvements in the Borrower's name or the Guarantor's name or the Bank may elect to complete construction in the Bank's name.

## **ARTICLE 8 - MISCELLANEOUS**

**8.1. Notices.** All notices, demands, requests, consents, approvals and other communications required or permitted hereunder (the "**Notices**") must be in writing and will be effective upon receipt. Notices may be given in any manner to which the parties may separately agree, including electronic mail. Without limiting the foregoing, first-class mail, facsimile transmission and commercial courier service are hereby agreed to as acceptable methods for giving the Notices. Regardless of the manner in which provided, the Notices may be sent to a party's address set forth below or to such other address as any party may give to the other for such purpose in accordance with this Section:

**To the Bank:** PNC Bank, National Association  
800 17th Street, N.W.  
Washington, DC 20006  
Attention: Douglas T. Brown, Senior Vice President Corporate Banking - Government Contracting  
Facsimile No.: (202) 835-5977  
Telephone No.: (202) 835-4992

**To the Borrower and the Guarantor:** Emergent BioSolutions Inc.  
Emergent Manufacturing Operations Baltimore LLC  
2273 Research Boulevard, Suite 400  
Rockville, Maryland 20850  
Attention: General Counsel  
Facsimile No.: (301) 795-1899  
Telephone No.: (301) 795-1800

**8.2. Preservation of Rights.** No delay or omission on the Bank's part to exercise any right or power arising hereunder will impair any such right or power or be considered a waiver of any such right or power, nor will the Bank's action or inaction impair any such right or power. The Bank's rights and remedies hereunder are cumulative and not exclusive of any other rights or remedies which the Bank may have under other agreements, at law or in equity.

**8.3. Illegality.** If any provision contained in this Agreement should be invalid, illegal or unenforceable in any respect, it shall not affect or impair the validity, legality and enforceability of the remaining provisions of this Agreement.

**8.4. Changes in Writing.** No modification, amendment or waiver of, or consent to any departure by the Borrower or the Guarantor from, any provision of this Agreement will be effective unless made in a writing signed by the Bank, and then such waiver or consent shall be effective only in the specific instance and for the purpose for which given. No notice to or demand on the Borrower or the Guarantor will entitle the Borrower or the Guarantor to any other or further notice or demand in the same, similar or other circumstance.

**8.5. Entire Agreement.** This Agreement (including the documents and instruments referred to herein) constitutes the entire agreement and supersedes all other prior agreements and understandings, both written and oral, between the parties with respect to the subject matter hereof.

**8.6. Counterparts.** This Agreement may be signed in any number of counterpart copies and by the parties hereto on separate counterparts, but all such copies shall constitute one and the same instrument. Delivery of an executed counterpart of a signature page to this Agreement by facsimile transmission shall be effective as delivery of a manually executed counterpart. Any party so executing this Agreement by facsimile transmission shall promptly deliver a manually executed counterpart, provided that any failure to do so shall not affect the validity of the counterpart executed by facsimile transmission.

**8.7. Successors and Assigns.** This Agreement will be binding upon and inure to the benefit of the Borrower and the Guarantor and the Bank and their respective heirs, executors, administrators, successors and assigns; provided, however, that the Borrower and the Guarantor may not assign this Agreement in whole or in part without the Bank's prior written consent and the Bank at any time may assign this Agreement in whole or in part.

**8.8. Interpretation.** In this Agreement, unless the Bank, the Borrower and the Guarantor otherwise agree in writing, the singular includes the plural and the plural the singular; words importing any gender include the other genders; references to statutes are to be construed as including all statutory provisions consolidating, amending or replacing the statute referred to; the word "or" shall be deemed to include "and/or", the words "including", "includes" and "include" shall be deemed to be followed by the words "without limitation" references to articles, sections (or subdivisions of sections) or exhibits are to those of this Agreement unless otherwise indicated; and references to agreements and other contractual instruments shall be deemed to include all subsequent amendments and other modifications to such instruments, but only to the extent such amendments and other modifications are not prohibited by the terms of this Agreement. Section headings in this Agreement are included for convenience of reference only and shall not constitute a part of this Agreement for any other purpose. Unless otherwise specified in this Agreement, all accounting terms shall be interpreted and all accounting determinations shall be made in accordance with GAAP. If this Agreement is executed by more than one party as the Borrower or the Guarantor, the obligations of such persons or entities will be joint and several.

**8.9. Certain Waivers.** The Borrower and the Guarantor hereby relieve and discharge the Bank from any and all liability and responsibility whatsoever arising out of the disbursement of Loan proceeds hereunder and agrees and acknowledges that the Bank does not assume any responsibility whatsoever for the method of disbursement, the application or use of Loan proceeds disbursed hereunder or as to any liens or claims whatsoever which might attach to or be filed against the Property.

**8.10. Indemnity.** The Borrower and the Guarantor agree to indemnify each of the Bank, each legal entity, if any, who controls the Bank and each of their respective directors, officers and employees (the “**Indemnified Parties**”), and to hold each Indemnified Party harmless from and against, any and all claims, damages, losses, liabilities and expenses (including all reasonable fees and charges of internal or external counsel with whom any Indemnified Party may consult and all third party expenses of litigation and preparation therefor) which any Indemnified Party may incur, or which may be asserted against any Indemnified Party by any person, entity or governmental authority (including any person or entity claiming derivatively on behalf of the Borrower or the Guarantor), in connection with or arising out of or relating to the matters referred to in this Agreement or in the other Loan Documents or the use of the proceeds of the Loan, whether (a) arising from or incurred in connection with any breach of a representation, warranty or covenant by the Borrower or the Guarantor, or (b) arising out of or resulting from any suit, action, claim, proceeding or governmental investigation, pending or threatened, whether based on statute, regulation or order, or tort, or contract or otherwise, before any court or governmental authority; provided, however, that the foregoing indemnity agreement shall not apply to any claims, damages, losses, liabilities and expenses solely attributable to an Indemnified Party’s gross negligence, willful misconduct or material breach of this Agreement. The indemnity agreement contained in this Section shall survive the termination of this Agreement, payment of any Loan and assignment of any rights hereunder. The Borrower and the Guarantor may participate at their expense in the defense of any such action or claim, and the Bank shall not stipulate to or enter into any judgment that results in an admission of fault by the Borrower or the Guarantor without the Borrower’s express written consent.

**8.11. Assignments and Participations.** At any time, without any notice to the Borrower or the Guarantor, the Bank may sell, assign, transfer, negotiate, grant participations in, or otherwise dispose of all or any part of the Bank’s interest in the Loan. The Borrower and the Guarantor hereby authorize the Bank to provide, without any notice to the Borrower and the Guarantor, any information concerning the Borrower and the Guarantor, including information pertaining to the Borrower’s and the Guarantor’s financial condition, business operations or general creditworthiness, to any person or entity which may succeed to or participate in all or any part of the Bank’s interest in the Loan.

**8.12. Governing Law and Jurisdiction.** This Agreement has been delivered to and accepted by the Bank and will be deemed to be made in the State of Maryland. **THIS AGREEMENT WILL BE INTERPRETED AND THE RIGHTS AND LIABILITIES OF THE PARTIES HERETO DETERMINED IN ACCORDANCE WITH THE LAWS OF THE STATE OF MARYLAND, EXCLUDING ITS CONFLICT OF LAWS RULES.** The Borrower and the Guarantor hereby irrevocably consent to the exclusive jurisdiction of any state or federal court in any county or judicial district in the State of Maryland; provided that nothing contained in this Agreement will prevent the Bank from bringing any action, enforcing any award or judgment or exercising any rights against the Borrower individually, against any security or against any property of the Borrower or the Guarantor within any other county, state or other foreign or domestic jurisdiction. The Bank, the Borrower and the Guarantor agree that the venue provided above is the most convenient forum for the Bank, the Borrower and the Guarantor. The Borrower and the Guarantor waive any objection to venue and any objection based on a more convenient forum in any action instituted under this Agreement.

**8.13. WAIVER OF JURY TRIAL. EACH OF THE BORROWER, THE GUARANTOR AND THE BANK IRREVOCABLY WAIVE ANY AND ALL RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY ACTION, PROCEEDING OR CLAIM OF ANY NATURE RELATING TO THIS AGREEMENT, ANY DOCUMENTS EXECUTED IN CONNECTION WITH THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED IN ANY OF SUCH DOCUMENTS. EACH OF THE BORROWER, THE GUARANTOR AND THE BANK ACKNOWLEDGE THAT THE FOREGOING WAIVER IS KNOWING AND VOLUNTARY.**

The Borrower and the Guarantor each acknowledge that it has read and understood all the provisions of this Agreement, including the waiver of jury trial, and has been advised by counsel as necessary or appropriate.

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WITNESS the due execution hereof as a document under seal, as of the date first written above.

**BORROWER:**

WITNESS / ATTEST:

EMERGENT BIOSOLUTIONS INC.

/s/ Lisa Richardson  
Print Name: Lisa Richardson  
Title: Senior Director, Treasury  
(Include title only if an officer of entity signing to the right)

By: /s/ R. Don Elsey (SEAL)  
Print name: R. D. Elsey  
Title: CFO

**GUARANTOR:**

WITNESS / ATTEST:  
OPERATIONS BALTIMORE LLC

EMERGENT MANUFACTURING

/s/ Lisa Richardson  
Print Name: Lisa Richardson  
Title: Senior Director, Treasury  
(Include title only if an officer of entity signing to the right)

By: /s/ R. Don Elsey (SEAL)  
Print Name: R. D. Elsey  
Title: CFO

**BANK:**

PNC BANK, NATIONAL ASSOCIATION

By: /s/ Douglas T. Brown (SEAL)  
Print Name: Douglas T. Brown  
Title: SVP

*[Signature Page to Construction Loan Agreement]*

## EXHIBIT C

### Financial Requirements

#### FINANCIAL COVENANTS:

- (a) The Consolidated Group will maintain at all times a minimum of unencumbered cash and liquid investments of \$50,000,000.00, which the Borrower shall certify at the end of each fiscal quarter.
- (b) The Consolidated Group will maintain as of the end of each fiscal quarter, on a rolling four quarters basis, a ratio of Funded Debt to EBITDA of less than 2.00 to 1.00.
- (c) The Consolidated Group will maintain as of the end of each fiscal quarter, on a rolling four quarters basis, a Debt Service Coverage Ratio of at least 1.25 to 1.00.

As used herein:

“**Current Maturities and Interest Expense**” means the current obligations and interest expense on Funded Debt.

“**Debt Service Coverage Ratio**” means the ratio of (i) EBITDA minus cash taxes of the Consolidated Group to (ii) the total of Current Maturities of the Consolidated Group plus interest expense.

“**EBITDA**” means net income attributable to the Borrower without duplication and to the extent reflected as a charge in the statement of net income attributable to the Borrower for such period, the sum of interest expense, income tax expense, depreciation, amortization and any extraordinary or non-recurring non-cash expenses attributed to minority positions in joint ventures.

“**Funded Debt**” means all indebtedness for borrowed money, including but not limited to capitalized lease obligations, reimbursement obligations in respect of letters of credit, and guarantees of any such indebtedness including Subordinated Debt.

“**Subordinated Debt**” means indebtedness that has been subordinated to the Borrower’s indebtedness to the Bank pursuant to a subordination agreement in form and content satisfactory to the Bank.

#### NEGATIVE COVENANTS:

- (a) The Consolidated Group shall not create, incur, guarantee, endorse (except endorsements in the course of collection), assume or suffer to exist any indebtedness, except (i) indebtedness to the Bank, (ii) open account trade debt incurred in the ordinary course of business and not past due, (iii) convertible debt or convertible debentures whether standalone or under a shelf registration, or (iv) other indebtedness disclosed on the Borrower’s latest financial statements which have been provided to the Bank prior to the date of this Agreement, except for indebtedness created, incurred, guaranteed, endorsed or assumed in connection with a merger or consolidation permitted pursuant to Section 5.4, so long as (1) such indebtedness does not exceed \$100,000,000 in the aggregate, and (2) if such indebtedness exceeds \$30,000,000 per transaction, such indebtedness does not cause the Consolidated Group not to be in pro forma compliance with the Financial Covenants set forth herein immediately after giving effect to such merger or consolidation.
- (b) The Borrower shall not declare or pay any dividends on or make any distribution with respect to any class of its equity, or purchase, redeem, retire or otherwise acquire any of its equity.
- (c) The Guarantor will not make or have outstanding any loans or advances to or otherwise extend credit to any person, firm or corporation, except in the ordinary course of business. The Consolidated Group will not make or have outstanding any loans or advances to or otherwise extend credit to any person, firm or corporation in excess of \$50,000,000, except for (1) sale-leaseback transactions, (2) contingent value rights, or (3) note receivables related to a deferred purchase price.

## EXHIBIT F

### Conditions for Closing

1. Title and Collateral Matters:

- (a) Survey. A current survey of the Property and legal description thereof, certified by a registered surveyor approved by the Bank, such certification to be addressed to the Bank and the title company issuing the Bank's title insurance policy and shall be in form and substance acceptable to the Bank.
- (b) Permits and Approvals. Evidence in such form as the Bank may require of the valid issuance of all necessary permits, licenses and approvals (including, without limitation, subdivision and zoning approvals) to construct and, to the extent generally available at such stage, to occupy and operate the improvements.
- (c) Utilities. Evidence in such form as the Bank may require showing the availability of all utility and municipal services required for the operation of the improvements.
- (d) Title Insurance Policy. A lender's title policy in form and substance acceptable to the Bank and issued by a title insurer acceptable to the Bank.

2. Construction Matters:

- (a) Construction Contract. A signed copy of the Construction Contract with the Contractor pursuant to which the Improvements will be constructed by the Contractor, which Construction Contract shall be subject to review and approval by the Bank.
  - (b) Budget. A project budget approved by the Bank and/or its Construction Consultant, to be certified by the Borrower as of the Closing Date, to be true
-



# Promissory Note

(Multi-Rate Options)

\$30,000,000.00

July 28, 2011

**FOR VALUE RECEIVED, EMERGENT BIOSOLUTIONS INC.**, a Delaware corporation (the **"Borrower"**), with an address at 2273 Research Boulevard, Suite 400, Rockville, Maryland 20850, promises to pay to the order of **PNC BANK, NATIONAL ASSOCIATION** (the **"Bank"**), in lawful money of the United States of America in immediately available funds at its offices located at 800 17th Street, N.W., Washington, DC 20006, or at such other location as the Bank may designate from time to time, the principal sum of THIRTY MILLION AND NO/100 DOLLARS (\$30,000,000.00) (the **"Facility"**), or so much thereof as shall have been advanced under that certain Construction Loan Agreement of even date herewith, between the Borrower and the Bank (as amended, modified or renewed from time to time, the **"Agreement"**) together with interest accruing from the date of initial advance on the outstanding principal balance hereof, as provided below:

**1. Advances.** This is a committed line of credit pursuant to which the Borrower may borrow, repay and reborrow, and the Bank, subject to the terms and conditions of this Note and the Loan Documents (as hereinafter defined), will make advances to the Borrower until the Expiration Date. The **"Expiration Date"** shall mean July 28, 2012, or such later date as may be designated by the Bank by written notice from the Bank to the Borrower. The Borrower acknowledges and agrees that in no event will the Bank be under any obligation to extend or renew the Facility or this Note beyond the Expiration Date. The Borrower may request advances hereunder upon giving oral or written notice to the Bank by 11:00 a.m. (Pittsburgh, Pennsylvania time) (a) on the day of the proposed advance, in the case of advances to bear interest under the Base Rate Option (as hereinafter defined) and (b) three (3) Business Days prior to the proposed advance, in the case of advances to bear interest under the LIBOR Option (as hereinafter defined), followed promptly thereafter by the Borrower written confirmation to the Bank of any oral notice. The aggregate unpaid principal amount of advances under this Note shall not exceed the face amount of this Note.

**2. Rate of Interest.** Each advance outstanding under this Note will bear interest at a rate or rates per annum as may be selected by the Borrower from the interest rate options set forth below (each, an **"Option"**):

(i) **Base Rate Option.** A rate of interest per annum which is at all times equal to (A) the Base Rate plus (B) fifty (50) basis points (0.50%). If and when the Base Rate (or any component thereof) changes, the rate of interest with respect to any advance to which the Base Rate Option applies will change automatically without notice to the Borrower, effective on the date of any such change. There are no required minimum interest periods for advances bearing interest under the Base Rate Option.

(ii) **LIBOR Option.** A rate per annum equal to (A) LIBOR for the applicable LIBOR Interest Period plus (B) three hundred (300) basis points (3.00%).

For purposes hereof, the following terms shall have the following meanings:

**"Base Rate"** shall mean the highest of (A) the Prime Rate, and (B) the sum of the Federal Funds Open Rate plus fifty (50) basis points (0.50%), and (C) the sum of the Daily LIBOR Rate plus one hundred (100) basis points (1.00%), so long as a Daily LIBOR Rate is offered, ascertainable and not unlawful.

**"Business Day"** shall mean any day other than a Saturday or Sunday or a legal holiday on which commercial banks are authorized or required by law to be closed for business in Pittsburgh, Pennsylvania.

**"Daily LIBOR Rate"** shall mean, for any day, the rate per annum determined by the Bank by dividing (x) the Published Rate by (y) a number equal to 1.00 minus the LIBOR Reserve Percentage.

**"Federal Funds Open Rate"** shall mean, for any day, the rate per annum (based on a year of 360 days and actual days elapsed) which is the daily federal funds open rate as quoted by ICAP North America, Inc. (or any successor) as set forth on the Bloomberg Screen BTMM for that day opposite the caption "OPEN" (or on such other substitute Bloomberg Screen that displays such rate), or as set forth on such other recognized electronic source used for the purpose of displaying such rate as selected by the Bank (an "Alternate Source") (or if such rate for such day does not appear on the Bloomberg Screen BTMM (or any substitute screen) or on any Alternate Source, or if there shall at any time, for any reason, no longer exist a Bloomberg Screen BTMM (or any substitute screen) or any Alternate Source, a comparable replacement rate determined by the Bank at such time (which determination shall be conclusive absent manifest error); provided however, that if such day is not a Business Day, the Federal Funds Open Rate for such day shall be the "open" rate on the immediately preceding Business Day. The rate of interest charged shall be adjusted as of each Business Day based on changes in the Federal Funds Open Rate without notice to the Borrower.

**"LIBOR"** shall mean, with respect to any advance to which the LIBOR Option applies for the applicable LIBOR Interest Period, the interest rate per annum determined by the Bank by dividing (the resulting quotient rounded upwards, at the Bank's discretion, to the nearest 1/100th of 1%) (i) the rate of interest determined by the Bank in accordance with its usual procedures (which determination shall be conclusive absent manifest error) to be the eurodollar rate two (2) Business Days prior to the first day of such LIBOR Interest Period for an amount comparable to such advance and having a borrowing date and a maturity comparable to such LIBOR Interest Period by (ii) a number equal to 1.00 minus the LIBOR Reserve Percentage.

**"LIBOR Interest Period"** shall mean, as to any advance to which the LIBOR Option applies, the period of one (1), two (2), three (3) or six (6) month/months as selected by the Borrower in its notice of borrowing or notice of conversion, as the case may be, commencing on the date of disbursement of an advance (or the date of conversion of an advance to the LIBOR Option, as the case may be) and each successive period selected by the Borrower thereafter; provided that, (i) if a LIBOR Interest Period would end on a day which is not a Business Day, it shall end on the next succeeding Business Day unless such day falls in the next succeeding calendar month in which case the LIBOR Interest Period shall end on the next preceding Business Day, (ii) the Borrower may not select a LIBOR Interest Period that would end on a day after the Expiration Date, and (iii) any LIBOR Interest Period that begins on the last Business Day of a calendar month (or a day for which there is no numerically corresponding day in the last calendar month of such LIBOR Interest Period) shall end on the last Business Day of the last calendar month of such LIBOR Interest Period.

**"LIBOR Reserve Percentage"** shall mean the maximum effective percentage in effect on such day as prescribed by the Board of Governors of the Federal Reserve System (or any successor) for determining the reserve requirements (including, without limitation, supplemental, marginal and emergency reserve requirements) with respect to eurocurrency funding (currently referred to as "Eurocurrency liabilities").

**“Prime Rate”** shall mean the rate publicly announced by the Bank from time to time as its prime rate. The Prime Rate is determined from time to time by the Bank as a means of pricing some loans to its borrowers. The Prime Rate is not tied to any external rate of interest or index, and does not necessarily reflect the lowest rate of interest actually charged by the Bank to any particular class or category of customers.

**“Published Rate”** shall mean the rate of interest published each Business Day in the Wall Street Journal “Money Rates” listing under the caption “London Interbank Offered Rates” for a one month period (or, if no such rate is published therein for any reason, then the Published Rate shall be the eurodollar rate for a one month period as published in another publication selected by the Bank).

LIBOR and the Daily LIBOR Rate shall be adjusted with respect to any advance to which the LIBOR Option or Base Rate Option applies, as applicable, on and as of the effective date of any change in the LIBOR Reserve Percentage. The Bank shall give prompt notice to the Borrower of LIBOR or the Daily LIBOR Rate as determined or adjusted in accordance herewith, which determination shall be conclusive absent manifest error.

If the Bank determines (which determination shall be final and conclusive) that, by reason of circumstances affecting the eurodollar market generally, deposits in dollars (in the applicable amounts) are not being offered to banks in the eurodollar market for the selected term, or adequate means do not exist for ascertaining LIBOR, then the Bank shall give notice thereof to the Borrower. Thereafter, until the Bank notifies the Borrower that the circumstances giving rise to such suspension no longer exist, (a) the availability of the LIBOR Option shall be suspended and (b) the interest rate for all advances then bearing interest under the LIBOR Option shall be converted at the expiration of the then current LIBOR Interest Period(s) to the Base Rate Option.

In addition, if, after the date of this Note, the Bank shall determine (which determination shall be final and conclusive) that any enactment, promulgation or adoption of or any change in any applicable law, rule or regulation, or any change in the interpretation or administration thereof by a governmental authority, central bank or comparable agency charged with the interpretation or administration thereof, or compliance by the Bank with any guideline, request or directive (whether or not having the force of law) of any such authority, central bank or comparable agency shall make it unlawful or impossible for the Bank to make or maintain or fund loans based on LIBOR, the Bank shall notify the Borrower. Upon receipt of such notice, until the Bank notifies the Borrower that the circumstances giving rise to such determination no longer apply, (a) the availability of the LIBOR Option shall be suspended and (b) the interest rate on all advances then bearing interest under the LIBOR Option shall be converted to the Base Rate Option either (i) on the last day of the then current LIBOR Interest Period(s) if the Bank may lawfully continue to maintain advances based on LIBOR to such day, or (ii) immediately if the Bank may not lawfully continue to maintain advances based on LIBOR.

The foregoing notwithstanding, it is understood that the Borrower may select different Options to apply simultaneously to different portions of the advances and may select up to up to six (6) different interest periods to apply simultaneously to different portions of the advances bearing interest under the LIBOR Option; provided that, for the purpose of determining the number of interest periods, advances bearing interest at the Base Rate Option shall be deemed to constitute an interest period. For example, if a portion of the advances is bearing interest at the Base Rate Option, then the Borrower would be able to select up to five (5) different interest periods to apply with respect to the LIBOR Option. Interest hereunder will be calculated based on the actual number of days that principal is outstanding over a year of 360 days. In no event will the rate of interest hereunder exceed the maximum rate allowed by law.

**3. Interest Rate Election.** Subject to the terms and conditions of this Note, at the end of each interest period applicable to any advance, the Borrower may renew the Option applicable to such advance or convert such advance to a different Option; provided that, during any period in which any Event of Default (as hereinafter defined) has occurred and is continuing, any advances bearing interest under the LIBOR Option shall, at the Bank’s sole discretion, be converted at the end of the applicable LIBOR Interest Period to the Base Rate Option, and the LIBOR Option will not be available to the Borrower with respect to any new advances (or with respect to the conversion or renewal of any existing advances) until such Event of Default has been cured by the Borrower or waived by the Bank. The Borrower shall notify the Bank of each election of an Option, each conversion from one Option to another, the amount of the advances then outstanding to be allocated to each Option and where relevant the interest periods therefor. In the case of converting to the LIBOR Option, such notice shall be given at least three (3) Business Days prior to the commencement of any LIBOR Interest Period. If no interest period is specified in any such notice for which the resulting advance is to bear interest under the LIBOR Option, the Borrower shall be deemed to have selected a LIBOR Interest Period of one month’s duration. If no notice of election, conversion or renewal is timely received by the Bank with respect to any advance, the Borrower shall be deemed to have elected the Base Rate Option. Any such election shall be promptly confirmed in writing by such method as the Bank may require.

**4. Advance Procedures.** A request for advance made by telephone must be promptly confirmed in writing by such method as the Bank may require. The Borrower authorizes the Bank to accept telephonic requests for advances, and the Bank shall be entitled to rely upon the authority of any person providing such instructions. The Borrower hereby indemnifies and holds the Bank harmless from and against any and all damages, losses, liabilities, costs and expenses (including reasonable attorneys’ fees and expenses) which may arise or be created by the acceptance of such telephone requests or making such advances except to the extent such damages, losses, liabilities, costs and expenses arise from the Bank’s intentional misconduct or grossly negligent act or omission. The Bank will enter on its books and records, which entry when made will be presumed correct, the date and amount of each advance, the interest rate and interest period applicable thereto, as well as the date and amount of each payment.

**5. Payment Terms.** Prior to the Expiration Date, monthly payments of interest only will be due and payable commencing on August 28, 2011. From and after the Expiration Date until July 28, 2017, in addition to monthly payments of interest, monthly payments of principal in an amount sufficient to amortize the outstanding principal balance of this Note as of the Completion Date over a term of twenty (20) years shall be due and payable on the first day of each calendar month. Any outstanding principal and accrued interest shall be due and payable in full on July 28, 2017 (the **“Maturity Date”**).

If any payment under this Note shall become due on a Saturday, Sunday or public holiday under the laws of the State where the Bank’s office indicated above is located, such payment shall be made on the next succeeding Business Day and such extension of time shall be included in computing interest in connection with such payment. The Borrower hereby authorizes the Bank to charge the Borrower’s deposit account at the Bank for any payment when due hereunder. Payments received will be applied to charges, fees and expenses (including attorneys’ fees), accrued interest and principal in any order the Bank may choose, in its sole discretion.

**6. Late Payments; Default Rate.** If the Borrower fails to make any payment of principal, interest or other amount coming due pursuant to the provisions of this Note within fifteen (15) calendar days of the date due and payable, the Borrower also shall pay to the Bank a late charge equal to the greater of five percent (5%) of the amount of such payment or \$100.00 (the **“Late Charge”**). Such fifteen (15) day period shall not be construed in any way to extend the due date of any such payment. Upon maturity, whether by acceleration, demand or otherwise, and at the Bank’s option upon the occurrence of any Event of Default (as hereinafter defined) and during the continuance thereof, each advance outstanding under this Note shall bear interest at a rate per annum (based on the actual number of days that principal is outstanding over a year of 360 days) which shall be three percentage points (3%) in excess of the interest rate in effect from time to time under this Note but not more than the maximum rate allowed by law (the **“Default Rate”**). The Default Rate shall continue to apply whether or not judgment shall be entered on this Note. Both the Late Charge and the Default Rate are imposed as liquidated damages for the purpose of defraying the Bank’s expenses incident to the handling of delinquent payments, but are in addition to, and not in lieu of, the Bank’s exercise of any rights and remedies hereunder, under the other Loan Documents or under applicable law, and any fees and expenses of any agents or attorneys which the Bank may employ. In addition, the Default Rate reflects the increased credit risk to the Bank of carrying a loan that is in default. The Borrower agrees that the Late Charge and Default Rate are reasonable forecasts of just compensation for anticipated and actual harm incurred by the Bank, and that the actual harm incurred by the Bank cannot be estimated with certainty and without difficulty.

**7. Prepayment.** The Borrower shall have the right to prepay any advance hereunder at any time and from time to time, in whole or in part; subject, however, to payment of any break funding indemnification amounts owing pursuant to paragraph 8 below.

**8. Yield Protection; Break Funding Indemnification.** The Borrower shall pay to the Bank on written demand therefor, together with the written evidence of the justification therefor, all direct costs incurred, losses suffered or payments made by Bank by reason of any change in law or regulation or its interpretation imposing any reserve, deposit, allocation of capital, or similar requirement (including without limitation, Regulation D of the Board of Governors of the Federal Reserve System) on the Bank, its holding company or any of their respective assets. In addition, the Borrower agrees to indemnify the Bank against any liabilities, losses or expenses (including, without limitation, loss of margin, any loss or expense sustained or incurred in liquidating or employing deposits from third parties, and any loss or expense incurred in connection with funds acquired to effect, fund or maintain any advance (or any part thereof) bearing interest under the LIBOR Option) which the Bank sustains or incurs as a consequence of either (i) the Borrower's failure to make a payment on the due date thereof in connection with any amounts bearing interest under the LIBOR Option, (ii) the Borrower's revocation (expressly, by later inconsistent notices or otherwise) in whole or in part of any notice given to Bank to request, convert, renew or prepay any advance bearing interest under the LIBOR Option, or (iii) the Borrower's payment or prepayment (whether voluntary, after acceleration of the maturity of this Note or otherwise) or conversion of any advance bearing interest under the LIBOR Option on a day other than the last day of the applicable LIBOR Interest Period. A notice as to any amounts payable pursuant to this paragraph given to the Borrower by the Bank shall, in the absence of manifest error, be conclusive and shall be payable upon demand. The Borrower's indemnification obligations hereunder shall survive the payment in full of the advances and all other amounts payable hereunder.

**9. Other Loan Documents.** This Note is issued in connection with loan agreement between the Borrower and the Bank dated on or before the date hereof, and the other agreements and documents executed in connection therewith or referred to therein, the terms of which are incorporated herein by reference (as amended, modified or renewed from time to time, collectively the "**Loan Documents**"), and is secured by the property described in the Loan Documents (if any) and by such other collateral as previously may have been or may in the future be granted to the Bank to secure this Note.

**10. Events of Default.** The occurrence of any of the following events will be deemed to be an "**Event of Default**" under this Note: (i) the nonpayment of any principal, interest or other indebtedness under this Note within seven (7) days of when due; (ii) the occurrence of any event of default or any default and the lapse of any notice or cure period under or contained in any Loan Document or any other document now or in the future evidencing or securing any debt, liability or obligation of any Obligor to the Bank; (iii) the filing by or against any Obligor of any proceeding in bankruptcy, receivership, insolvency, reorganization, liquidation, conservatorship or similar proceeding (and, in the case of any such proceeding instituted against any Obligor, such proceeding is not dismissed or stayed within 30 days of the commencement thereof, provided that the Bank shall not be obligated to advance additional funds hereunder during such period); (iv) any assignment by any Obligor for the benefit of creditors, or any levy, garnishment, attachment or similar proceeding is instituted against any property of any Obligor held by or deposited with the Bank; (v) a default with respect to any other indebtedness of any Obligor for borrowed money in excess of \$10,000,000, if the effect of such default is to cause or permit the acceleration of such debt; (vi) the commencement of any foreclosure or forfeiture proceeding, execution or attachment against any collateral securing the obligations of any Obligor to the Bank; (vii) the entry of a final judgment for the payment of money in excess of \$10,000,000 against any Obligor and the failure of such Obligor to discharge the judgment within ten (10) days of the entry thereof; (viii) any material adverse change in business, assets, operations, financial condition or results of operations of the Consolidated Group; (ix) any Obligor ceases doing business as a going concern; (x) any representation or warranty made by any Obligor to the Bank in any Loan Document or any other documents now or in the future evidencing or securing the obligations of any Obligor to the Bank, is false, erroneous or misleading in any material respect; or (xi) the wrongful revocation or attempted revocation, in whole or in part, of any guarantee by any Obligor. As used herein, the term "**Obligor**" means any Borrower and any guarantor of, or any pledgor, mortgagor or other person or entity providing collateral support for, the Borrower's obligations to the Bank existing on the date of this Note or arising in the future. As used herein, the "**Consolidated Group**" means the Borrower and all of its subsidiary and affiliate entities on a consolidated basis.

Notwithstanding the foregoing, if any default or failure to observe or perform any covenant or other agreement hereunder or under the Loan Documents occurs (a "**General Default**"), such General Default is curable, and no specific cure period otherwise applies to such General Default, the General Default may be cured if the Borrower, after receiving written notice from the Bank demanding cure of such General Default cures the General Default within twenty (20) days.

Upon the occurrence of an Event of Default: (a) the Bank shall be under no further obligation to make advances hereunder; (b) if an Event of Default specified in clause (iii) or (iv) above shall occur, the outstanding principal balance and accrued interest hereunder together with any additional amounts payable hereunder shall be immediately due and payable without demand or notice of any kind; (c) if any other Event of Default shall occur, the outstanding principal balance and accrued interest hereunder together with any additional amounts payable hereunder, at the Bank's option and without demand or notice of any kind, may be accelerated and become immediately due and payable; (d) at the Bank's option, this Note will bear interest at the Default Rate from the date of the occurrence of the Event of Default; and (e) the Bank may exercise from time to time any of the rights and remedies available under the Loan Documents or under applicable law.

**11. Right of Setoff.** In addition to all liens upon and rights of setoff against the Borrower's money, securities or other property given to the Bank by law, the Bank shall have, with respect to the Borrower's obligations to the Bank under this Note and to the extent permitted by law, a contractual possessory security interest in and a contractual right of setoff against, and the Borrower hereby assigns, conveys, delivers, pledges and transfers to the Bank all of the Borrower's right, title and interest in and to, all of the Borrower's deposits, moneys, securities and other property now or hereafter in the possession of or on deposit with, or in transit to, the Bank or any other direct or indirect subsidiary of The PNC Financial Services Group, Inc., whether held in a general or special account or deposit, whether held jointly with someone else, or whether held for safekeeping or otherwise, excluding, however, all IRA, Keogh, and trust accounts. Every such security interest and right of setoff may be exercised without demand upon or notice to the Borrower. Every such right of setoff shall be deemed to have been exercised immediately upon the occurrence of an Event of Default hereunder without any action of the Bank, although the Bank may enter such setoff on its books and records at a later time.

**12. Power to Confess Judgment.** THE BORROWER HEREBY IRREVOCABLY AUTHORIZES AND EMPOWERS ANY ATTORNEY OF ANY COURT OF RECORD, AFTER THE OCCURRENCE OF ANY EVENT OF DEFAULT HEREUNDER, TO APPEAR FOR THE BORROWER AND, WITH OR WITHOUT COMPLAINT FILED, CONFESS JUDGMENT, OR A SERIES OF JUDGMENTS, AGAINST THE BORROWER IN FAVOR OF THE BANK OR ANY HOLDER HEREOF FOR THE ENTIRE PRINCIPAL BALANCE OF THIS NOTE, ALL ACCRUED INTEREST AND ALL OTHER AMOUNTS DUE HEREUNDER, TOGETHER WITH COSTS OF SUIT AND AN ATTORNEY'S COMMISSION OF FIFTEEN PERCENT (15%) OF THE PRINCIPAL AMOUNT OF THE OBLIGATIONS THEN OUTSTANDING; PROVIDED HOWEVER, (A) IF THE ACTUAL ATTORNEY'S FEES INCURRED BY THE BANK OR OTHER HOLDER HEREOF ARE LESS THAN FIFTEEN PERCENT (15%) OF SUCH PRINCIPAL AMOUNT THEN OUTSTANDING AND ALL OBLIGATIONS OWED TO THE BANK BY THE BORROWER HAVE BEEN PAID, THE BANK WILL REFUND (TO THE EXTENT ACTUALLY COLLECTED) TO THE BORROWER AN AMOUNT EQUAL TO THE DIFFERENCE BETWEEN FIFTEEN PERCENT (15%) OF SUCH PRINCIPAL AMOUNT THEN OUTSTANDING AND THE AMOUNT OF SUCH ACTUAL ATTORNEY'S FEES, OR (B) IF THE ACTUAL ATTORNEY'S FEES INCURRED BY THE BANK OR OTHER HOLDER HEREOF EXCEED FIFTEEN PERCENT (15%) OF SUCH PRINCIPAL AMOUNT THEN OUTSTANDING, WHETHER BY REASON OF JUDGMENT BEING CONTESTED OR OTHERWISE, THE BORROWER SHALL PAY TO THE BANK ON DEMAND THE AMOUNT OF ANY SUCH EXCESS AND FOR DOING SO THIS NOTE OR A COPY VERIFIED BY AFFIDAVIT SHALL BE SUFFICIENT WARRANT. THE BORROWER HEREBY FOREVER WAIVES AND RELEASES ALL ERRORS IN SAID PROCEEDINGS AND ALL RIGHTS OF APPEAL AND ALL RELIEF FROM ANY AND ALL APPRAISEMENT, STAY OR EXEMPTION LAWS OF ANY STATE NOW IN FORCE OR HEREAFTER ENACTED. INTEREST ON ANY SUCH JUDGMENT SHALL ACCRUE AT THE DEFAULT RATE.

NO SINGLE EXERCISE OF THE FOREGOING POWER TO CONFESS JUDGMENT, OR A SERIES OF JUDGMENTS, SHALL BE DEEMED TO EXHAUST THE POWER, WHETHER OR NOT ANY SUCH EXERCISE SHALL BE HELD BY ANY COURT TO BE INVALID, VOIDABLE, OR VOID, BUT THE POWER SHALL CONTINUE UNDIMINISHED AND IT MAY BE EXERCISED FROM TIME TO TIME AS

**OFTEN AS THE BANK SHALL ELECT UNTIL SUCH TIME AS THE BANK SHALL HAVE RECEIVED PAYMENT IN FULL OF THE DEBT, INTEREST AND COSTS.**

**13. Miscellaneous.** All notices, demands, requests, consents, approvals and other communications required or permitted hereunder (“**Notices**”) must be in writing (except as may be agreed otherwise above with respect to borrowing requests) and will be effective upon receipt. Notices may be given in any manner to which the parties may separately agree, including electronic mail. Without limiting the foregoing, first class mail, facsimile transmission and commercial courier service are hereby agreed to as acceptable methods for giving Notices. Regardless of the manner in which provided, Notices may be sent to a party’s address as set forth above or to such other address as any party may give to the other for such purpose in accordance with this section. No delay or omission on the Bank’s part to exercise any right or power arising hereunder will impair any such right or power or be considered a waiver of any such right or power, nor will the Bank’s action or inaction impair any such right or power. No modification, amendment or waiver of, or consent to any departure by the Borrower from, any provision of this Note will be effective unless made in a writing signed by the Bank, and then such waiver or consent shall be effective only in the specific instance and for the purpose for which given. The Borrower agrees to pay on demand, to the extent permitted by law, all reasonable costs and expenses incurred by the Bank in the enforcement of its rights in this Note and in any security therefor, including without limitation reasonable fees and expenses of the Bank’s counsel. If any provision of this Note is found to be invalid by a court, all the other provisions of this Note will remain in full force and effect. The Borrower and all other makers and indorsers of this Note hereby forever waive presentment, protest, notice of dishonor and notice of non-payment. The Borrower also waives all defenses based on suretyship or impairment of collateral. If this Note is executed by more than one Borrower, the obligations of such persons or entities hereunder will be joint and several. This Note shall bind the Borrower and its heirs, executors, administrators, successors and assigns, and the benefits hereof shall inure to the benefit of the Bank and its successors and assigns; provided, however, that the Borrower may not assign this Note in whole or in part without the Bank’s written consent and the Bank at any time may assign this Note in whole or in part.

This Note has been delivered to and accepted by the Bank and will be deemed to be made in the State of Maryland. **THIS NOTE WILL BE INTERPRETED AND THE RIGHTS AND LIABILITIES OF THE BANK AND THE BORROWER DETERMINED IN ACCORDANCE WITH THE LAWS OF THE STATE OF MARYLAND, EXCLUDING ITS CONFLICT OF LAWS RULES.** The Borrower hereby irrevocably consents to the exclusive jurisdiction of any State or federal court in the county or judicial district in the State of Maryland; provided that nothing contained in this Note will prevent the Bank from bringing any action, enforcing any award or judgment or exercising any rights against the Borrower individually, against any security or against any property of the Borrower within any other county, state or other foreign or domestic jurisdiction. The Borrower acknowledges and agrees that the venue provided above is the most convenient forum for both the Bank and the Borrower. The Borrower waives any objection to venue and any objection based on a more convenient forum in any action instituted under this Note.

**14. Commercial Purpose.** The Borrower represents that the indebtedness is being incurred by the Borrower solely for the purpose of acquiring or carrying on a business, professional or commercial activity, and not for personal, family or household purposes.

**15. WAIVER OF JURY TRIAL.** **THE BORROWER IRREVOCABLY WAIVES ANY AND ALL RIGHTS THE BORROWER MAY HAVE TO A TRIAL BY JURY IN ANY ACTION, PROCEEDING OR CLAIM OF ANY NATURE RELATING TO THIS NOTE, ANY DOCUMENTS EXECUTED IN CONNECTION WITH THIS NOTE OR ANY TRANSACTION CONTEMPLATED IN ANY OF SUCH DOCUMENTS. THE BORROWER ACKNOWLEDGES THAT THE FOREGOING WAIVER IS KNOWING AND VOLUNTARY.**

**The Borrower acknowledges that it has read and understood all the provisions of this Note, including the confession of judgment and the waiver of jury trial, and has been advised by counsel as necessary or appropriate.**

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WITNESS the due execution hereof as a document under seal, as of the date first written above, with the intent to be legally bound hereby.

WITNESS / ATTEST:

EMERGENT BIOSOLUTIONS INC.,  
a Delaware corporation

/s/ Lisa Richardson  
Print Name: Lisa Richardson  
Title: Senior Director, Treasury  
(Include title only if an officer of entity signing to the right)

By: /s/ R. Don Elsey (SEAL)  
Print Name: R. D. Elsey  
Title: CFO

STATE OF MARYLAND )  
) ss: )  
COUNTY OF Montgomery )

On this, the 28th day of July, 2011, before me, a Notary Public, the undersigned officer, personally appeared R. Don Elsey, who acknowledged himself/herself to be the CFO of Emergent BioSolutions Inc., a Delaware corporation, and that he/she, in such capacity, being authorized to do so, executed the foregoing instrument for the purposes therein contained by signing on behalf of said corporation.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

/s/ Kimberly L. Ridgely  
Notary Public  
My commission expires: 11-11-2012

Kimberly L. Ridgely

*[Signature Page to Promissory Note]*



## Loan and Security Agreement

**THIS LOAN AND SECURITY AGREEMENT** (the “**Agreement**”) is entered into as of this 3<sup>rd</sup> day of August, 2011, by and between **EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC. AND EMERGENT BIOSOLUTIONS INC.** (separately and together, joint and severally, “**Borrower**”) with an address at 2273 Research Blvd., Suite 400, Rockville, MD 20850 and **PNC EQUIPMENT FINANCE, LLC** (“**Lender**”), with an address at 1000 Westlake Drive, Suite 200, Berwyn, PA 19312.

### 1. **LOAN.**

(a) **Agreement to Lend.** Lender hereby agrees, subject to the conditions set forth herein, to make a loan or loans (collectively, the “**Loan**”) to Borrower, the respective principal amounts, interest rates, repayment terms and other provisions relating to which are set forth on the applicable Request For Advance (as hereinafter defined). The proceeds of each Loan will be used for the purpose of acquiring the personal property listed on the applicable Request For Advance (the “**Collateral**”).

(b) **Repayment of Loan; Evidence of Debt.** Borrower hereby unconditionally promises to pay to the order of Lender the unpaid principal amount of each Loan, together with interest thereon. Lender shall maintain in accordance with its usual practice an account or accounts evidencing the indebtedness of Borrower to Lender resulting from each Loan made by Lender, including the amounts of principal and interest payable and paid to Lender from time to time hereunder. The entries made in the accounts properly maintained pursuant to the preceding sentence shall be prima facie evidence of the existence and amounts of the obligations recorded therein; provided that Lender’s failure to maintain such accounts or any error therein shall not in any manner affect Borrower’s obligation to repay each Loan in accordance with the terms of this Agreement except to the extent that such failure or error results or would result in an overpayment from Borrower to Lender under the applicable Loan. In the event of any default by Borrower in payment or performance of any of the Obligations (as hereinafter defined), and the lapse or expiration of any applicable cure period for such default, Lender may declare this Agreement and any other note, schedule, supplement, lease, guaranty, agreement, instrument or document executed in conjunction herewith (collectively, the “**Loan Documents**”) to be in default hereunder and Lender may proceed with its remedies against Borrower in accordance with paragraph 26, below, with respect to any or all of the Loan Documents.

(c) **Lender’s Discretion.** The Loan is not a committed line of credit. Borrower acknowledges and agrees that Loans made under this Agreement, if any, shall be made at Lender’s sole discretion. Lender may decline to make any Loan requested by Borrower pursuant to any Request For Advance hereunder at any time and for any reason without prior notice to Borrower.

2. **SECURITY.** The security for the repayment of the Obligations shall include but not be limited to the Collateral, guaranties and other documents heretofore, contemporaneously or hereafter executed and delivered to Lender, which shall secure the repayment of the Loan, all amounts set forth on each Request For Advance and all other loans, advances, debts, liabilities, obligations, covenants, including under any interest or currency swap, future, option or other interest rate protection or similar agreement, and duties owing by Borrower to Lender or any direct or indirect subsidiary of The PNC Financial Services Group, Inc., of any kind or nature, present or future (including any interest accruing thereon after maturity, or after the filing of any petition in bankruptcy, or the commencement of any insolvency, reorganization or like proceeding relating to Borrower, whether or not a claim for post-filing or post-petition interest is allowed in such proceeding), whether or not evidenced by any note, guaranty, lease, schedule or other instrument, whether arising under any agreement, instrument or document, whether or not for the payment of money, whether arising by reason of an extension of credit, loan, equipment lease or guaranty, whether direct or indirect, absolute or contingent, joint or several, due or to become due, now existing or hereafter arising, and any amendments, extensions, renewals and increases of or to any of the foregoing, and all costs and expenses of Lender incurred in any way in connection therewith, including but not limited to reasonable attorneys’ fees and expenses (collectively, the “**Obligations**”).

3. **GRANT OF SECURITY INTEREST.** To secure the Obligations, Borrower, as debtor, hereby assigns and grants to Lender, as secured party, a continuing lien on and security interest in the Collateral.

4. **TERMS.** The obligations of the parties under this Agreement shall commence upon the written acceptance hereof by Lender and shall end upon full performance and observation of each and every term, condition and covenant set forth in this Agreement and any extensions, modifications or amendments hereto. The payment terms for the respective Loan listed on the applicable Request For Advance shall commence on the date indicated on such Request For Advance and shall terminate upon payment in full of such Loan. Any interim payments shall also be set forth in such Request For Advance.

5. **PAYMENTS.** All payments, including any interim payments, in respect of the Loan as described in the applicable Request For Advance shall be in the amount stated in such Request For Advance. Payments are an absolute obligation of Borrower due and payable as set forth on the applicable Request For Advance irrespective of any claims, demands, set-offs, actions, suits or proceedings that Borrower may have or assert against Lender (except for a good faith claim by Borrower that Lender’s accounts have not been properly maintained or are erroneous) or any vendor of any of the Collateral. Payments shall be made to Lender at P.O. Box 640306 Pittsburgh, PA 15264-0306, or at such other place as Lender or its successors or assigns may designate in writing to Borrower from time to time.

6. **DELINQUENT PAYMENT PENALTY.** If any payment or other amount due hereunder is not paid within ten (10) days of when due, Lender may impose a delinquent interest rate on such unpaid amount at a rate per annum equal to the then current Prime Rate (as hereinafter defined) with respect to all such delinquent amounts. Interest shall accrue at said rate whether or not judgment hereon has been entered. As used herein, “Prime Rate” shall mean the rate publicly announced by PNC Bank, National Association, from time to time as its prime rate.

7. **ADVANCES.** Lender may, at Borrower’s request, subject to the conditions set forth in this paragraph 7, make such advances, deposits and reimbursements as may be required for payment for, and purchase of, the Collateral and each such advance, deposit or reimbursement shall be an advance of principal of the Loan. The Lender’s obligation to make any such advance, deposit or reimbursement is subject to the conditions that as of the date of such advance, deposit or reimbursement:

(a) **No Event of Default.** No Event of Default (as hereinafter defined) or event which with the passage of time, the giving of notice or both would constitute an Event of Default shall have occurred and be continuing;

(b) **Authority Documents.** Lender shall have received certified copies of resolutions, incumbency certificates, opinions of counsel and other proof of authorization satisfactory to Lender; and

(c) **Receipt of Loan Documents.** Lender shall have received a Request For Advance in form and substance satisfactory to Lender which shall have been completed and executed by Borrower (each, a “**Request For Advance**”) which, upon delivery to and acceptance by Lender, will become part of the Loan Documents, and such other instruments and documents which the Lender may reasonably request in connection with the transactions provided for in this Agreement, all in form and substance satisfactory to Lender and duly executed by the Borrower.

8. **DELIVERY AND INSTALLATION.** Borrower will select the Collateral and the supplier, and will order the Collateral from such supplier. Lender shall not be liable for loss or damage for any reason such as failure of or delay in delivery, delivery to wrong location, delivery of improper Collateral or property other than the Collateral, defects in or damage to the Collateral, governmental regulations, strikes, embargoes or other causes, circumstances or events. If the cost of any item of Collateral differs from the price set forth in the purchase order or the applicable Request For Advance, the payments due on the applicable Loan shall be changed to fully reflect any such difference.

9. **WARRANTY OF BORROWER'S QUIET POSSESSION.** Lender covenants, subject to the disclaimer of warranties set forth immediately below, that so long as Borrower faithfully performs this Agreement, Borrower may quietly possess and use the Collateral without interference by Lender, or by any party claiming by or through Lender.

10. **DISCLAIMER OF WARRANTIES.** BORROWER ACKNOWLEDGES AND AGREES THAT (i) THE COLLATERAL AND EACH PART THEREOF IS OF A SIZE, DESIGN, CAPACITY, AND MANUFACTURE SELECTED BY AND ACCEPTABLE TO BORROWER, (ii) BORROWER IS SATISFIED THAT THE COLLATERAL AND EACH PART THEREOF IS SUITABLE FOR ITS RESPECTIVE PURPOSE, (iii) LENDER IS NOT A MERCHANT, MANUFACTURER OR A DEALER IN PROPERTY OF SUCH KIND, (iv) THE COLLATERAL AND EACH PART THEREOF IS ENCUMBERED HEREUNDER, SUBJECT TO ALL APPLICABLE LAWS AND GOVERNMENTAL REGULATIONS NOW IN EFFECT OR HEREAFTER ADOPTED AND IN THE STATE AND CONDITION WHEN THE SAME FIRST BECAME SUBJECT TO THIS AGREEMENT, WITHOUT REPRESENTATION OR WARRANTY OF ANY KIND BY LENDER, AND (v) LENDER MAKES NO WARRANTY OR REPRESENTATION EITHER EXPRESS OR IMPLIED, AS TO THE COLLATERAL, (A) THE CONDITION, FITNESS, DESIGN, QUALITY, CAPACITY, WORKMANSHIP, OPERATION, AND MERCHANTABILITY OF THE COLLATERAL, (B) ANY OTHER MATTER WHATSOEVER, IT BEING AGREED THAT ALL SUCH RISKS, AS BETWEEN LENDER AND BORROWER, ARE TO BE BORNE BY BORROWER, AND THE BENEFITS OF ANY AND ALL IMPLIED WARRANTIES AND REPRESENTATIONS OF LENDER ARE HEREBY WAIVED BY BORROWER. Lender is not responsible or liable for any direct, indirect, incidental, or consequential damage to, or loss resulting from, the installation, operation, or use of the Collateral or any product manufactured thereby. Borrower's recourse for breach of any representation or warranty of the vendor or supplier is limited to such vendor or supplier. Notwithstanding the foregoing, Borrower's obligations to make payment or otherwise under this Agreement shall be and are absolute and unconditional.

11. **NATURE OF COLLATERAL.** The Collateral shall remain personal property, notwithstanding the manner in which it may be affixed to any real property. Borrower shall obtain and cause to be recorded, where appropriate, at its own expense, from each landlord, owner, mortgagee or any person having an encumbrance or lien upon the real property where the Collateral is located, a waiver of any lien, encumbrance or interest which such person might have or hereafter obtain or claim with respect to the Collateral. Borrower, at its expense, will protect and defend the title to the Collateral and will otherwise take all action required to keep the Collateral free and clear of all claims, levies, liens and encumbrances except for the security interest of Lender. Lender assumes no liability and makes no representation as to the treatment by Borrower of this Agreement, the Collateral, or the payments due hereunder for financial, accounting or tax purposes.

12. **LENDER'S RIGHT OF INSPECTION.** Lender, or its authorized agents, shall have the right upon five (5) business days' prior written notice and during normal business hours to enter upon the premises where the Collateral is located (to the extent Borrower can permit) for the purpose of inspection of the Collateral and for no other purpose. In no event shall such inspection interfere with Borrower's conduct of its business, and Lender or its agents shall at all times abide by and be subject to Borrower's normal policies and procedures relating to third party invitees.

13. **USE OF COLLATERAL.** Borrower represents that it is using the Collateral for a business or commercial purpose and not for personal, family or household use. Borrower shall use the Collateral in conformity with (i) all statutes and regulations of each governmental authority having jurisdiction over Borrower or the Collateral and its use; and (ii) all policies of insurance relating to the Collateral or its use. In addition, Borrower shall not (i) use the Collateral in any manner that would impair the applicability of manufacturer's warranties or render the Collateral unfit for its originally intended use; or (ii) permit anyone other than authorized and competent personnel to operate the Collateral.

14. **ALTERATIONS.** Without Lender's prior written consent, which consent shall not be unreasonably withheld, and except as previously disclosed to the Lender or its affiliates in connection with plans or specifications regarding construction activities on the premises, Borrower shall make no material alterations, modifications or attachments to the Collateral which impair its economic value, economic and useful life, or functional utility. Under no circumstances shall any such alteration, modification or attachment be encumbered by Borrower or result in the creation of a mechanic's or materialman's lien, excepting as may arise by operation of law pending payment within ordinary business terms.

15. **MAINTENANCE AND REPAIRS.** At its expense Borrower shall maintain, operate, repair and make all modifications to the Collateral in a manner consistent with Borrower's general practice and in accordance with good industry practice, manufacturer's warranty requirements and specifications and Borrower's established operation, maintenance and repair programs, without discrimination as to such Collateral, so as to keep the Collateral in good working order, and so as to comply with all applicable laws or applicable governmental actions and so as not to incur liability (whether or not there is a lack of compliance) under any environmental law or otherwise account for any release of, or exposure to, any hazardous material. Lender shall not be required to maintain, repair or replace the Collateral or part thereof and Borrower hereby waives the right, however arising, to (i) require Lender to maintain, repair or replace any of the Collateral or part thereof, or (ii) make repairs at the expense of Lender pursuant to any applicable law. Subject to any applicable confidentiality requirements imposed by Borrower, Lender may review Borrower's established operating procedures and maintenance records to assure compliance with this section. Upon installation, any replacement parts shall be deemed part of the Collateral.

16. **RISK OF LOSS, DAMAGE AND THEFT.**

(a) Borrower will bear all risk of loss, damage, theft or destruction, partial or complete, to the Collateral from and after delivery of the Collateral to a carrier FOB point of origin, whether the terms of shipment require or authorize the Collateral to be shipped by carrier, to be delivered to Borrower's place or places of business, or provide that Borrower accept possession of or title to the Collateral at any other location. Borrower shall promptly notify Lender of any theft of or loss or damage to the Collateral.

(b) Neither total nor partial loss of use or possession of the Collateral shall abate the requirement to make the payments set forth on the applicable Request For Advance.

(c) The Collateral shall be deemed subjected to total loss if it has sustained physical damage and the estimated cost of repair exceeds 75% of its fair market value on the date of damage. Borrower's duty to make the payment on the Loan secured by the Collateral subjected to total loss shall be discharged by paying to Lender, on demand, all sums due hereunder. The amount of applicable insurance proceeds, if any, actually received by Lender shall be subtracted from the amount for which Borrower is liable under this paragraph 16.

(d) To the extent commercially reasonable or required to maintain the Borrower's business as normally conducted, Borrower shall cause the Collateral subjected to partial loss to be restored to original capability. Lender shall, upon receiving satisfactory evidence of restoration, promptly pay to Borrower, or such other party as Borrower shall direct, the proceeds of any insurance or compensation received by Lender, by reason of such partial loss.

(e) Lender shall not be obligated to undertake the collection of any claim against any person for either total or partial loss of the Collateral. After Borrower discharges its obligations to Lender under either paragraph 16(c) or 16(d) above, Borrower may, for Borrower's own account, proceed to recover from third parties and shall be entitled to retain any amount recovered. Lender shall supply Borrower with any necessary assignment of claim.

17. **INDEMNIFICATION.**

(a) **Non-Tax Liability.** Borrower agrees to indemnify each of Lender, its directors, officers and employees and each legal entity, if any, which controls Lender (the "Indemnified Parties") and to hold each Indemnified Party harmless from and against any and all third party claims, damages, losses, liabilities and expenses (including all reasonable fees and charges of external counsel with whom any Indemnified Party may consult and all reasonable expenses of litigation and preparation therefor) which any Indemnified Party may incur in connection with or arising out of the matters referred in this Agreement or any related document by any person, entity or governmental authority (including any person or entity claiming derivatively on behalf of Lender); whether (i) arising from or incurred in connection with any breach of a representation, warranty or covenant by Borrower; (ii) the manufacture, installation, use, condition (including, but not limited to, patent or other defects and whether or not discoverable by Borrower or Lender), operation, ownership, selection, delivery, leasing, removal or return of the Collateral (except to the extent removed or returned by an Indemnified Party or its agents), regardless of where, how or by whom operated; or (iii) arising out of or resulting from any suit, action, claim, proceeding or governmental investigation, pending or threatened, whether based on statute, regulation or order, or tort, or contract or otherwise, before any court or governmental authority, which arises out of or relates to this

Agreement or any related document; provided, however, that the foregoing indemnity agreement shall not apply to claims, damages, losses, liabilities and expenses to the extent attributable to an Indemnified Party's gross negligence, willful misconduct or breach of this Agreement or any related document. The indemnity agreement contained in this Paragraph shall survive the termination of this Agreement, prepayment of any amounts due and assignment of any rights hereunder. Borrower may participate at its expense in the defense of any such action or claim, and Lender shall not, without Borrower's express prior written consent, stipulate or enter into any decree, judgment or other resolution of a claim that constitutes or has the effect of being an admission of fault by the Borrower.

(b) **Direct Tax Costs.** Borrower agrees to indemnify, protect, and hold harmless each Indemnified Party, from and against any and all taxes, license fees, assessments and other governmental charges, fees, fines or penalties of whatsoever kind or character and by whomsoever payable, which are levied, assessed, imposed or incurred during the term of this Agreement, (i) on or relating to the Collateral, including any tax on the sale, ownership, use, leasing, shipment, transportation, delivery or operation thereof, (ii) on the exercise of any option, election or performance of any obligation by Borrower hereunder, (iii) of the kind generally referred to in items (i) and (ii) above which may remain unpaid as of the date of delivery of the Collateral to Borrower irrespective of when the same may have been levied, assessed, imposed or incurred, and (iv) by reason of all gross receipts and like taxes on or measured by rents payable hereunder levied by any state or local taxing authority having jurisdiction where the Collateral is located. Borrower agrees to comply with all state and local laws requiring the filing of ad valorem tax returns relating to the Collateral. Any statements for such taxes received by Lender shall be promptly forwarded to Borrower. This subparagraph shall not be deemed to obligate Borrower to pay (i) any taxes, fees, assessments and charges which may have been included in the Loan amount financed by Lender as set forth in the related Request For Advance, other than as payable pursuant to the terms of such Request For Advance, or (ii) any income or like taxes against Lender on or measured by the net income from the payments hereunder. Borrower shall not be obligated to pay any amount under this subparagraph so long as it shall, at its expense and in good faith and by appropriate proceedings, contest the validity or the amount thereof unless such contest would adversely affect the lien or security interest of Lender on the Collateral or would subject the Collateral to forfeiture or sale.

(c) **Indemnity Payment.** The amount payable pursuant to subparagraphs 17(a) and 17(b) shall be payable upon demand of Lender accompanied by a statement describing in reasonable detail such loss, liability, injury, claim, expense or tax and setting forth the computation of the amount so payable.

(c) **Survival.** The indemnities and assumptions of liabilities and obligations provided for in this paragraph 17 shall continue in full force and effect notwithstanding the expiration or other termination of this Agreement.

18. **BORROWER'S ASSIGNMENT.** Without Lender's prior written consent, which consent shall not be unreasonably withheld, Borrower shall not assign, bail, lease, hypothecate, encumber, transfer or dispose of the Collateral or any interest in this Agreement nor knowingly impair Lender's security interest on the Collateral. No assignment, whether or not with Lender's consent, shall release Borrower, or any guarantor from any of its respective obligations or otherwise materially adversely affect any rights or remedies of Lender under this Agreement. Any attempted assignment without Lender's written consent shall be void and of no effect. Borrower shall not assign this Agreement, nor shall this Agreement or any rights under this Agreement or in the Collateral inure to the benefit of any trustee in bankruptcy, receiver, creditor, or other successor of Borrower whether by operation of law or otherwise.

19. **LENDER'S ASSIGNMENT.** All rights of Lender hereunder, in the payments and in the Collateral may be assigned, pledged, mortgaged, transferred, or otherwise disposed of, either in whole or in part, without prior notice to Borrower. No such assignee shall be

obligated to perform any duty, covenant, or condition required to be performed by Lender under the terms of this Agreement unless such assignee expressly assumes such obligations. Lender shall remain liable to Borrower hereunder to perform such duty, covenant, and condition unless such assignee expressly assumes Lender's obligations, in which event Borrower hereby releases Lender from such obligations. Such assignee shall have all rights, powers and remedies given to Lender by this Agreement, and shall, following written notice to Borrower of such assignment along with any supporting documentation reasonably requested by Borrower, be named as lender loss payee or co-insured under all policies of insurance maintained pursuant to paragraph 20 hereof. If Lender assigns this Agreement or the monies due or to become due hereunder or any other interest herein, Borrower agrees not to assert against Lender's assignee any defense, set-off, recoupment, claim or counterclaim which Borrower may have against Lender under this Agreement or any related agreement. Subject to paragraph 18 hereof and this paragraph 19, this Agreement inures to the benefit of, and is binding upon, the heirs, legatees, personal representatives, successors and assigns of the parties hereto.

20. **INSURANCE.** Borrower will at its own expense insure the Collateral in compliance with the terms and conditions of the applicable Request For Advance, in form and in an amount satisfactory to Lender with insurance carriers approved by Lender. The proceeds of any insurance claim due to the theft or loss of or damage to the Collateral shall be applied as provided in paragraph 16 hereof. In addition to the compliance with the terms and conditions of the applicable Schedule and the other terms and conditions of this paragraph 20, Borrower shall comply with the following conditions:

(a) Borrower, prior to the inception of the term of this Agreement, shall deliver to Lender all required policies of insurance or, in the alternative, other proper evidence of insurance, which shall be sufficiently detailed to advise Lender of all types of coverage and inclusions;

(b) Borrower shall cause each insurer to agree by endorsement to the policies that each insurer will give at minimum thirty (30) days' written notice to Lender before any policy will be altered or canceled for any reason, including, without limitation, failure of the Borrower to pay premiums;

(c) All coverage must be in effect upon delivery, or when Borrower assumes the risk of loss, whichever is earlier, and will provide coverage without geographic limitation;

(d) All policies must provide that Lender is an additional insured for all aspects of general liability insurance, and is lender loss payee for all aspects of insurance relating to the theft or loss of or damage to the Collateral;

(e) Borrower will furnish renewal policies or renewal evidence of insurance listing Lender as an additional insured and lender loss payee, as required by this Agreement, no later than thirty (30) days prior to the expiration of any insurance required hereby;

(f) Borrower appoints Lender its attorney-in-fact to apply any insurance proceeds received with respect to the Collateral.

21. **FURTHER ASSURANCES.** Borrower agrees that if the location of any Collateral changes from the location listed in the applicable Request For Advance, or if Borrower changes its name or form or jurisdiction of organization (or if a natural person or general partnership, changes his, her or its principal residence), or establishes a name in which it may do business, Borrower will promptly notify Lender of the additions or changes. If Lender shall so request, Borrower shall execute and deliver to Lender such documents, including UCC financing and continuation statements as Lender shall deem necessary or desirable for purposes of continuing this Agreement or recording or filing to protect the interest of Lender in the Collateral. By its signature hereon, Borrower hereby authorizes Lender to execute and file against Borrower any such UCC financing, amendment and continuation statements. All filing fees and expenses shall be borne by Borrower. Borrower shall also execute such other agreements, documents and instruments including schedules, supplements and assignments as may be reasonably required by Lender to further set forth the terms hereof and secure the repayment of the Loan and protect Lender's interest in the Collateral.

22. **FURNISHING FINANCIAL INFORMATION.** In the event that the following information is no longer publically available, Borrower shall provide Lender with the following:

(a) Within thirty (90) days after the end of each of the first three quarterly periods of Borrower's fiscal year, a balance sheet, statement of cash flows and a statement of income of Borrower ("**Financial Statements**") as of the close of such quarterly period from the beginning of the fiscal year to the date of such statement, prepared in accordance with generally accepted accounting principles, consistently applied, and in such reasonable detail as Lender may request, certified as true, complete and correct by an authorized officer of Borrower.

(b) As soon as practicable, but in any event within ninety (120) days after the end of each fiscal year, a copy of its annual audited Financial Statements certified without qualification by an independent certified public accountant of recognized standing.

(c) In a timely manner such Financial Statements, reports and other information as the Borrower shall send from time to time to its stockholders and/or file with the Securities and Exchange Commission and/or other materials which Lender shall reasonably request.

23. Intentionally omitted.

24. **PERFORMANCE OF OBLIGATIONS OF BORROWER BY LENDER.** If Borrower fails to perform any of its material obligations under this Agreement within twenty (20) days of written notice of such failure or any lesser period as expressly provided herein, Lender may perform the same for the

account of Borrower without waiving Borrower's failure as a default. All sums paid or expense or liability incurred by Lender in such performance (including reasonable legal fees) together with interest thereon at the highest contract rate enforceable against Borrower, but never at a higher rate than fifteen percent (15%) per annum simple interest, shall be payable by Borrower upon demand as additional sums due as an Obligation.

25. **EVENTS OF DEFAULT.** Any of the following events or conditions shall constitute an event of default ("**Event of Default**") hereunder and entitle the Lender, at its option, to avail itself of the remedies more fully set forth in paragraph 26 hereof:

- (a) Non-payment by the Borrower of any payment or other amount provided for in this Agreement which continues for a period of seven (7) days following the date when due;
- (b) Following the lapse of any notice or cure period, Borrower shall (i) fail to perform any covenant or requirement relating to insurance or environmental matters; (ii) fail to keep the Collateral free of any claims, levies, liens and encumbrances; (iii) fail to prevent the Collateral from being subject to a foreclosure or forfeiture proceeding, execution or attachment; or (iv) terminate this Agreement or any other Loan Document prior to payment in full of all amounts due hereunder;
- (c) The filing by or against Borrower of any proceeding in bankruptcy, receivership, insolvency, reorganization, liquidation, conservatorship, or similar proceeding (and in the case of any such proceeding instituted against Borrower, such proceeding is not dismissed or stayed within thirty (30) days of the commencement thereof, provided that Lender shall not be obligated to advance additional funds during such period);
- (d) Borrower shall make an assignment for the benefit of creditors, or any levy, garnishment, attachment or similar proceedings instituted against any property of Borrower held by or deposited with Lender;
- (e) A final judgment for the payment of money in excess of \$500,000 is rendered against Borrower, or any attachment proceedings is instituted with respect to any significant portion of Borrower's assets or property, and the same shall remain undischarged for a period of thirty (30) days during which execution shall not be effectively stayed;
- (f) Borrower, or any affiliate of Borrower, shall default in the payment of principal and/or interest when due (whether by acceleration or otherwise) or shall default in the performance of any obligation or indebtedness owed to Lender or to any subsidiary or affiliate of Lender (whether directly as a lender to Borrower or as one lender in a bank syndicate agreeing to lend to Borrower or Borrower's affiliate, or as holder of a participation in a loan by another lender to Borrower or Borrower's affiliate), which obligation shall remain in default for lack of performance or which indebtedness shall remain unpaid and unsatisfied following the conclusion of any applicable grace period in respect to such obligation or indebtedness;
- (g) Borrower shall make any material change in the nature of its business as carried on as of the date hereof that is likely to materially adversely affect the value of the Collateral;
- (h) Any event described in subparagraphs 25(c) through 25(g) hereof shall occur with respect to any guarantor or any other party liable for payment or performance of this Agreement;
- (i) Any certificate, statement, representation, warranty or financial statement heretofore or hereafter furnished pursuant to or in connection with this Agreement by or on behalf of Borrower or any guarantor or other party liable for payment or performance of this Agreement is false in any material respect at the time as of which the facts therein set forth were stated or certified, or omits any substantial contingent or unliquidated liability or claim against Borrower or any such guarantor or other party, or, upon the date of execution of this Agreement or any Request For Advance, there shall have been any materially adverse change in any of the facts disclosed by any such certificate, statement, representation or warranty, which shall not have been disclosed in writing to Lender at or prior to the time of execution of this Agreement or such Request For Advance;
- (j) An event of default shall have occurred under any other agreement wherein the Lender or any affiliate of the Lender is, at the time of such default, the "Lender" or "Lessor" and the Borrower or any affiliate of the Borrower is the "Borrower" or "Lessee".
- (k) The Borrower shall fail to perform any non-monetary covenant, obligation, term or condition of this Agreement or any other Loan Document not described in this Paragraph 25 which failure continues for a period of thirty (30) days following the earlier of the date when Borrower became aware of such failure or the date of written notice thereof to Borrower by Lender.

26. **REMEDIES.** Upon the happening of any Event of Default hereunder, the rights and duties of the parties shall be as set forth in this Section. Lender may elect, in its sole discretion, to do one or more of the following upon the occurrence of an Event of Default, and at any time thereafter:

- (a) Lender may demand that Borrower deliver the Collateral to Lender at Lender's normal place of business for delivery of such Collateral whereupon Borrower shall promptly deliver the Collateral to Lender at that place or those places reasonably designated by Lender. If Borrower does not so deliver the Collateral, Borrower shall make the Collateral available for retaking and authorizes Lender, its employees and agents, upon reasonable prior written notice, to enter the premises of Borrower and any other premises (insofar as Borrower can permit) for the purpose of retaking. In no event shall such retaking involve a breach of peace or of Borrower's operations that do not involve such Collateral, and Lender shall be solely responsible for all claims for injuries to persons or property suffered through or loss caused by retaking. Any repossession accomplished under this paragraph 26 shall not release Borrower from liability for damages of Lender sustained by reason of Borrower's default hereunder.
- (b) Lender may revoke Borrower's privilege of making payments in installments causing acceleration of all remaining payments through the remaining term of this Agreement, and, upon Lender's demand, as liquidated damages, and not as a penalty, Borrower shall promptly pay to Lender the aggregate of (i) all payments, principal and interest, accrued and unpaid prior to the date of such Event of Default, (ii) all future payment due through the end of the term of this Agreement or through the end of any extension thereof, as the case may be, (iii) all reasonable costs and expenses incurred by Lender in the repossession, recovery, storage, repair, inspection, appraisal, refurbishing, sale, release or other disposition of the Collateral, and (iv) reasonable attorney's fees and costs, including any fees or costs incurred by Lender in defending any action relating to this Agreement or participating in any bankruptcy or insolvency proceeding to which Borrower is a party, or otherwise incurred due to Borrower's default. In the event that any court having jurisdiction shall determine that in calculating damages hereunder as a result of a default by Borrower that sums payable in the future under the Agreement must be discounted to present value, the discount rate to be applied in such case shall equal the discount rate of the Federal Reserve Bank of Cleveland then in effect on the earlier of the date of entry of judgment on such claim or the date of payment of such sum by Borrower.
- (c) In its sole discretion, Lender may sell the Collateral or any part thereof, at public auction or by private sale or lease at such time or times and upon such terms as Lender may determine, free and clear of any rights of Borrower and, if notice thereof is required by law, any notice in writing of such sale or Agreement by Lender to Borrower given not less than ten (10) days prior to the date thereof shall constitute reasonable notice thereof to Borrower. All proceeds of the sale less (i) all expenses incurred in retaking the Collateral, making necessary repairs to the Collateral and enforcing this Agreement, (ii) all direct damages that Lender shall have sustained by reason of Borrower's default, and (iii) reasonable attorney's fees and expenses shall be credited against Borrower's liability hereunder as and when received by Lender. Sums in excess of Borrower's liability shall belong to Borrower. Borrower shall be liable for any deficiency.
- (d) The provisions of this paragraph 26 shall not prejudice Lender's right to recover or prove damages for unpaid amounts accrued prior to default, or bar an action for a deficiency as herein provided, and the bringing of an action with an entry of judgment against Borrower shall not bar Lender's right to repossess any or all of the Collateral.
- (e) Lender's remedies shall be available to Lender's successors and assigns, shall be in addition to all other remedies provided to it under the Uniform Commercial Code (specifically, the remedies set forth in 13 Pa. C.S. §§ 2A523(a), (b) and (c)) or by any other applicable law, and may be exercised concurrently or consecutively. **BORROWER WAIVES ANY AND ALL RIGHTS TO NOTICE AND TO JUDICIAL HEARING WITH RESPECT TO THE REPOSSESSION OF THE COLLATERAL BY LENDER IN THE EVENT OF A DEFAULT HEREUNDER BY BORROWER.**

27. **BORROWER REPRESENTATIONS AND WARRANTIES.** In order to induce Lender to enter into this Agreement and to make the Loan to Borrower, Borrower represents and warrants, as of the date hereof, and as of the date of execution of any Request For Advance hereunder, that:

- (a) The Borrower is duly organized or incorporated, validly existing and in good standing under the laws of the State of its incorporation or organization and has the power and authority to own and operate its assets and to conduct its business as now or proposed to be carried on, and is duly qualified, licensed and in good standing to do business in all jurisdictions where its ownership of property or the nature of its business requires such qualification or licensing. The Borrower and the Guarantor are each duly authorized to execute and deliver the Loan Documents executed by it, all necessary action to authorize the execution and delivery of the Loan Documents has been properly taken, and the Borrower is and will continue to be duly authorized to borrow under this Agreement and to perform all of the other terms and provisions of the Loan Documents.

- (b) There are no actions, suits, proceedings or governmental investigations pending or, to the knowledge of the Borrower, threatened against the Borrower, which could result in a material adverse change in its business, assets, operations, condition (financial or otherwise) or results of operations and there is no basis known to the Borrower for any action, suit, proceeding or investigation which could result in such a material adverse change.
- (c) There does not exist any Event of Default under this Agreement or any default or violation by the Borrower of or under any of the terms, conditions or obligations of: (a) its articles or certificate of incorporation, regulations or bylaws if the Borrower is a corporation or its other organizational documents as applicable; (b) any indenture, mortgage, deed of trust, franchise, permit, material contract, material agreement, or other instrument to which it is a party or by which it is bound; or (c) any law, ordinance, regulation, ruling, order, injunction, decree, condition or other requirement applicable to or imposed upon it by any law, the action of any court or any governmental authority or agency; and the consummation of this Agreement and the transactions set forth herein will not result in any such default or violation or Event of Default.
- (d) Under the laws of the state(s) in which the Collateral is to be located, the Collateral consists solely of personal property.
- (e) The financial statements of Borrower (copies of which have been furnished to Lender) have been prepared in accordance with generally accepted accounting principles consistently applied, and accurately and completely present Borrower's financial condition and the results of its operations as of the date of and for the period covered by such statements, and since the date of such statements there has been no material adverse change in such conditions or operations.
- (f) The address stated on page one of this Agreement is the principal office of Borrower and the place where all books and records concerning the Collateral are kept; the address set forth on the applicable Request For Advance is the location at which the applicable Collateral is kept; and Borrower does not conduct business under a trade, assumed, or fictitious name.

**28. GOVERNING LAW AND JURISDICTION.** This Agreement has been delivered and accepted and will be deemed to be made in the State of Maryland. THIS AGREEMENT AND ALL AGREEMENTS, INSTRUMENTS AND DOCUMENTS HERETOFORE, NOW OR HEREAFTER EXECUTED BY BORROWER AND DELIVERED TO LENDER RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY WILL BE INTERPRETED AND THE RIGHTS AND LIABILITIES OF THE PARTIES HERETO DETERMINED IN ACCORDANCE WITH THE LAWS OF THE STATE OF MARYLAND, EXCLUDING ITS CONFLICT OF LAWS RULES. Borrower hereby irrevocably consents to the exclusive jurisdiction of any state or federal court in the county or judicial district of the State of Maryland; provided that nothing contained in this Agreement will prevent Lender from bringing any action, enforcing any award or judgment or exercising any rights against Borrower individually, against any security or against any of Borrower's property within any other county, state or foreign or domestic jurisdiction. Lender and Borrower agree that the venue provided above is the most convenient forum for both parties. Borrower waives any objection to venue and any objection based on a more convenient forum in any action instituted under this Agreement.

**29. NOTICES.** All notices, demands, requests, consents, approvals and other communications required or permitted hereunder ("**Notices**") must be in writing and will be effective upon receipt. Notices may be given in any manner to which the parties may separately agree, including electronic mail; provided that Notices relating to any Event of Default shall not be given by electronic mail. Without limiting the foregoing, first-class mail, facsimile transmission and commercial courier service are hereby agreed to as acceptable methods for giving Notices. Regardless of the manner in which provided, Notices may be sent to a party's address as set forth above or to such other address as any party may give to the other for such purpose in accordance with this paragraph.

**30. MISCELLANEOUS**

- (a) In this Agreement, unless Lender and Borrower otherwise agree in writing, the neuter gender includes the masculine and feminine; the singular includes the plural and the plural the singular; the word "or" shall be deemed to include "and/or" and the words "including", "includes" and "include" shall be deemed to be followed by the words "without limitation". Whenever the word Lender is used herein, it shall include all assignees of Lender. If there is more than one Borrower named in this Agreement, the liability of each shall be joint and several.
- (b) Reference to agreements and other contractual instruments shall be deemed to include all subsequent amendments and other modifications to such instruments, but may to the extent such amendments and other modifications are not prohibited by the terms of this Agreement. Section headings in this Agreement are included for convenience of reference only and shall not constitute a part of this Agreement for any other purpose. Unless otherwise specified by this Agreement, all accounting terms shall be interpreted and all accounting determinations shall be in accordance with GAAP.
- (c) Time is of the essence in the performance of this Agreement and each and all of its provisions.
- (d) If any provision of this Agreement is held invalid or unenforceable, the remaining provisions will not be affected thereby, and to this end, the provisions of this Agreement are declared severable.
- (e) If there is any conflict between the terms of any Request For Advance and this document, or between any Request For Advance and any other documents, the terms of the Request For Advance shall control.
- (f) Borrower will reimburse Lender for Lender's expenses (including the reasonable fees and expenses of Lender's outside counsel) in connection with any amendments or modifications to this Agreement or any other Loan Document, and in connection with any collection or enforcement actions hereunder or thereunder.
- (g) This Agreement, the Requests For Advance, and any other Loan Documents executed and delivered pursuant hereto or thereto constitute the entire agreement between Lender or Borrower with respect to the Collateral and the subject matter of this Agreement and supersede all other prior agreements and understandings whether oral or written between the parties with respect to the subject matter hereof. This Agreement may not be changed, waived, amended or terminated except by written agreement signed by both Lender and Borrower, except that Lender may insert on the applicable Request For Advance the serial numbers of the Collateral after delivery thereof. No express or implied waiver by Lender of any Event of Default hereunder shall in any way be, or be construed to be, a waiver of any future and/or subsequent Event of Default whether similar in kind or otherwise but shall be effective only in the specific instance and for the purpose for which given. No Notice to Borrower in any case will entitle Borrower to any other or further Notice in the same, similar or other circumstances.
- (h) Borrower hereby authorizes Lender to make appropriate announcements of the lending arrangements entered into between Lender and Borrower, including but not limited to announcements which are commonly known as tombstones, in such publications and to such selected parties as Lender deems appropriate in its sole and absolute discretion. Borrower shall not issue any press release or other public disclosures, whether written or oral, of the existence or terms of this Agreement without Lender's prior written consent; provided, that the foregoing shall not prohibit Borrower from making any disclosures to or filings with any governmental authority, or from disclosing this Agreement to Borrower's accountants, attorneys and other agents or to Borrower's lenders, or from reflecting the terms of this Agreement in any financial statements or reports made public in the ordinary course of Borrower's business.

**31. COUNTERPARTS.** This Agreement may be signed in any number of counterpart copies and by the parties hereto on separate counterparts, but all such copies shall constitute one and the same instrument. Delivery of an executed counterpart of a signature page to this Agreement by facsimile transmission shall be effective as delivery of a manually executed counterpart. Any party executing this Agreement by facsimile transmission shall promptly deliver a manually executed counterpart, provided that any failure to do so shall not affect the validity of the counterpart executed by facsimile transmission.

**32. WAIVER OF JURY TRIAL.** EACH OF LENDER AND BORROWER HEREBY WAIVES ANY RIGHT TO DEMAND A JURY TRIAL WITH RESPECT TO ANY ACTION OR PROCEEDING INSTITUTED BY LENDER OR BORROWER IN CONNECTION WITH THIS AGREEMENT OR ANY TRANSACTION RELATED HERETO. BORROWER AND LENDER ACKNOWLEDGE THAT THE FOREGOING WAIVER IS KNOWING AND VOLUNTARY.

**Borrower acknowledges that it has read and understood all the provisions of this Agreement, including the waiver of jury trial, and has been advised by counsel as necessary or appropriate.**

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WITNESS the due execution hereof with the intent to be legally bound.

WITNESS/ATTEST:

**BORROWER:  
EMERGENT  
MANUFACTURING  
OPERATIONS  
BALTIMORE LLC**

By: /s/ Lisa Richardson  
(SEAL)

By: /s/ Kirsten Noerr

Name: Lisa Richardson

Name: Kirsten Noerr

Title: Senior Director, Treasury

Title: VP Finance

WITNESS/ATTEST:

**BORROWER: EMERGENT  
BIOSOLUTIONS INC.**

By: /s/ Lisa Richardson  
(SEAL)

By: /s/ Kirsten Noerr

Name: Lisa Richardson

Name: Kirsten Noerr

Title: Senior Director, Treasury

Title: VP Finance

LENDER:  
**PNC EQUIPMENT FINANCE, LLC**

By: /s/ Theresa M. Woodman (SEAL)

Name: Theresa M. Woodman

Title: Assistant Vice President

Loan & Security Agreement.doc Rev. 3/01

**Loan and Security Agreement – Rev. 4/07 (3/01)**

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AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE	OF	PAGES
			1	1	1
2. AMENDMENT/MODIFICATION NO. 00014	3. EFFECTIVE DATE 09/27/2011	4. REQUISITION/PURCHASE REQ. NO. N/A	5. PROJECT NO. (If applicable)		
6. ISSUED BY Centers for Disease Control and Prevention (PGO) Building & Facilities Contracts Branch 2920 Brandywine Road, MS-K71 Atlanta, GA 30341-5539	CODE 2540	7. ADMINISTERED BY (If other than Item 6)		CODE	
8. NAME AND ADDRESS OF CONTRACTOR EMERGENT BIODEFENSE OPERATIONS LANSING LLC 3500 N. MARTIN LUTHER KING JR BLVD # 1  LANSING, MI 48906-2933		(✓)	9A. AMENDMENT OF SOLICITATION NO.		
CODE 026489018			10A. MODIFICATION OF CONTRACT/ORDER NO. 200-2009-30162		
FACILITY CODE		X	10B. DATED (SEE ITEM 13) 09/30/2008		
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS					
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is ___ extended, ___ is not extended.					
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning ___ copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. IF by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.					
12. ACCOUNTING AND APPROPRIATION DATA (If required) N/A					
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.					
(✓)	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
X	FAR 52.243-1, Changes-Fixed Price				
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).				
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
	D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return ___ copies to the issuing office.					
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) The purpose of this modification is to: a. Extend the period of performance is extended through December 31, 2011; b. This extension covers product and shipping charges previously funded under CLINs 0005 and 0008 and is not for additional doses. c. Total contract value and total funding remain unchanged as a result of this modification.					
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.					
15A. NAME AND TITLE OF SIGNER (Type or print) Daniel Abdum-Nabi President, Emergent BioSolutions, Inc.		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Christine N. Godfrey			
15B. CONTRACTOR/OFFEROR  /s/ Daniel Abdum-Nabi (Signature of person authorized to sign)	15C. DATE SIGNED 09/28/2011	16B. UNITED STATES OF AMERICA BY /s/ Christine N. Godfrey (Signature of Contracting Officer)	16C. DATE SIGNED 9/29/11		

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE	Page 1 of 1
2. AMENDMENT/MODIFICATION NO.		3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (if applicable)	
Modification No. 0012		See Block 16C	N/A	N/A	
6. ISSUED BY	CODE	7. ADMINISTERED BY (if other than Item 6)		CODE	
U.S. DEPT OF HEALTH AND HUMAN SERVICES OS/ASPRWARDA 330 Independence Ave, SW, Rm G640 Washington, D.C. 20201	N/A	See Block 6		N/A	
8. NAME AND ADDRESS OF CONTRACTOR			9A. AMENDMENT OF SOLICITATION NO.		
EMERGENT BIODEFENSE OPERATIONS LANSING INC 330303 EMERGENT BIODEFENSE OPERATIONS LANS 3500 N. MARTIN LUTHER KING BLVD #M1 LANSING 489062933 DUNS: 026489018 TIN: 39-3412788			9B. DATED (SEE ITEM 11)		
			<input checked="" type="checkbox"/> 10A. MODIFICATION OF CONTRACT ORDER NO.		
			Contract No. HHSO100200700037C		
			10B. DATED (SEE ITEM 13) 09/25/2007		
CODE	N/A	FACILITY CODE	N/A		
<b>11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS</b>					
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is <input type="checkbox"/> extended, <input type="checkbox"/> is not extended.					
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:					
(a) By completing Items 8 and 15, and returning ___ copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATA SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and data specified.					
12. ACCOUNTING AND APPROPRIATION DATA (if required)					
Not Applicable					
<b>13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.</b>					
<input type="checkbox"/>	A. THE CHANGE ORDER IS ISSUED PURSUANT TO (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
<input type="checkbox"/>	B. THE ABOVE NUMBERED CONTRACT ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.105(b).				
<input type="checkbox"/>	C. THE SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
<input checked="" type="checkbox"/>	D. OTHER (Specify type of modification and authority) FAR 40.1 Authority and Mutual Agreement of the Parties				
<b>E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return One (1) copies to the issuing office.</b>					
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)					
[Description continues on the next page]					
The purpose of this modification is to 1) extend the period of performance of this Contract, as noted in section F. 1. of the Contract, at no additional cost from September 1, 2011 to October 31, 2011 and 2) extend the dates for contract deliverables for associated Milestones, as noted in F. 3. of the Contract, to October 31, 2011.					
All other terms and conditions remain unchanged by reason of this modification. Period of Performance: 09/01/2011 to 10/31/2011 (changed)					
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, or here to be changed, remain unchanged and in full force and effect					
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)		
R. Donald Elsey, Treasurer			Darrick A. Early, Contracting Officer		
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA		16C. DATE SIGNED	
BY /s/ R. Don Elsey (Signature of person authorized to sign)	8/18/2011	BY /s/ Darrick A. Early (Signature of Contracting Officer)		8/24/2011	

Centers for Disease Control  
 and Prevention (CDC)  
 Atlanta GA 30333

September 30, 2011

Emergent Biodefense Lansing Operations  
 ATTN: Michael Wernicke  
 3500 N Martin Luther King Jr. Blvd. #1  
 Lansing, MI 48906-2933

Subject: Notice of Award Letter, Awarding Solicitation 2011-N-13414 for Acquiring Doses of Anthrax Vaccine Absorbed (AVA), also known as BioThrax

Dear Mr. Wernicke:

In accordance with FAR 15.504, this notice of award documents the Government's acceptance of the agreement reached during discussions earlier today and described in your letter to me dated September 30, 2011. A formal contract will be issued within 15 working days from date of this letter. The following applies to this award:

1. The pricing agreement is as follows:

Dose Quantities for Delivery			Dose Price (\$US)		Total Value (\$US)		
CLIN	Period of Performance	# of Doses	4-year	5-year	4-year	5-year [Price = \$[*] + 4-year Price, beginning CLIN 3]	Annual Price Escalator
			<sup>3</sup> 42 months	<sup>3</sup> 48 months			
			<48 months	<60 months			
0001	01 Oct 2011 – 30 Sep 2012	[**]	[**]	[**]	[**]	[**]	[**]
0002	01 Oct 2012 – 30 Sept 2013	[**]	[**]	[**]	[**]	[**]	[**]%
0003	01 Oct 2013 – 30 Sep 2014	[**]	[**]	[**]	[**]	[**]	[**]%
0004	01 Oct 2014 – 30 Sep 2015	[**]	[**]	[**]	[**]	[**]	[**]%
0005	01 Oct 2015 – 30 Sep 2016	[**]	[**]	[**]	[**]	[**]	[**]%
<b>Total</b>		<b>44,750,000</b>			<b>\$1,235,292,500.00</b>	<b>\$ 1,253,167,500.00</b>	

- Contract number 200-2011-42084 shall apply to the award of this 5 year contract.
- HHSAR clause 352.232.-72 Limitation of Government's obligation applies to the contract. In accordance with HHSAR 352.232-72, contract 200-2011-42084 is incrementally funded in the amount of \$125,009,128.00 under the following Cost Accounting Number (CAN).  
**939ZFCF 2642 2011 75-X-0943 5664311101**
- As shown in the chart above, 4 year product means remaining expiry dating upon date of delivery of <sup>3</sup>42 months and 48 months; \$[\*] per dose for product delivered under CLIN 0001.
- As shown in the chart above, 5 year product means remaining expiry dating upon date of delivery of <sup>3</sup>48 months and 60 months; \$[\*] to be added to the 4 year dose price (as adjusted for annual escalation) for product delivered under CLINs 0003, 0004, and 0005.
- As shown in the chart above, annual dose price escalation of [\*]% applies.
- Delivery of product shall be FOB Origin.

Thank you for working with CDC to get the new BioThrax contract awarded.

Should you have additional questions, please contact me at 770-488-2647 or vhubbs@cdc.gov.

Sincerely,

/s/ Vivian S. Hubbs

Vivian S. Hubbs  
 Contracting Officer  
 Procurement and Grants Office

cc: OPHPR

## CERTIFICATION

I, Fuad El-Hibri certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Emergent BioSolutions Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information, and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2011

/s/Fuad El-Hibri  
Fuad El-Hibri  
Chief Executive Officer

## CERTIFICATION

I, R. Don Elsey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Emergent BioSolutions Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information, and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2011

/s/R. Don Elsey  
R. Don Elsey  
Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the nine months ended September 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Fuad El-Hibri, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2011

/s/Fuad El-Hibri  
Fuad El-Hibri  
Chief Executive Officer



CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the nine months ended September 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, R. Don Elsey, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2011

/s/R. Don Elsey  
R. Don Elsey  
Chief Financial Officer