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 March 31, 2012

OR

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

For the transition period from to

Commission file number: 001-33137

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

Delaware	**14-1902018**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
2273 Research Boulevard, Suite 400 Rockville, Maryland	**20850**
(Address of Principal Executive Offices)	*(Zip Code)*

(301) 795-1800
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☑ Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☑ Yes o No

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

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

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

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

Emergent BioSolutions Inc.

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Part I. Financial Information

Part II. Other Information

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

PART I. FINANCIAL INFORMATION

ITEM 1. ***FINANCIAL STATEMENTS***

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

	March 31, 2012	December 31, 2011
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 150,425	$ 143,901
Investments	-	1,966
Accounts receivable	43,652	74,153
Inventories	17,319	14,661
Deferred tax assets, net	441	1,735
Income tax receivable, net	19,798	9,506
Restricted cash	-	220
Prepaid expenses and other current assets	7,907	8,276
Total current assets	239,542	254,418
Property, plant and equipment, net	218,749	208,973
In-process research and development	41,800	51,400
Goodwill	5,502	5,502
Assets held for sale	-	11,765
Deferred tax assets, net	8,349	13,999
Other assets	745	807
Total assets	$ 514,687	$ 546,864
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 28,316	$ 40,530
Accrued expenses and other current liabilities	1,134	1,170
Accrued compensation	9,982	20,884
Contingent value rights, current portion	-	1,748
Long-term indebtedness, current portion	3,280	5,360
Deferred revenue	283	1,362
Total current liabilities	42,995	71,054
Contingent value rights, net of current portion	-	3,005
Long-term indebtedness, net of current portion	57,592	54,094
Other liabilities	2,005	1,984
Total liabilities	102,592	130,137
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 36,160,162 and 36,002,698 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively	36	36
Additional paid-in capital	222,746	220,654
Accumulated other comprehensive loss	(3,229)	(3,313)
Retained earnings	190,041	196,869
Total Emergent BioSolutions Inc. stockholders' equity	409,594	414,246
Noncontrolling interest in subsidiaries	2,501	2,481
Total stockholders' equity	412,095	416,727
Total liabilities and stockholders' equity	$ 514,687	$ 546,864

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

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

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

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

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

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

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

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

	Three Months Ended March 31,	
	2012	2011
Cash flows from operating activities:	(Unaudited)	
Net loss	$ (8,022)	$ (23,173)
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	2,712	2,441
Depreciation and amortization	2,373	2,235
Deferred income taxes	6,944	2,879
Non-cash development expenses from joint ventures	1,212	2,550
Change in fair value of contingent value rights	(3,005)	581
Impairment of in-process research and development	9,600	-
Excess tax benefits from stock-based compensation	862	(39)
Other	(19)	13
Changes in operating assets and liabilities:		
Accounts receivable	30,501	27,350
Inventories	(2,658)	(9,441)
Income taxes	(11,154)	(15,238)
Prepaid expenses and other assets	443	923
Accounts payable	(1,988)	(736)
Accrued expenses and other liabilities	(11)	(33)
Accrued compensation	(10,895)	(10,525)
Deferred revenue	(1,075)	(2,510)
Net cash provided by (used in) operating activities	15,820	(22,723)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(22,329)	(8,432)
Proceeds from sale of assets	11,765	-
Proceeds from maturity of investments	1,966	-
Purchase of investments	-	(4,309)
Net cash used in investing activities	(8,598)	(12,741)
Cash flows from financing activities:		
Proceeds from borrowings on long-term indebtedness	9,621	-
Issuance of common stock subject to exercise of stock options	242	4,198
Excess tax benefits from stock-based compensation	(862)	39
Principal payments on long-term indebtedness	(8,203)	(842)
Contingent value right payment	(1,748)	-
Release of restricted cash deposit	220	-
Net cash provided by (used in) financing activities	(730)	3,395
Effect of exchange rate changes on cash and cash equivalents	32	(25)
Net increase (decrease) in cash and cash equivalents	6,524	(32,094)
Cash and cash equivalents at beginning of period	143,901	169,019
Cash and cash equivalents at end of period	$ 150,425	$ 136,925

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

EMERGENT BIOSOLUTIONS INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Basis of presentation and consolidation

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

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

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

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

2. Fair value measurements

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

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

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

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

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

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

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

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

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

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

3. Inventories

Inventories consist of the following:

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

Total inventories	$ 17,319	$ 14,661

4. In-process research and development and goodwill

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

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

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

5. Assets held for sale

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

6. Long-term debt

The components of long-term indebtedness are as follows:

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

7. Stockholders' equity

Preferred stock

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

Common stock

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

Stock options and restricted stock units

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

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

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

	2006 Plan		2004 Plan		
	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2011	3,090,909	$ 17.36	53,156	$ 8.86	$ 6,238,427
Granted	675,581	15.83	-	-	
Exercised	(20,739)	11.68	-	-	
Forfeited	(57,001)	20.20	-	-	
Outstanding at March 31, 2012	3,688,750	$ 17.07	53,156	$ 8.86	$ 5,152,087
Exercisable at March 31, 2012	2,157,105	$ 16.05	53,156	$ 8.86	$ 4,858,991

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

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

8. Variable interest entities

In July 2008, the Company entered into a collaboration with the University of Oxford ("Oxford") and certain Oxford researchers to conduct clinical trials to advance a vaccine product candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium ("OETC"). The Company has a 51% equity interest in OETC and controls the OETC Board of Directors. In addition, the Company has certain funding and service obligations related to its investment. In July 2011, the Company entered into an intercompany loan agreement with OETC, under which the Company agreed to provide OETC with a loan of up to $14.0 million to fund future clinical and development costs for the tuberculosis vaccine product candidate. The loan value can be increased to up to $23.0 million at the sole discretion of the Company. The loan bears interest at the rate of 8% per annum. Principal and interest on the outstanding balance will be due and payable in December 2014 or upon occurrence of either an event of default or the closing of a debt or equity financing by OETC that results in net proceeds equal to or in excess of $30.0 million in a single transaction or a series of related transactions. Under the terms of the loan, OETC is required to comply with certain non-financial covenants. As of March 31, 2012, there have been no draws under this loan. The Company evaluates its variable interests in OETC on a quarterly basis and has

determined that it is the primary beneficiary as it has the power to direct the activities of OETC that most significantly impact OETC's economic performance and will absorb the majority of expected losses. Accordingly, the Company consolidates OETC. As of March 31, 2012 and 2011, respectively, assets of $506,000 and $413,000 and liabilities of $1.8 million and $513,000 related to OETC were included within the Company's consolidated balance sheet. During the three months ended March 31, 2012 and 2011, respectively, OETC incurred net losses of $2.4 million and $3.6 million of which $1.2 million and $1.8 million is included in the Company's consolidated statement of operations.

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

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

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

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

9. Collaboration Agreements

Abbott Laboratories

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

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

Pfizer Inc.

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

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

10. Earnings per share

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

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

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

11. Segment information

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

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

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

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this quarterly report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, including information with respect

to our plans and strategy for our business, include forward-looking statements that involve risks and uncertainties. You should review the "Special Note Regarding Forward-Looking Statements" and the "Risk Factors" sections of this quarterly report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Product Portfolio

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

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

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

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

Product Sales

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

Contracts and Grants

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

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

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

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

Manufacturing Infrastructure

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

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

Critical Accounting Policies and Estimates

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

Financial Operations Overview

Revenues

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

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

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

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

Cost of Product Sales

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

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

Research and Development Expenses

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

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

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

Selling, General and Administrative Expenses

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

In-process Research and Development and Goodwill

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

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

Results of Operations

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

Revenues

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

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

Cost of Product Sales

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

Research and Development Expenses

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

The increase in spending on Biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials. The decrease in spending for NuThrax was primarily due to the timing of clinical trial activities. The increase in spending for our large-scale manufacturing for BioThrax program was primarily due to non-clinical studies and preparation for the manufacturing of consistency lots. The spending for BioThrax related programs was related to clinical and non-clinical studies to support applications for marketing approval of these programs. The increase in spending for PreviThrax was primarily due to optimization and stability studies. The decrease in spending for Anthrivig was primarily due to the substantial completion of clinical trial activities. The decrease in spending for Thravixa was primarily due to timing of clinical trial activities. The decrease in spending for our other biodefense activities was primarily due to decreased spending associated with our double mutant recombinant protective antigen anthrax vaccine in light of reduced funding by the U.S. government for this product candidate. As such, we expect that spending for our double mutant recombinant protective antigen anthrax vaccine will be minimal in the future.

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

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

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

	Three Months ended March 31,	
(in thousands)	**2012**	**2011**
Biodefense:		
NuThrax	$ 2,606	$ 3,699
Large-scale manufacturing for BioThrax	4,697	3,246

BioThrax related programs	2,464	1,710
PreviThrax	4,503	3,115
Anthrivig	103	635
Thravixa	533	1,308
Other Biodefense	261	980
Total Biodefense	15,167	14,693
Biosciences:		
Tuberculosis vaccine	3,231	5,904
TRU-016	2,782	5,025
ES301 (formerly DRACO)	1,053	1,961
Zanolimumab	592	-
X1	65	907
Influenza vaccine	101	824
Typhella	133	840
Other Biosciences	1,269	3,347
Total Biosciences	9,226	18,808
Other	1,853	1,258
Total	$ 26,246	$ 34,759

Selling, General and Administrative Expenses

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

Impairment of in-process research and development

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

Total Other Income (Expense)

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

Income Taxes

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

Net Loss Attributable to Noncontrolling Interest

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

Liquidity and Capital Resources

Sources of Liquidity

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

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

Cash Flows

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

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

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

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

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

Net cash used in investing activities for the three months ended March 31, 2012 was $8.6 million, primarily due to capital expenditures of $22.3 million related to the construction and related costs of our facility in Baltimore, Maryland, and infrastructure investments and other equipment, partially offset by net proceeds from the sale of our two Frederick, MD buildings of $11.8 million and the maturity of U.S. Treasury securities of $2.0 million.

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

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

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

Debt Financing

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

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

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

Funding Requirements

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

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

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

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

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

Our exposure to market risk is currently confined to our cash and cash equivalents that have maturities of less than three months and our long-term indebtedness. We currently do not hedge interest rate exposure or foreign currency exchange exposure, and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, we believe that an increase in market rates would likely not have a significant impact on the realized value of our cash and cash equivalents, but any increase in market rates would likely increase the interest expense associated with our debt.

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2012. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2012, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

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

PART II. OTHER INFORMATION

ITEM 1. ***LEGAL PROCEEDINGS***

Not applicable.

ITEM 1A. RISK FACTORS

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

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

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

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

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

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

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

result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the Federal Acquisition Regulations, and agency-specific regulations supplemental to the Federal Acquisition Regulations, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities

and incorporate other requirements such as the Anti-Kickback Act and the Foreign Corrupt Practices Act, or FCPA;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

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

Risks Related to Our Financial Position and Need for Additional Financing

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Manufacturing and Manufacturing Facilities

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

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

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

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

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

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

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

Under our current contract with the CDC, we have the option to perform shipping services at no cost to the U.S. government. If we perform these shipping services, we are contractually required to ship BioThrax at a prescribed temperature range, and variations from that temperature range could result in loss product and could adversely affect our profitability. Delays, lot failures, shipping deviations, spoilage or other loss during shipping could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

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

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

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

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

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

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

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

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

If we are unable to obtain supplies for our manufacture of BioThrax or our product candidates in sufficient quantities and at an acceptable cost, our ability to manufacture BioThrax or to develop and commercialize our product candidates could be impaired, which could harm our revenues, lead to a termination of one or more of our contracts, lead to delays in clinical trials or otherwise harm our business.

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

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

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

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

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

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

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

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

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

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

adversely affect supplies of our product candidates. The sanctions that might be imposed include:

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

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

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

Our research and development and manufacturing processes may involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we, the third parties that conduct clinical trials on our behalf and the third parties that manufacture our product candidates are subject to federal, state, local and foreign laws and regulations governing the use, manufacture, distribution, storage, handling, disposal and recordkeeping with respect to these materials. The Public Health Security and Bioterrorism Preparedness and Response Act and the Agricultural Protection Act require us to register with the CDC and the Animal and Plant Health Inspection Service, our possession, use or transfer of select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires stringent safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel and establishes a comprehensive national database of registered entities.

We are also subject to a variety of environmental laws in Michigan, including those regarding underground storage tanks. One such tank on our Lansing, Michigan campus has leaked in the past. The State of Michigan removed the tank, continues to monitor the situation and has agreed to indemnify us for any resulting liabilities. In the event that the State of Michigan does not indemnify us, or if our insurance does not cover the exposure of any remediation that may be necessary, we may be required to spend significant amounts on remediation efforts. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS, U.S. Department of Agriculture and the DoD.

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

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

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

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

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

Risks Related to Product Development

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

We have invested a significant portion of our efforts and financial resources in the development of our vaccines and therapeutic product candidates and the acquisition of additional product candidates. In addition to BioThrax sales, our ability to generate near term revenue is dependent on the success of our development programs and collaboration programs, on the U.S. government's interest in providing development funding for or procuring certain of our product candidates, on the interest of non-governmental organizations in providing grant funding for development of certain of our product candidates and on the commercial viability of our product candidates. The commercial success of our product candidates will depend on many factors, including accomplishing the following in an economical manner:

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

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

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

Before obtaining regulatory approval for the sale of our product candidates, we and our collaborative partners must conduct extensive preclinical studies and clinical trials to establish proof of concept, safety and efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and the outcome of such trials is uncertain. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results.

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

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

- § regulators or institutional review boards may not authorize us, or our collaborators, to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- § we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- § we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- § regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;
- § regulators may determine that service providers we use in the conduct of a clinical trial are precluded from providing such services;
- § we or our collaborative partners may experience delay in beginning the clinical trial;
- § we may experience competition in recruiting clinical investigators;
- § the cost of our clinical trials could escalate and become cost prohibitive;
- § any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- § regulatory requirements, policy and guidelines could change;

- we may experience limitations in our ability to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials;
- we or our collaborators may fail to adequately manage the increasing number, size and complexity of our clinical trials;
- any or all of our collaborators, the FDA and foreign regulatory agencies may interpret data differently;
- third parties conducting and overseeing the operations of our clinical trials may fail to perform their contractual or regulatory obligations in a timely fashion;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials or may experience delays in patient enrollment and variability in the number and types of patients available for clinical trials; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

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

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

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

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

Under the Project BioShield Act of 2004, or Project BioShield, the Secretary of HHS, or the Secretary, can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the Secretary to authorize the emergency use of medical products that have not yet been approved by the FDA. However, our biodefense product candidates might not be selected by the Secretary under this authority. Moreover, this authority could result in increased competition for our products and product candidates.

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

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

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

Risks Related to Commercialization

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Acquisition Strategy

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

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

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

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

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

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

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

Since our inception we have pursued a strategy of growing our business through licensing and acquisition. We commenced operations in September 1998 through an acquisition of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how, all from the Michigan Biologic Products Institute. We acquired vaccine and therapeutic product candidates through our acquisition of Microscience Limited in 2005, our acquisition of substantially all of the assets of ViVacs GmbH in 2006, our acquisition of Trubion Pharmaceuticals, Inc. in October 2010 and our acquisition of certain assets of Vaxgen, Inc. in 2008, Avanir Pharmaceuticals, Inc. in 2008 and TenX BioPharma, Inc. in May 2011. We have been unsuccessful in our efforts to develop and commercialize many of the product candidates acquired by these acquisitions.

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

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

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

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

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

are unable to manage and advance these activities effectively, our ability to operate our business successfully and maximize the value of our product or our product candidates could suffer, which could materially and adversely affect our business, financial condition and prospects for future growth.

Risks Related to Regulatory Approvals

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

efforts will be successful, which could preclude our ability to commercialize this product candidate in the European Union. We and our collaborators may not be able to obtain regulatory approvals to commercialize our products in any market. The failure to obtain regulatory approval in foreign jurisdictions could materially harm our business.

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not do so, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties. For example, we license an oligonucleotide adjuvant, CPG 7909, for use in NuThrax from Pfizer. One of the licensed U.S. patents has been revoked by the U.S. Patent and Trademark Office, as a result of a patent interference between Pfizer and a third party.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Information Technology

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

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

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

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

Risks Related to Our Common Stock

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

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

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

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

These provisions include:

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

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

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

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

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

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

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

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through April 30, 2012, our common stock has traded as high as $27.00 per share and as low as $4.40 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including:

- § the success of competitive products or technologies;
- § results of clinical trials of our product candidates or those of our competitors and success in our research and development programs;
- § decisions and procurement policies by the U.S. government affecting BioThrax and our biodefense product candidates;
- § regulatory developments in the U.S. and foreign countries;
- § public concern as to the safety of drugs developed by us or others;
- § announcements of issuances of common stock or acquisitions by us;
- § the announcement and timing of new product introductions by us or others;
- § termination or delay of development program(s) by our collaborative partners, or delay in achievement of collaboration milestones;
- § announcements of technological innovations or new therapeutic products or methods by us or others;
- § acts or omissions of our licensees, collaborators and suppliers;
- § developments or disputes concerning patents or other proprietary rights;
- § the recruitment or departure of key personnel;
- § variations in our financial results or those of companies that are perceived to be similar to us;
- § market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- § general economic, industry and market conditions or other external factors, such as disaster or crisis; and
- § the other factors described in this "Risk Factors" section.

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

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 8.8 million shares of our common stock outstanding as of April 30, 2012 have the right to require us to register these shares of common stock under specified circumstances.

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

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

Not applicable.

Purchases of Equity Securities

Not applicable.

ITEM 3. ***DEFAULTS UPON SENIOR SECURITIES***

Not applicable.

ITEM 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

ITEM 5. ***OTHER INFORMATION***

Amendment to Consulting Agreement with Robert Kramer

On May 3, 2012, we entered into an amendment, or Amendment, to a consulting agreement, or Consulting Agreement, that we entered into on September 6, 2011 with Robert G. Kramer. Under the Consulting Agreement, Mr. Kramer has provided us with services as interim executive vice president, corporate services division since January 1, 2012, and as interim executive vice president and president, biosciences

division from September 2011 to December 2011. Under the terms of the Consulting Agreement, we agreed to pay Mr. Kramer $37,500 per month for his services, to reimburse Mr. Kramer for reasonable out-of-pocket expenses, and to consider Mr. Kramer for a grant of up to 20,000 restricted stock units after approximately one year of service, to be granted in the sole discretion of the compensation committee of our Board of Directors. The Consulting Agreement expires on December 5, 2012. The Amendment, which is dated effective January 1, 2012, sets forth specific goals to be met by Mr. Kramer in 2012 and does not modify or amend any other provisions of the Consulting Agreement.

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

Pfizer Agreement

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

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

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

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

ITEM 6. ***EXHIBITS***

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

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

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

Date: May 4, 2012

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

Date: May 4, 2012

EXHIBIT INDEX

Exhibit Number	Description
10.1	Employment Agreement, effective January 1, 2012, between Emergent Product Development UK Ltd and Dr. Steven Chatfield (incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011 filed with the SEC on March 9, 2012)
10.2	Modification No. 14 to Contract No. HHS0100200700037C, effective January 3, 2012, between Emergent BioDefense Operations Lansing LLC, formerly known as Emergent BioDefense Operations Lansing Inc., and the Department of Health and Human Services (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011 filed with the SEC on March 9, 2012)
10.3	Third Amendment to Lease Agreement, dated effective February 27, 2012, between Brandywine Research LLC and the Registrant (incorporated by reference to Exhibit 10.47 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011 filed with the SEC on March 9, 2012)
10.4#†	Solicitation, Offer and Award, dated effective September 30, 2011, from the Centers for Disease Control and Prevention to Emergent BioDefense Operations Lansing LLC
10.5#†	Consulting Agreement, dated effective September 6, 2011, between Emergent BioSolutions Inc. and Robert Kramer
10.6#†	Amendment to Consulting Agreement, dated effective January 1, 2012, between Emergent BioSolutions Inc. and Robert Kramer
31.1	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101. INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linksbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

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

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

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

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

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Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

Exhibit 10.4

SOLICITATION, C [redacted]

2. CONTRACT NO.	3. SOLICITATION NO.	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO.
200-2011-42084	2011-N-13414	[redacted] SEALED BID (IFB) [redacted] NEGOTIATED (RFP)	09/30/2011	0000HCGE-2011-05429

7. ISSUED BY — CODE 8219

Centers for Disease Control and Prevention (CDC)
Procurement and Grants Office (PGO)
2920 Brandywine Road
Atlanta, GA 30341-5539

8. ADDRESS OFFER TO *(If other than Item 7)*

Approved as to Form and Legality: _____

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder."

SOLICITATION

9. Sealed offers in original and __ __ copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in _____ until 2:00p local time 09/30/2011

CAUTION – LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE *(NO COLLECT CALLS)* AREA CODE NUMBER EXT:	C. E-MAIL ADDRESS
	Christine N. Godfrey	(770) 488-2519	

11. TABLE OF CONTENTS

(X)		DESCRIPTION	[redacted]	(X)		DESCRIPTION	[redacted]
		PART I – THE SCHEDULE				PART II – CONTRACT CLAUSES	
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	22
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	2			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	6	X	J	LIST OF ATTACHMENTS	35
X	D	PACKAGING AND MARKING	9			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
X	E	INSPECTION AND ACCEPTANCE	10		[redacted]	REPRESENTATIONS, CERTIFICATIONS, AND	
X	F	DELIVERIES OR PERFORMANCE	13	X		OTHER STATEMENTS OF OFFERORS	36
X	G	CONTRACT ADMINISTRATION DATA	16		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	H	SPECIAL CONTRACT REQUIREMENTS	19		M	EVALUATION FACTORS FOR AWARD	

OFFER *(Must be fully completed by offeror)*

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within _____ calendar days *(60 calendar days unless a different period is inserted by the offeror)* from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT *(See Section I, Clause No. 52-232-8)*	10 CALENDAR DAYS %	20 CALENDAR DAYS %	30 CALENDAR DAYS %	[redacted] %
[redacted]				

AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

[redacted]

CODE	FACILITY	16. NAME AND ADDRESS OF PERSON AUTHORIZED TO SIGN OFFER [redacted]
026489018		EMERGENT BIODEFENSE OPERATIONS LANSING LLC 2500 N MARTIN LUTHER KING JR BLVD # 1 LANSING, MI 48906-2933

15B. TELEPHONE NO. AREA CODE NUMBER EXT.	15C. [redacted] CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE

AWARD *(To be completed by Government)*

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION
See Section B	$125,009,128.00	9392FCF 2642 2011 75-X-0943 5664311101

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:
[redacted] 10 U.S.C. 2304(c)( ) [redacted] 41 U.S.C. 253(c)( )

23. SUBMIT INVOICES TO ADDRESS SHOWN IN *(4 copies unless otherwise specified)* ITEM

24. ADMINISTERED BY *(If other than Item 7)*	CODE	25. PAYMENT WILL BE MADE BY	CODE
	8219		434

Section B - Supplies or Services and Prices/Costs

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below	[**] Doses	$[**]	$[**]
	Funding in the amount of $125,009,128.00 was provided on the letter notice of award dated September 30, 2011.			
0001A	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0001B	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0001C	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0001D	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]

Option 1 Additional Quantity Items:

0002	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below	[**] Doses	$[**]	$[**]
0002A	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0002B	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0002C	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0002D	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]

Option 2 Additional Quantity Items:

0003	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below	[**] Doses	$[**]	$[**]
0003A	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0003B	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0003C	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0003D	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]

Option 3 Additional Quantity Items:

0004	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below	[**] Doses	$[**]	$[**]
0004A	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0004B	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0004C	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0004D	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]

Option 4 Additional Quantity Items:

0005	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below	[**]Doses	$[**]	$[**]
0005A	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0005B	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0005C	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]
0005D	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below		$[**]	$[**]

B.1 Alternate CLINS

[**].

TOTAL DOSES TO BE DELIVERED **44,750,000**

TOTAL VALUE AT [**] PRODUCT **$[**]**

TOTAL VALUE AT [**] PRODUCT **$1,253,167,500.00**

B.2 Option for Increased Quantity – Separately Priced Line Items

The Government may require the delivery of the numbered line items, identified in the Schedule above as option items, in incremental quantities

a) From a minimum order of [**] doses per order, and at the price stated in the Schedule above, up to the maximum quantity identified for each numbered line item. Each option line item may be exercised more than once, until the cumulative number of doses to be delivered under each option is delivered. The total doses ordered hereunder shall not exceed 44,750,000 doses over the 5 year period of performance, unless changed by formal modification to the contract. Each CLIN, including the alternate CLINs (with the same number and a lettered suffix) collectively function as one option. [**].
b) [**].
c) The Contracting Officer may exercise the option by written notice to the Contractor. The Contractor will be notified in writing, by letter or email, at least one (1) business day before the option to acquire more product is exercised. After that written notification, a funded, unilateral modification will be issued to actually exercise the option and order the doses.

B.3 Use of product by the US Government

To the extent that third parties contact DSNS to obtain doses of BioThrax®, DSNS will notify such third parties that Emergent sells AVA on the commercial market.

B.4 Price Protections.

Should the Government be unable to pick up product within [**] days of a scheduled delivery date while Emergent is ready, able and willing to deliver released lots of BioThrax, on the scheduled delivery date, the pricing for such lots shall be based on the remaining expiry dating as of the scheduled delivery date. This does not apply if the shipment is rescheduled at the Contractor's request. Further, this does not apply if there are unresolved issues with the quality, safety, and/or efficacy of the delivered product.

Section C – Statement of Work

C.1 Vaccine Production and cGMP Compliance:

a) The Contractor shall manufacture BioThraxâ in accordance with current Good Manufacturing Practices (cGMP) guidelines. The Contractor shall manufacture 44,750,000 doses of Final Drug Product (FDP) in 5 mL, ten dose vials in accordance with the targeted delivery schedule from October 1, 2011 – September 30, 2016**.**

b) BioThrax® shall be delivered on any business day, except Federal holidays, within the scheduled month in accordance with the targeted delivery schedule. Contractor shall notify the Government promptly upon becoming aware of any deviations from the targeted delivery schedule. All changes to the targeted delivery schedule must be approved by the Contracting Officer and/or the Contracting Officer's Representative (COR).

c) Quantities for each scheduled delivery shall be of a specific quantity.

d) The Contractor shall perform all requisite assays and release tests, including but not limited to potency, identity, and stability testing in accordance with the FDA approved Biologic License Application (BLA-License Number 1755, STN 103821, and any approved change).

e) All BioThraxâ delivered under this contract shall be labeled with an expiration date consistent with its current product license at the time of manufacture.

f) The Contractor shall provide primary and secondary points of contact who shall be available 24 hours per day, seven days per week to be notified in case of a public health emergency.

g) The Contractor shall report to the Government material correspondence from the FDA regarding the quality, safety, or efficacy of BioThrax®.

h) The Contractor shall provide the Government with access to and/or provide copies of the following documents: (1) Form 483s form FDA inspections of Contractor's Lansing facility, (2) Establishment Inspection Reports (EIRs) from FDA inspections of Contractor's Lansing facility; (3) Warning Letters relating to BioThrax®; and Contractor's Annual Safety Report to FDA regarding BioThrax®. These documents will be provided to the Contracting Officer within [**] business days of receipt.

i) The Government shall be notified of any issues with the safety and efficacy of BioThrax® and/or manufacturing or quality of the FDA-licensed production lines at the Contractor's Lansing facility within [**] business days of the determination of potential to be reported to FDA.

j) The Government shall have the option to conduct quarterly inspections of the Contractor's Lansing facility. Such inspections shall be performed by the COR or the COR's designee(s).

k) If the contractor should obtain FDA approval for the manufacture and production of BioThrax® having [**] while under this contract, the Government will accept delivery of those doses with the longer shelf life in addition to doses with a shorter shelf life. Contractor may invoice only for those doses actually delivered under contract in accordance with Section B.

l) The product shall be delivered in accordance with cGMP (current Good Manufacturing Practices).

m) At least [**] business days prior to the product being ready for pick up by the SNS, the Contractor shall provide to the Contracting Officer and Contracting Officer's Representative (COR):
   a. The date the product will be ready for loading on the truck(s) scheduled by the SNS
   b. Physical address of the product pick up location (facility name, address, point of contact name and telephone number)
   c. Certificate(s) of Analysis
   d. FDA Lot Release(s)
   e. Number of pallets, vials, and doses to be loaded

n) At least [**] hours before each scheduled pick up by the SNS, Contractor shall provide the following to the Contracting Officer and COR:
   a. Packing Slip
   b. Actual number of pallets, vials and doses to be loaded

c. Diagram of product shipment pallet (how many vials per box, per pallet)

o) Within [**] business days after delivery, the Government shall provide the Contractor the SNS destination location(s) for the lot(s) delivered.

p) Within [**] hours after the product has been picked up by the SNS, the Contractor shall provide to the Contracting Officer and COR:
   a. The remaining ambient exposure time letter disclosing accumulated ambient temperature exposure until the point that SNS (or SNS-designated personnel) assumed responsibility for temperature control, per Section E.3, for each lot from the Contractor's Quality Department. The letter should indicate that the product was manufactured and released in accordance with cGMP and has met all acceptance criteria to allow for Government distribution.

q) Funds provided shall be paid on a price per doses basis only on those products delivered to the SNS under contract.

r) Under the CLINs of this contract the products shall have an [**] product. The Contractor shall target [**] of the total [**] remaining when the Government takes delivery of the product. If [**] dated product is approved by the FDA, the product shall have an [**]. The Contractor shall target [**] of the total [**] remaining when the Government takes delivery of the product. In the event that product with lower than targeted [**] should be delivered, product with an [**] greater than or equal to [**] shall be deemed [**] product. A product with an [**] greater than or equal to [**] shall be deemed [**] product. A product with an [**] greater than or equal to [**] shall be deemed [**] product. [**] when the Government takes delivery of the product according to the pricing table and Section B.1in Section B.

C.2 Delivery Schedule:

CLIN (includes alternate CLINS)	Delivery Period	# of Doses
0001	October 1, 2011 to September 30, 2012	[**]
0002	October 1, 2012 to September 30, 2013	[**]
0003	October 1, 2013 to September 30, 2014	[**]
0004	October 1, 2014 to September 30, 2015	[**]
0005	October 1, 2015 to September 30, 2016	[**]

The number under quantity shows the number of doses per year that the Contractor anticipates delivering during the period shown. Should the projected number of doses not be delivered in a specific period, the Contractor shall adjust the delivery schedule to make up for deficiencies in prior deliveries. Further, the Contractor may accelerate deliveries within each CLIN or into a subsequent CLIN, if production capacity permits such delivery and the CLIN is funded to a level to pay for the accelerated delivery. Accelerated delivery is subject to approval by the COR. Ultimately, the Contractor shall deliver a total of 44,750,000 doses by September 30, 2016.

C.3 Audits/Site Visits:

a) Pre-award Site Visit: The Government reserves the right to conduct a pre-award site visit of the manufacturing plant.

b) Site Visits/Audits: The Government shall perform annual site visits/security audits as deemed necessary by the Government throughout the period of performance of the contract.

c) Quality: The Government may visit the Lansing site for purposes of assessing quality on an annual basis or as deemed necessary by the Government throughout the period of performance of the contract.

d) The contractor shall facilitate cGMP site-visit or inspection as requested by FDA/CBER at the time of production of product lots destined for the SNS.

e) Quality Management System (QMS): Contractor shall submit evidence of its QMS to the Contracting Officer within 90 days after contract award.

f) Notice: The Government shall provide 2 weeks advance notice prior to the Contractor of all site visits and audits. The notice will include a statement concerning the intended scope of the audit and a list of the required documents or access to personnel.

g) All audits shall be conducted between normal business hours i.e. 8 a.m. through 4 p.m., Monday through Friday.

C.4 Meetings and Reports:

a) The contractor shall participate in a quarterly meeting (teleconference and/or face-to-face) to discuss performance under the contract. These meetings should provide status updates and discuss on-going manufacturing, clinical, regulatory, and shipment issues as applicable. These meetings shall be coordinated by the COR and/or Contracting Officer

b) Risk Mitigation Plan: The plan should identify manufacturing, quality, regulatory, and shipment risks and countermeasures to mitigate these risks. This report should be updated annually or as deemed necessary by the USG.

c) Additional reporting requirements**:**

1. Contractor shall notify DSNS in its quarterly reports if Contractor undertakes post-marketing commitments for Phase 4 studies in the event of emergency use authorization.

2. Contractor shall provide DSNS with drafts of supplements to its BLA for BioThrax® that are material to the manufactured product and to the contract.

Section D – Packaging and Marking

D.1 Method of Delivery

Unless otherwise specified by the Contracting Officer, delivery of the items other than BioThrax® to be furnished to the Government under this contract (including invoices) shall be made by first class mail, overnight carrier or e-mail.

D.2 Packaging

Packaging shall be consistent with the FDA approved labeling and packaging for this product at the time of manufacture.

Section E - Inspection and Acceptance

FAR SOURCE	**TITLE AND DATE**
52.246-1	**Contractor Inspection Requirements (Apr 1984)**
52.246-2	**Inspection of Supplies – Fixed Price (Aug 1996)**
52.246-16	**Responsibility for Supplies (Apr 1984)**

E.1 Inspection and Acceptance (Apr 2009)

E.1.1 Inspection and acceptance of the articles, services, and documentation called for herein shall be accomplished by the Contracting Officer, or his duly authorized representative.

E.1.2 The Contractor shall only tender for acceptance those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or re-performance of nonconforming services at no increase in contract price. The Government must exercise its post-acceptance rights:

(1) Within a reasonable time after the defect was discovered or should have been discovered; and

(2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(End of Clause)

E.2 Contractor Inspection Requirements

The Contractor is responsible for performing or having performed all inspections and tests necessary to substantiate that the supplies or services furnished under this contract conform to contract requirements, including any applicable technical requirements for specified manufacturers' parts. This clause takes precedence over any Government inspection and testing required in the contract's specifications, except for specialized inspections or tests specified to be performed solely by the Government.

(End of Clause)

E.3 Temperature Control and Monitoring

E.3.1 FOB Origin Deliveries: The Contractor shall be responsible for maintaining product temperature control until the product leaves Contractor's validated [**]°C storage facility for loading onto the carrier designated by the Government. The Contractor shall provide the Government with an ambient exposure letter that covers the time until the product leaves the Contractor's validated [**]°C storage facility. Upon transfer of the product to the Government, the responsibility for temperature control shall transfer to the Government as well as the responsibility for logging ambient exposure time (temperatures between [**] °C). The Government shall provide and place TempTale(s) on each pallet of product while the product is inside the Contractor's validated [**]°C storage facility. The Contractor shall be responsible for placing the product onto the truck(s) of the Government -designated carrier. The Government should be allowed access to the pallets at least one hour prior to the loading of the pallets to place the TempTale(s) on the pallets. The Government's acceptance of the aforementioned responsibility applies only to temperature control and does not indicate its acceptance of the lot(s).

E.3.2 FOB Destination Deliveries: The Contractor shall be responsible for maintaining product temperature control until the point that SNS personnel (or SNS-designated personnel) open the truck door(s) at the delivery location. The time the truck door(s) is(are) opened will be documented according to the DSNS Receiving procedure as well as on the Contractor's controlled receiving log. The time recorded on the Contractor's controlled receiving log will be verified and annotated by the SNS personnel and used as the official time for the opening of the truck door(s). At this time, the responsibility for temperature control will transfer to SNS as well as the responsibility for logging ambient exposure time (temperatures between [**]°C). TempTale(s) will continue recording ambient temperature until the lot(s) is(are) stored in SNS' storage facility. The Government's acceptance of the aforementioned responsibility applies only to temperature control and does not indicate its acceptance of the lot(s).

E.4 DSNS Quality Control Unit (QCU) Acceptance Procedure for BioThrax (AVA)

At the time the product is picked up by DSNS personnel or delivered to a designated DSNS delivery location all AVA product will be placed into DSNS Quarantine pending receipt of the required lot distribution documentation and the remaining ambient exposure time letter from the Contractor. The Contractor shall supply the Government:

a. Notification of practices that may impact DSNS shipping procedures, if applicable

b. All items outlined in Section F.3.

E.4.1 Acceptance Process and Timeframe (FOB Origin Delivery)

1) Contractor shall deliver to the Government, via e-mail or facsimile:

   a) All required documentation outlined in Sections F.3.2

   b) Notification of the date and time that the product was delivered (Picked Up by the Government or Delivered In Place).

2) Acceptance Timeframe: The Government shall have [**] full business days, after receipt of all documentation required per Section E.4.1.1), to establish that the requirements of Section E.5 have been satisfied and provide Contractor notice that SNS accepts the lot(s).

   a) For purposes of this acceptance timeframe, business days are defined as 9:00AM to 5:00PM Eastern Time, Monday through Friday, excluding U.S. Government Holidays.

   b) For the avoidance of doubt, DSNS shall provide the Contractor with a written acceptance or refusal of BioThrax® lot(s) no later than 5:00PM on the [**] business day after receipt of the documentation.

E.4.2 Acceptance Process and Timeframe (FOB Destination Delivery only)

Contractor shall have the option to ship product for delivery to the SNS, at no additional cost to the Government, up to [**] times per calendar year. COR consent for Contractor delivery under this option is required. It is anticipated that consent for delivery will not be unreasonably withheld, conditioned or delayed by the Government, and it is recognized that the Government requires time to make arrangments for planned deliveries. In the event that delivery under this option can't be worked out between the COR and the Contractor, or is denied, the COR must coordinate the issue with the Contracting Officer (CO). The Contractor can appeal a significant delay or denial with the CO and DSNS management and have an appeal addressed at least in a preliminary manner, within [**] business days.

1) The Contractor shall request consent from the COR for Contractor delivery under this option at least [**] days prior to the planned delivery time so that arrangements can be made to accept delivery. If possible, the Contracting Officer shall provide Contractor with the SNS location and point of contact information for the delivery [**] days prior to delivery to the SNS.

2) At least [**] hours prior to delivery to the SNS, Contractor shall provide to the Government:

   a) Certificate(s) of Analysis

   b) FDA Lot Releases

   c) Number of pallets, vials and doses to be delivered

   d) Name of Security Representative who will be accompanying the delivery

   e) Estimated Time of Arrival for the delivery at the SNS location

3) With each shipment, contractor will provide:

   a) Bill of Lading

   b) Packing Slip

   c) Shipping Directives

   d) Contractor's shipping instructions for Drivers

   e) Identification Number for truck(s)

   f) Diagram of product shipment pallet (how many vials per box, per pallet and positioning in truck(s))

4) Within [**] business days after delivery, Contractor shall provide to the Contracting Officer:

   a) Confirmation from the Contractor's Quality Department that the product remained within the acceptable temperature ranges during shipping.

   b) The remaining ambient exposure time for each lot from the Contractor's Quality Department.

   c) Post-Transit product delivery checklist

5) Acceptance Timeframe: Following the receipt of the lot distribution documentation in Section E.4.2 parts 1 through 4 ("Documentation") from the Contractor, DSNS will have a maximum of [**] business days to provide written notification to Contractor of acceptance or refusal of the delivered BioThrax lot(s). Contractor shall provide DSNS the Documentation via email or facsimile. If the Documentation is sent by the Contractor and received by DSNS prior to 9:00AM on a given business day, the tolling of the [**] allotted business days set forth in the acceptance timeframe shall begin on that business day. If the Documentation is sent by Contractor and received by DSNS after 9:00AM on a given business day, the tolling of the [**] business days set forth in the acceptance timeframe will begin on the next business day.

   a) For purposes of this acceptance timeframe, business days are defined as 9:00AM to 5:00PM Eastern Time, Monday through Friday, excluding U.S. Government Holidays.

   b) For the avoidance of doubt, DSNS shall provide the Contractor with a written acceptance or refusal of BioThrax® lot(s) no later than 5:00PM on the [**] business day after receipt of the documentation.

E.5 DSNS QCU Release for BioThrax (AVA)

The DSNS QCU recommends that the temperature acceptance range for AVA, using the temperature monitoring device accuracy of [**]°C, would be [**]°C to [**]°C. This temperature is consistent with licensed label specifications ([**]°C to [**]°C) and takes into account Emergent rounding practices (memo dated 8/12/09) , and the accuracy of the temperature monitoring device (TempTale Bio).

TempTale device alarms will be set for shipments to alert for possible temperature deviations for further evaluation. DSNS QCU will review the temperature data for SNS internal processes. As a clarification and guide for SNS, the table below outlines temperature limits acceptable during the period that Contractor is responsible for maintaining product temperature control and the resulting actions under each scenario. This table is based on the TempTale with an accuracy of [**]°C. If any of the following changes occur while the Government is responsible for temperature monitoring and control, DSNS QCU will seek guidance from the Contractor:

Temperature Range	Action
< [**]°C	· AVA Pallet will be placed into DSNS quarantine pending further disposition
[**]°C	· Acceptable for use by the SNS
[**]°C	· AVA Pallet will be placed into DSNS quarantine · Release of product by QCU will be pending quality disposition investigation, and remaining ambient exposure for the lot
>[**]°C	· AVA Pallet will be placed into DSNS quarantine pending further disposition

Temperature deviations during shipping are the responsibility of the Government for FOB Origin deliveries and the responsibility of Emergent for FOB Destination deliveries. Deviations during shipping shall not delay the Government's acceptance of the lots when FOB Origin and shall be evaluated and fully documented by the Party responsible for temperature control and monitoring in accordance with standard procedures. When deliveries are FOB Destination, deviations during shipment shall delay the Government's acceptance. Contractor shall include an Event Description and Contractor's Product Impact Assessment in the Contractor's Certification Letter, per Section E.4.2.4), for each lot impacted by such deviations. Contractor shall state in the Certification Letter that, "A Full Deviation Report, including root cause analysis and corrective and preventative actions will be submitted to the Government within [**] business days of report completion." The Party responsible for temperature control and monitoring is also responsible for root cause analysis and defining appropriate corrective and preventative actions.

Section F - Deliveries or Performance

FAR SOURCE	TITLE AND DATE
52.211-17	Delivery of Excess Quantities (Sept 1989)
52.242-15	Stop-Work Order (Aug 1989)
52.242-15 Alternate I	Stop-Work Order - Alternate I (Apr 1984)
52.242-17	Government Delay of Work (Apr 1984)
52.247-30	FOB Origin, Contractor's Facility (Feb 2006)

F.1 Period of Performance

The period of performance of this contract shall be five (5) years, from September 30, 2011 through September 29, 2016.

F.2 Product Delivery

F.2.1 Product Pick Up by SNS (FOB Origin Deliveries)

a) The delivery of BioThrax® product shall be F.O.B Origin at the Contractor designated pick up location.

b) The place of product pick up by the SNS will be provided by the Contractor to the Contracting Officer and COR at least [**] business days prior to scheduled pick up.

c) Contractor may provide a Delivery-In-Place service, fulfilling the requirements of a F.O.B Origin delivery by meeting the following requirements:

   a. Contractor shall store lot(s) to be delivered in a validated [**]°C storage facility at no additional cost to the Government for pick-up at the next scheduled delivery or [**] days after the Delivery-In-Place acceptance date, (as scheduled by the SNS), whichever comes first.

   b. Contractor shall submit all lot documentation as required under Section F.3.2 below for the lot(s) to be delivered.

      i. Pre-notification deadlines under Section F.3.2 shall not apply for Delivery-In-Place services.

      ii. Once Contractor has provided these documents, the Government's evaluation of these documents will be completed in accordance with Section E.4.1 above.

   c. Contractor maintains responsibility for temperature control until lot(s) leave the validated [**]°C storage facility per Section E.3 above.

   d. Contractor maintains responsibility for physical integrity of lot(s) until they are placed onto the SNS designated carrier per Section E.3 above.

F.2.2 Product Delivery by Emergent (FOB Destination deliveries)

a) If agreed to by the COR and/or CO in accordance with clause E.4.2, the delivery of BioThrax® product shall be F.O.B Destination at the SNS designated delivery location.

b) The place of product delivery to the SNS will be provided by the Contracting Officer to the Contractor at least [**] days prior to scheduled pick up.

c) Contractor shall ensure lot(s) are delivered via a validated [**]°C carrier at no additional cost to the Government.

d) Each BioThrax lot will be shipped to the SNS with [**] temperature monitoring devices TempTale(s) assigned for the purpose of recording ambient temperatures during shipment until the point of delivery. The temperatures recorded by the TempTale(s) will be the only temperatures analyzed to determine whether each BioThrax lot was shipped within the FDA approved temperature range.

e) Contractor shall submit all lot documentation as required under Section F.3.2 below for the lot(s) to be delivered.

   a. SNS evaluation of these documents will be completed in accordance with Section E.4.2 above.

F.3 Deliverables

F.3.1 Product Schedule

CLIN	Delivery Period	# of Doses
0001	October 1, 2011 to September 30, 2012	[**]
0002	October 1, 2012 to September 30, 2013	[**]
0003	October 1, 2013 to September 30, 2014	[**]
0004	October 1, 2014 to September 30, 2015	[**]
0005	October 1, 2015 to September 30, 2016	[**]

At the time of issuance of this contract document, formalizing the letter notice of award 200-2011-M-41852 dated September 30, 2011, [**]..

F.3.2 Delivery Documentation

For product delivered FOB Destination, the Contractor shall deliver the documentation as outlined in Section E.4.2, items 2), 3) and 4), within the timeframes specified therein, to the Contracting Officer and COR.

For product delivered FOB Origin, the Contractor shall deliver, within the specified timeframes, the following documents to the Contracting Officer and COR:

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a. At least [**] business days prior to each product pick up by the SNS, the Contractor shall provide to the Contracting Officer and COR:
    i. The delivery date:
        i. For FOB Origin deliveries, shall be the date the product will be ready for loading on the truck(s) scheduled by the SNS
        ii. For FOB Destination deliveries, shall be the date the product will arrive at the SNS designated delivery location
    ii. Physical address of the product pick up location (facility name, address, point of contact name and telephone number)
    iii. Certificate(s) of Analysis
    iv. FDA Lot Release(s)
    v. Forecasted number of 40”x48” pallets, number of vials, and doses to be loaded

b. At least [**] hours before each scheduled pick up by the SNS the Contractor shall provide the following to the Contracting Officer and COR:
    i. Packing Slip
    ii. Actual number of pallets, vials and doses to be loaded
    iii. Diagram of product shipment pallet (how many vials per box, per pallet)

c. Within [**] hours after the product has been picked up by the Government, the Contract shall provide to the Contracting Officer and COR the remaining ambient exposure time letter disclosing temperature control until the point that SNS (or SNS-designated personnel) assumed responsibility for temperature control, per Section E.3, for each lot from the Contractor’s Quality Department. The letter should indicate that the product was manufactured and released in accordance with cGMP and has met all acceptance criteria to allow for government distribution.

F.3.3 Periodic Reports

a. The Contractor shall participate in a quarterly meeting (teleconference and/or face-to-face) to discuss performance under the contract. These meetings should provide status updates and discuss on-going manufacturing, clinical, regulatory, and shipment issues as applicable. These meetings shall be coordinated by the COR and/or Contracting Officer.

b. Risk Mitigation Plan: The risk mitigation plan should identify manufacturing, quality, regulatory, and shipment risks and countermeasures to mitigate these risks. This plan should be updated annually or as deemed necessary by the Government .

c. Additional reporting requirements:

1. Contractor will notify DSNS in its quarterly reports if Contractor undertakes post-marketing commitments for Phase 4 studies in the event of emergency use authorization.

2. Contractor will provide DSNS with drafts of supplements to its BLA for BioThrax® that are material to the manufactured product and to the contract.

F.4 Excusable Delay

The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God, or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. Furthermore, the Contractor will not be in default under this contract if it is unable to deliver AVA doses in accordance with any delivery schedule because of the action or inaction of the FDA, except the extent that such action or inaction is a direct consequence of the negligence or fault of the Contractor. Additionally, the Contractor will not be in default of this contract in the event that deliveries are delayed as a result of another Government agency placing an order for AVA doses that is determined to have priority over this contract under the Defense Priority Allocation System or as a result of allocating up to 10 lots of BioThrax® to improvement programs, including fill/finish and manufacturing process improvements. The Contractor shall notify the Contracting Officer in writing within [**] business days after the excusable delay is recognized, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

Section G - Contract Administration Data

G.1 Electronic Subcontracting Reporting System (eSRS) (Dec 2005)

G.1.1 The Contractor shall register with the Electronic Subcontracts Reporting System (eSRS) for the submission of its Individual Subcontract Report (SF 294) and the Annual Summary Reports (SF 295). Before registering in eSRS, the Contractor information must be correct in Central Contractor Registration database. The eSRS is a world wide web-based application available at: http://www.esrs.gov. The eSRS website provides training and instruction for data submission.

(End of Clause)

G.2 Invoice Submission

(a) The Contractor shall submit the original contract invoice/voucher to the CDC Finance Management Office (FMO) to the following email address: fmoapinv@cdc.gov

(b) The contractor shall **simultaneously submit an invoice/voucher via email** to the cognizant contracting officer at cnp9@cdc.gov and to the cognizant CDC Contracting Officer’s Representatives at gtv4@cdc.gov and bmk7@cdc.gov.

(c) In accordance with 5 CFR part 1315 (Prompt Payment), CDC's Financial Management Office is the designated billing office for the purpose of determining the payment due date under FAR 32.904.

(d) The Contractor shall include (as a minimum) the following information on each invoice:

(1) Contractor’s Name & Address

(2) Contractor’s Tax Identification Number (TIN)

(3) Purchase Order/Contract Number and Task Order Number, if Appropriate

(4) Invoice Number

(5) Invoice Date

(6) Contract Line Item Number and Description of Item

(7) Quantity

(8) Unit Price & Extended Amount for each line item

(9) Shipping and Payment Terms

(10) Total Amount of Invoice

(11) Name, title and telephone number of person to be notified in the event of a defective invoice

(12) Payment Address, if different from the information in (c) (1).

(13) DUNS + 4 Number

G.3 Contracting Officer (Jul 1999)

G.3.1 The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.

G.3.2 No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

(End of Clause)

G.4 Project Officer/Contracting Officer's Representative

G.4.1 Performance of the work here under shall be subject to the technical directions of the designated Project Officer/Contracting Officer's Representative (COR) for this contract.

G.4.2 As used herein, technical directions are directions to the Contractor which fill in details, suggest possible lines of inquiry, or otherwise complete the general scope of work set forth herein. These technical directions must be within the general scope of work, and may not alter the scope of work or cause changes of such a nature as to justify an adjustment in the stated contract price/cost, or any stated limitation thereof. In the event that the Contractor feels that full implementation of any of these directions may exceed the scope of the contract, he or she shall notify the originator of the technical direction and the Contracting Officer in a letter separate of any required report(s) within [**] weeks of the date of receipt of the technical direction and no action shall be taken pursuant to the direction. If the Contractor fails to provide the required notification within the said [**] week period that any technical direction exceeds the scope of the contract, then it shall be deemed for purposes of this contract that the technical direction was within the scope. No technical direction, nor its fulfillment, shall alter or abrogate the rights and obligations fixed in this contract.

G.4.3 The Government Project Officer/COR is not authorized to change any of the terms and conditions of this contract. Changes shall be made only by the Contracting Officer by properly written modification(s) to the contract.

G.4.4 The Government will provide the Contractor with a copy of the delegation memorandum for the Project Officer/COR. Any changes in Project Officer's/COR delegation will be made by the Contracting Officer in writing with a copy being furnished to the Contractor.

(End of Clause)

G.5 Payment by Electronic Funds Transfer (Dec 2005)

G.5.1 The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer – Central Contractor Registration, in Section I, requires the Contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

G.5.2 In addition to Central Contractor Registration, the Contractor shall make the designation by submitting the form titled "ACH Contractor/Miscellaneous Payment Enrollment Form" to the address indicated below. The form may be obtained by contacting the CDC Financial Management Office at (404) 498-4050.

G.5.3 In cases where the Contractor has previously provided such designation, i.e., pursuant to a prior contract/order, and been enrolled in the program, the form is not required unless the designated financial institution has changed.

G.5.4 The completed form shall be mailed after award, but no later than 14 calendar days before an invoice is submitted, to the following address:

The Centers for Disease Control and Prevention
Financial Management Office (FMO)
P.O. Box 15580
Atlanta, GA 30333
Or – Fax copy to: 404-638-5342

G.6 Notification of Utilization

The USG agrees to notify the contractor of any ultimate use of the government owned vaccine provided by the Contractor to the SNS with the exception of classified information. This information is necessary for the investigation of adverse event claims and adverse event reporting.

The notice shall include the recipient, intended purpose of the use, projected date of use, number of doses, and the lot number from which the product will be used.

G.7 Contract Communications/Correspondence (Jul 1999)

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number from Page 1 of the contract.

(End of Clause)

Section H - Special Contract Requirements

H.1 Privacy Act Applicability (Apr 2000)

H.1.1 Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title45/45cfr5b_main_02.tpl

H.1.2 The Project Officer/COR is hereby designated as the official who is responsible for monitoring Contractor compliance with the Privacy Act.

H.1.3 The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act system notice.

NOTE: Clinical trials cannot be initiated until the System Notice has been published and the Contracting Officer notifies the contractor.

(End of Clause)

H.2 Non-Disclosure Agreement for Contractor and Contractor Employees (Mar 2006)

H.2.1 Contractor's employees shall sign Contractor's non-disclosure agreement (NDA) per Exhibit 1 below..

H.2.2 During the contract performance period, the Contractor is responsible for ensuring that all additional or replacement Contractor's employees, meeting criteria per H.2.1 above, sign a NDA and it is made available upon demand to the Contracting Officer and the Project Officer/COR.

H.2.3 The Contractor shall prepare and maintain a current list of employees working under NDAs provided with specific access to Sensitive But Unclassified Information as designated by the DSNS and submit to the Contracting Officer upon request during the contract period of performance. The list should, at a minimum, include: contract number, employee's name, position, date of hire and NDA requirement.

H.2.4 NDA methodology described above is preliminary at the time of issuance of this contract document, formalizing the letter notice of award 200-2011-M-41852 dated September 30, 2011. The Contractor and the Government will further discuss the NDA requirement by June 30, 2012 and will incorporate a revised version of clause H.2 via modification by July 31, 2012. The Government and the Contractor agree that the goal is to protect the Government's interests and information, and provide adequate protection of the Government's Sensitive But Unclassified (SBU) information, while not placing an undue administrative burden on the Contractor. Not all Contractor employees will be required to sign NDAs. Contractor employees with a need to know Government SBU information must sign an NDA. The Contractor must provide an initial list and annual updates to the Government listing the individual Contractor employees who are subject to and have signed NDAs applicable to this contract.

H.3 Laboratory License Requirements (May 1998)

The contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended). This requirement shall also be included in any subcontract for services under the contract.

H.4 Disposition of Information

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the Project Officer/COR, which approval shall not be unreasonably withheld, conditioned, or delayed; provided, however, that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity for submission to any

securities exchange on which the Contractor's (or parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H.5 Identification and Disposition of Data

The contractor shall be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be relevant to this contract. The contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.6 Manufacturing Standards

The Current Good Manufacturing Practice Regulation (cGMP) (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packaging of this product.

If at any time during the life of the contract, the Contractor fails to comply with the cGMP in the manufacturing, processing and packing of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by CBER and CDER, the contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the contractor fails to take such material failure is identified to cure such material failure. If the contractor fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

H.7 Prohibition on Contractor Involvement with Terrorist Activities

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to Executive Order 13224 and Public Law 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.8 Liability Protection under the PREP Act

The Public Readiness & Emergency Preparedness Act (PREP Act), Pub. L. 109-148, Division C, 119 Stat. 2818 to 2832, amended the Public Health Service Act, 42, U.S.C. 243 et seq., to provide targeted liability protections. The Government agrees that the medical countermeasure delivered by the Contractor under this contract will be administered in humans, in accordance with the declaration under the PREP Act issued by the Secretary of the Department of Health and Human Services on October 1, 2008 pursuant to section 319F-3(b) of the Public Health Service Act, 42, U.S.C 247-d-6d. The declaration provides targeted liability protections for anthrax countermeasures based on a credible risk that the threat of exposure to *Bacillus anthracis* and the resulting disease constitutes a public health emergency.

Section I - Contract Clauses

Section I-1 - Clauses Incorporated By Reference

FAR Ref	DateTitle
52.203-3	Apr-84Gratuities
52.204-4	May-11Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
52.227-1	Dec-07Authorization and Consent
52.227-2	Dec-07Notice and Assistance Regarding Patent and Copyright Infringement
52.229-3	Apr-03Federal, State, and Local Taxes
52.232-11	Apr-84Extras
52.232-18	Apr-84Availability of Funds
52.223-3	Jan-97Hazardous Material Identification and Material Safety Data.
52.233-4	Oct-04Applicable Law for Breach of Contract Claim
52.242-13	Jul-95Bankruptcy
52.243-1	Aug-87Changes - Fixed-Price
52.244-5	Dec-96Competition in Subcontracting
52.245-1	Aug-10Government Property
52.245-9	Aug-10Uses and Charges
52.247-30	Feb-06F.O.B. Origin, Contractor's Facility
52.247-34	Nov-91F.O.B. Destination
52.249-2	May-04Termination for the Convenience of the Government (Fixed-Price)
52.249-8	Apr-84Default (Fixed-Price Supply and Service)(Over the Simplified Acquisition Threshold)
352.201-70	Jan-06Paperwork Reduction Act
352.202-1	Jan-06Definitions
352.203-70	Jan-06Anti-Lobbying (Over Simplified Acquisition Threshold)
352.222-70	Jan-10Contractor Cooperation in Equal Employment Opportunity Investigations
352.223-70	Jan-06Safety and Health
352.227-70	Jan-06Publications and Publicity
352.231-71	Jan-01Pricing of Adjustments
352.242-73	Jan-06Withholding of Contract Payments
352.270-4	Jan-06Protection of Human Subjects
352.270-5	Jan-06Care of Laboratory Animals

Section I-2 - Clauses Incorporated In Full Text

I.2.1 52.212.-4 Contract Terms and Conditions—Commercial Items (June 2010)

(a) Inspection/Acceptance. The Contractor shall only tender for acceptance those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. If repair/replacement or reperformance will not correct the defects or is not possible, the Government may seek an equitable price reduction or adequate consideration for acceptance of nonconforming supplies or services. The Government must exercise its post-acceptance rights—

(1) Within a reasonable time after the defect was discovered or should have been discovered; and

(2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item

(b) Assignment. The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act (31 U.S.C. 3727). However, when a third party makes payment (e.g., use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.

(c) Changes. Changes in the terms and conditions of this contract may be made only by written agreement of the parties.

(d) Disputes. This contract is subject to the Contract Disputes Act of 1978, as amended (41 U.S.C. 601-613). Failure of the parties to this contract to reach agreement on any request for equitable adjustment, claim, appeal or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause at FAR 52.233-1, Disputes, which is incorporated herein by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.

(e) Definitions. The clause at FAR 52.202-1, Definitions, is incorporated herein by reference.

(f) Excusable delays. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement of any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch, and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(g) Invoice.

(1) The Contractor shall submit an original invoice and three copies (or electronic invoice, if authorized) to the address designated in the contract to receive invoices. An invoice must include— (i) Name and address of the Contractor;

(ii) Invoice date and number;

(iii) Contract number, contract line item number and, if applicable, the order number;

(iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;

(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;

(vi) Terms of any discount for prompt payment offered;

(vii) Name and address of official to whom payment is to be sent;

(viii) Name, title, and phone number of person to notify in event of defective invoice; and

(ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.

(x) Electronic funds transfer (EFT) banking information.

(A) The Contractor shall include EFT banking information on the invoice only if required elsewhere in this contract.

(B) If EFT banking information is not required to be on the invoice, in order for the invoice to be a proper invoice, the Contractor shall have submitted correct EFT banking information in accordance with the applicable solicitation provision, contract clause (e.g., 52.232-33, Payment by Electronic Funds Transfer—Central Contractor Registration, or 52.232-34, Payment by Electronic Funds Transfer—Other Than Central Contractor Registration), or applicable agency procedures.

(C) EFT banking information is not required if the Government waived the requirement to pay by EFT.

(2) Invoices will be handled in accordance with the Prompt Payment Act (31 U.S.C. 3903) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR Part 1315.

(h) Patent indemnity. The Contractor shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

(i) Payment.—

(1) Items accepted. Payment shall be made for items accepted by the Government that have been delivered to the delivery destinations set forth in this contract.

(2) Prompt payment. The Government will make payment in accordance with the Prompt Payment Act (31 U.S.C. 3903) and prompt payment regulations at 5 CFR Part 1315.

(3) Electronic Funds Transfer (EFT). If the Government makes payment by EFT, see 52.212-5(b) for the appropriate EFT clause.

(4) Discount. In connection with any discount offered for early payment, time shall be computed from the date of the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on the date which appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

(5) Overpayments. If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall—

(i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment including the—

(A) Circumstances of the overpayment (e.g., duplicate payment, erroneous payment, liquidation errors, date(s) of overpayment);

(B) Affected contract number and delivery order number, if applicable;

(C) Affected contract line item or subline item, if applicable; and

(D) Contractor point of contact.

(ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.

(6) Interest.

(i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the Treasury as provided in Section 611 of the Contract Disputes Act of 1978 (Public Law 95-563), which is applicable to the period in which the amount becomes due, as provided in (i)(6)(v) of this clause, and then at the rate applicable for each six-month period as fixed by the Secretary until the amount is paid.

(ii) The Government may issue a demand for payment to the Contractor upon finding a debt is due under the contract.

(iii) Final decisions. The Contracting Officer will issue a final decision as required by 33.211 if—

(A) The Contracting Officer and the Contractor are unable to reach agreement on the existence or amount of a debt within 30 days;

(B) The Contractor fails to liquidate a debt previously demanded by the Contracting Officer within the timeline specified in the demand for payment unless the amounts were not repaid because the Contractor has requested an installment payment agreement; or

(C) The Contractor requests a deferment of collection on a debt previously demanded by the Contracting Officer (see 32.607-2).

(iv) If a demand for payment was previously issued for the debt, the demand for payment included in the final decision shall identify the same due date as the original demand for payment.

(v) Amounts shall be due at the earliest of the following dates:

(A) The date fixed under this contract.

(B) The date of the first written demand for payment, including any demand for payment resulting from a default termination.

(vi) The interest charge shall be computed for the actual number of calendar days involved beginning on the due date and ending on—

(A) The date on which the designated office receives payment from the Contractor;

(B) The date of issuance of a Government check to the Contractor from which an amount otherwise payable has been withheld as a credit against the contract debt; or

(C) The date on which an amount withheld and applied to the contract debt would otherwise have become payable to the Contractor.

(vii) The interest charge made under this clause may be reduced under the procedures prescribed in 32.608-2 of the Federal Acquisition Regulation in effect on the date of this contract.

(j) Risk of loss. Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon:

(1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or

(2) Delivery of the supplies to the Government at the destination specified in the contract, if transportation is f.o.b. destination.

(k) Taxes. The contract price includes all applicable Federal, State, and local taxes and duties.

(l) Termination for the Government's convenience. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

(m) Termination for cause. The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(n) Title. Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.

(o) Warranty. The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.

(p) Limitation of liability. Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.

(q) Other compliances. The Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract.

(r) Compliance with laws unique to Government contracts. The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 18 U.S.C. 431 relating to officials not to benefit; 40 U.S.C. 3701, et seq., Contract Work Hours and Safety Standards Act; 41 U.S.C. 51-58, Anti-Kickback Act of 1986; 41 U.S.C. 265 and 10 U.S.C. 2409 relating to whistleblower protections; 49 U.S.C. 40118, Fly American; and 41 U.S.C. 423 relating to procurement integrity.

(s) Order of precedence. Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order:

(1) The schedule of supplies/services.

(2) The Assignments, Disputes, Payments, Invoice, Other Compliances, and Compliance with Laws Unique to Government Contracts paragraphs of this clause.

(3) The clause at 52.212-5.

(4) Addenda to this solicitation or contract, including any license agreements for computer software.

(5) Solicitation provisions if this is a solicitation.

(6) Other paragraphs of this clause.

(7) The Standard Form 1449.

(8) Other documents, exhibits, and attachments.

(9) The specification.

(t) Central Contractor Registration (CCR).

(1) Unless exempted by an addendum to this contract, the Contractor is responsible during performance and through final payment of any contract for the accuracy and completeness of the data within the CCR database, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain registered in the CCR database after the initial registration, the Contractor is required to review and update on an annual basis from the date of initial registration or subsequent updates its information in the CCR database to ensure it is current, accurate and complete. Updating information in the CCR does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.

(2)(i) If a Contractor has legally changed its business name, "doing business as" name, or division name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in FAR Subpart 42.12, the Contractor shall provide the responsible Contracting Officer a minimum of one business day's written notification of its intention to (A) change the name in the CCR database; (B) comply with the requirements of Subpart 42.12; and (C) agree in writing to the timeline and procedures specified by the responsible Contracting Officer.

The Contractor must provide with the notification sufficient documentation to support the legally changed name.

(ii) If the Contractor fails to comply with the requirements of paragraph (t)(2)(i) of this clause, or fails to perform the agreement at paragraph (t)(2)(i)(C) of this clause, and, in the absence of a properly executed novation or change-of-name agreement, the CCR information that shows the Contractor to be other than the Contractor indicated in the contract will be considered to be incorrect information within the meaning of the "Suspension of Payment" paragraph of the electronic funds transfer (EFT) clause of this contract.

(3) The Contractor shall not change the name or address for EFT payments or manual payments, as appropriate, in the CCR record to reflect an assignee for the purpose of assignment of claims (see Subpart 32.8, Assignment of Claims). Assignees shall be separately registered in the CCR database. Information provided to the Contractor's CCR record that indicates payments, including those made by EFT, to an ultimate recipient other than that Contractor will be considered to be incorrect information within the meaning of the "Suspension of payment" paragraph of the EFT clause of this contract.

(4) Offerors and Contractors may obtain information on registration and annual confirmation requirements via the internet at http://www.ccr.gov or by calling 1-888-227-2423 or 269-961-5757.

I.2.2 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items (Nov 2011)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.222-50, Combating Trafficking in Persons (Feb 2009) (22 U.S.C. 7104(g)).

___Alternate I (Aug 2007) of 52.222-50 (22 U.S.C. 7104(g)).

(2) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(3) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Pub. L. 108-77, 108-78).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

__ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 253g and 10 U.S.C. 2402).

_X_ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (Apr 2010) (Pub. L. 110-252, Title VI, Chapter 1 (41 U.S.C. 251 note)).

__ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (June 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

X__ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Jul 2010) (Pub. L. 109-282) (31 U.S.C. 6101 note).

__ (5) 52.204-11, American Recovery and Reinvestment Act—Reporting Requirements (Jul 2010) (Pub. L. 111-5).

_X_ (6) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Dec 2010) (31 U.S.C. 6101 note).

__ (7) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (section 740 of Division C of Pub. L. 111-117, section 743 of Division D of Pub. L. 111-8, and section 745 of Division D of Pub. L. 110-161).

__ (8) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) (15 U.S.C. 657a).

__ (9) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Jan 2011) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

__ (10) [Reserved]

__ (11)(i) 52.219-6, Notice of Total Small Business Set-Aside (Nov 2011) (15 U.S.C. 644).

__ (ii) Alternate I (Nov 2011).

__ (iii) Alternate II (Nov 2011).

__ (12)(i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644).

__ (ii) Alternate I (Oct 1995) of 52.219-7.

__ (iii) Alternate II (Mar 2004) of 52.219-7.

_X_ (13) 52.219-8, Utilization of Small Business Concerns (Jan 2011) (15 U.S.C. 637(d)(2) and (3)).

_X_ (14)(i) 52.219-9, Small Business Subcontracting Plan (Jan 2011) (15 U.S.C. 637(d)(4)).

__ (ii) Alternate I (Oct 2001) of 52.219-9.

__ (iii) Alternate II (Oct 2001) of 52.219-9.

__ (iv) Alternate III (Jul 2010) of 52.219-9.

__ (15) 52.219-13, Notice of Set-Aside of Orders (Nov 2011)(15 U.S.C. 644(r)).

__ (16) 52.219-14, Limitations on Subcontracting (Nov 2011) (15 U.S.C. 637(a)(14)).

_X_ (17) 52.219-16, Liquidated Damages—Subcon-tracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).

__ (18)(i) 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (Oct 2008) (10 U.S.C. 2323) (if the offeror elects to waive the adjustment, it shall so indicate in its offer).

__ (ii) Alternate I (June 2003) of 52.219-23.

__ (19) 52.219-25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting (Dec 2010) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323).

__ (20) 52.219-26, Small Disadvantaged Business Participation Program— Incentive Subcontracting (Oct 2000) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323).

__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011) (15 U.S.C. 657 f).

__ (22) 52.219-28, Post Award Small Business Program Rerepresentation (Apr 2009) (15 U.S.C. 632(a)(2)).

__ (23) 52.219-29 Notice of Set-Aside for Economically Disadvantaged Women-Owned Small Business Concerns (Nov 2011).

__ (24) 52.219-30 Notice of Set-Aside for Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Nov 2011).

_X_ (25) 52.222-3, Convict Labor (June 2003) (E.O. 11755).

_X_ (26) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (Jul 2010) (E.O. 13126).

_X_ (27) 52.222-21, Prohibition of Segregated Facilities (Feb 1999).

_X_ (28) 52.222-26, Equal Opportunity (Mar 2007) (E.O. 11246).

_X_ (29) 52.222-35, Equal Opportunity for Veterans (Sep 2010)(38 U.S.C. 4212).

_X_ (30) 52.222-36, Affirmative Action for Workers with Disabilities (Oct 2010) (29 U.S.C. 793).

_X_ (31) 52.222-37, Employment Reports on Veterans (Sep 2010) (38 U.S.C. 4212).

_X_ (32) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

_X_ (33) 52.222-54, Employment Eligibility Verification (Jan 2009). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

__ (34)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

__ (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

__ (35) 52.223-15, Energy Efficiency in Energy-Consuming Products (Dec 2007) (42 U.S.C. 8259b).

__ (36)(i) 52.223-16, IEEE 1680 Standard for the Environmental Assessment of Personal Computer Products (Dec 2007) (E.O. 13423).

__ (ii) Alternate I (Dec 2007) of 52.223-16.

_X_ (37) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Aug 2011) (E.O. 13513).

_X_ (38) 52.225-1, Buy American Act—Supplies (Feb 2009) (41 U.S.C. 10a-10d).

__ (39)(i) 52.225-3, Buy American Act—Free Trade Agreements—Israeli Trade Act (June 2009) (41 U.S.C. 10a-10d, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, Pub. L. 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, and 110-138).

__ (ii) Alternate I (Jan 2004) of 52.225-3.

__ (iii) Alternate II (Jan 2004) of 52.225-3.

__ (40) 52.225-5, Trade Agreements (Nov 2011) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).

_X_ (41) 52.225-13, Restrictions on Certain Foreign Purchases (June 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

__ (42) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).

__ (43) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).

__ (44) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 255(f), 10 U.S.C. 2307(f)).

__ (45) 52.232-30, Installment Payments for Commercial Items (Oct 1995) (41 U.S.C. 255(f), 10 U.S.C. 2307(f)).

_X_ (46) 52.232-33, Payment by Electronic Funds Transfer—Central Contractor Registration (Oct 2003) (31 U.S.C. 3332).

__ (47) 52.232-34, Payment by Electronic Funds Transfer—Other than Central Contractor Registration (May 1999) (31 U.S.C. 3332).

__ (48) 52.232-36, Payment by Third Party (Feb 2010) (31 U.S.C. 3332).

__ (49) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

__ (50)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

__ (ii) Alternate I (Apr 2003) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

__ (1) 52.222-41, Service Contract Act of 1965 (Nov 2007) (41 U.S.C. 351, et seq.).

__ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 1989) (29 U.S.C. 206 and 41 U.S.C. 351, et seq.).

__ (3) 52.222-43, Fair Labor Standards Act and Service Contract Act—Price Adjustment (Multiple Year and Option Contracts) (Sep 2009) (29 U.S.C. 206 and 41 U.S.C. 351, et seq.).

__ (4) 52.222-44, Fair Labor Standards Act and Service Contract Act—Price Adjustment (Sep 2009) (29 U.S.C. 206 and 41 U.S.C. 351, et seq.).

__ (5) 52.222-51, Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment—Requirements (Nov 2007) (41 351, et seq.).

__ (6) 52.222-53, Exemption from Application of the Service Contract Act to Contracts for Certain Services—Requirements (Feb 2009) (41 U.S.C. 351, et seq.).

__ (7) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Mar 2009) (Pub. L. 110-247).

__ (8) 52.237-11, Accepting and Dispensing of $1 Coin (Sept 2008) (31 U.S.C. 5112(p)(1)).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records—Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Apr 2010) (Pub. L. 110-252, Title VI, Chapter 1 (41 U.S.C. 251 note)).

(ii) 52.219-8, Utilization of Small Business Concerns (Dec 2010) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $650,000 ($1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(iii) [Reserved]

(iv) 52.222-26, Equal Opportunity (Mar 2007) (E.O. 11246).

(v) 52.222-35, Equal Opportunity for Veterans (Sep 2010) (38 U.S.C. 4212).

(vi) 52.222-36, Affirmative Action for Workers with Disabilities (Oct 2010) (29 U.S.C. 793).

(vii) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(viii) 52.222-41, Service Contract Act of 1965 (Nov 2007) (41 U.S.C. 351, et seq.).

(ix) 52.222-50, Combating Trafficking in Persons (Feb 2009) (22 U.S.C. 7104(g)).

___Alternate I (Aug 2007) of 52.222-50 (22 U.S.C. 7104(g)).

(x) 52.222-51, Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (Nov 2007) (41 U.S.C. 351, et seq.).

(xi) 52.222-53, Exemption from Application of the Service Contract Act to Contracts for Certain Services-Requirements (Feb 2009) (41 U.S.C. 351, et seq.).

(xii) 52.222-54, Employment Eligibility Verification (Jan 2009).

(xiii) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Mar 2009) (Pub. L. 110-247). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xiv) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

I.2.3 52.217-6 Option for Increased Quantity. (Mar 1989)

The Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within any time during the period of performance Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

(End of clause)

I.2.4 52.217-7 Option for Increased Quantity—Separately Priced Line Item. (Mar 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within any time during the period of performance. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

(End of clause)

I.2.5 52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 66 months.

(End of clause)

Section J - List of Attachments

[Note to SEC for confidential treatment review: Exhibit 4 was not attached to the agreement by the parties.]

Section K - Representations, Certifications, and Other Statements of Offerors

Online Representations and Certification Application (ORCA) (Dec 2005)

(a) All Contractors are required to complete electronic annual representations and certifications at http://orca.bpn.gov in conjunction with registration in the Central Contractor Registration (CCR) database per FAR 4.1102 and FAR 4.1201. Certifications in ORCA are required prior to the submission of contract proposals.

(b) Contractors shall update the representations and certifications submitted to ORCA as necessary, but at least annually, to ensure they are kept current, accurate, and complete. All Contractors with current contracts shall notify the Contracting Officer in writing when changes are made to ORCA. The representations and certifications are effective until one year from date of submission or update to ORCA.

(End of Clause)

SUMMARY OF RELATED ACTIVITIES

The following specific information must be provided by the offeror pertaining to the Project Director, Principal Investigator, and each of any other proposed key professional individuals designated for performance under any resulting contract.

a. Identify the total amount of all presently active federal contracts/cooperative agreements/grants and commercial agreements citing the committed levels of effort for those projects for each of the key individuals* in this proposal.

Professional's Name and Title/Position:

Identifying Number	Agency	Total Effort Committed

*If an individual has no obligation(s), so state.

b. Provide the total number of outstanding proposals, exclusive of the instant proposal, having been submitted by your organization, not presently accepted but in an anticipatory stage, which will commit levels of effort by the proposed professional individuals*.

Professional's Name and Title/Position:

Identifying Number	Agency	Total Effort Committed

*If no commitment of effort is intended, so state.

C. Provide a statement of the level of effort to be dedicated to any resultant contract awarded to your organization for those individuals designated and cited in this proposal.

Name	Title/Position	Total Proposed Effort

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy. Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
ORIGINAL CONTINUATION EXEMPTION	GRANT CONTRACT FELLOWSHIP COOPERATIVE AGREEMENT OTHER	
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project (*Respond to one of the following*)
This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. _____, the expiration date _____ IRB Registration No. _____

This Assurance, on file with (*agency/dept*) _____ covers this activity.
Assurance No. _____, the expiration date _____ IRB Registration/Identification No. _____ (*if applicable*)

No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph _____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: Full IRB Review on (date of IRB meeting) _____ or Expedited Review on (date)
If less than one year approval, provide expiration date _____
This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.

10. Name and Address of Institution

11. Phone No. *(with area code)*

12. Fax No. *(with area code)*

13. Email:

14. Name of Official

15. Title

16. Signature

Date

Authorized for Local Reproduction

Sponsored by HHS

Instructions for Protection of Human Subjects Assurance identification/

IRB Certification/Declaration of Exemption Form

Box 1: Check Request Type: Original (New Award), Continuation, or Exemption (Do Not Use)

Box 2: Check Type of Award Mechanism: Grant, Contract, Cooperative Agreement, Fellowship, Other

Box 3:: Insert **National Institute of Justice** as Name of Federal Department or Agency

Box 4: List Title of Application

Box 5: List Name as requested

Box 6: For Assurance Status of this Project, four options for response are provided:

Option 1) Assurance on file with HHS and IRB has approved. (NOTE: The Federalwide Assurance number, expiration date, and IRB registration number must be provided here. The Certification of IRB review and approval must also be provided.)

Option 2) Assurance on file with another Federal agency or department and IRB has approved. (NOTE: The Assurance number, expiration date, and IRB registration number must be provided here. The Certification of IRB review and approval must also be provided.)

Option 3) No Assurance has been filed. The institution declares that it will provide and Assurance and Certification of IRB review and approval upon request.

All applicants should check the third option unless the applicant has already submitted this research application to and received approval or exemption from an IRB with an Assurance on file.

Option 4) Exemption Status: Use this option only if one of the exemptions listed in the regulation applies. Your IRB approval of exemption memo must be provided, or you may apply for an exemption from NIJ. See Exemption Request Information.

Box 7: For Certification of IRB Review, if an Assurance is on file (that is, if Option 1 or 2 was selected in Box 6), two options for response are provided.

Option 1) Select this option if IRB approval was provided for this project, provide the date and indicate whether the approval was the result of a Full or Expedited IRB Review.

Option 2) Select this option if this project has not yet received IRB certification.

Box 8: Comments: If applicable, indicate that "This project will not involve human subjects."

Box 10-17: Complete as indicated. The signing official must be a representative of the applicant institution, i.e., Director, Office of Sponsored Research or Chair, IRB.

DISCLOSURE OF LOBBYING ACTIVITIES
Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action:	**2. Status of Federal Action:**	**3. Report Type:**
a. contract	a. bid/offer/application	a. initial filing
b. grant	b. initial award	b. material change
c. cooperative agreement	c. post-award	**For Material Change Only:**
d. loan		year _____ quarter _____
e. loan guarantee		date of last report _____
f. loan insurance		

4. Name and Address of Reporting Entity:
Prime **Subawardee**
Tier _____, *if known*:

5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:

Congressional District, *if known*:

Congressional District, *if known*: 4c

6. Federal Department/Agency:	**7. Federal Program Name/Description:** CFDA Number, *if applicable*: _____
8. Federal Action Number, *if known:*	9. **Award Amount**, *if known*: $
10. a. Name and Address of Lobbying Registrant *(if individual, last name, first name, MI)*:	**b. Individuals Performing Services** *(including address if different from No. 10a)* *(last name, first name, MI)*:
11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.	Signature: Print Name: Title: Telephone No.: Date:
Federal Use Only:	Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks “Subawardee,” then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., “RFP-DE-90-001.”

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, State and zip code of the lobbying registered under the Lobbying Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

(b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a). Enter Last Name, First Name, and Middle Initial (MI).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

ACH VENDOR/MISCELLANEOUS PAYMENT

ENROLLMENT FORM

This form is used for Automated Clearing House (ACH) payments with an addendum record that contains payment-related information processed through the Vendor Express Program.

PRIVACY ACT STATEMENT

The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 U.S.C. 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to vendor’s financial institution. Failure to provide the requested information may delay or prevent the receipt of payments.

AGENCY INFORMATION

FEDERAL PROGRAM AGENCY
Centers for Disease Control & Prevention

AGENCY IDENTIFIER:	AGENCY LOCATION CODE (ALC):	ACH FORMAT:

CDC 7509-0421 CCD+ CTX CTP

ADDRESS
P. O. Box 15580, MS D06

Atlanta, GA 30333

CONTACT PERSON:
Customer Service

TELEPHONE NUMBER:
(404) 718-8100

ADDITIONAL INFORMATION
FAX: (404) 638-5342

PAYEE/COMPANY INFORMATION

PAYEE/COMPANY NAME:

SSN or TAXPAYER ID NO.

ADDRESS:

DUNS+4 NUMBER

CITY STATE ZIP

CONTACT PERSON/NAME:

TELEPHONE NUMBER:

FINANCIAL INSTITUTION INFORMATION

FINANCIAL INSTITUTION NAME:

ADDRESS (OR BRANCH):

CITY: STATE: ZIP:

NINE-DIGIT ROUTING TRANSIT NUMBER:

DEPOSITOR ACCOUNT NUMBER:

TYPE OF ACCOUNT:
CHECKING SAVINGS

ACH COORDINATOR NAME OR AUTHORIZED OFFICIAL AT FINANCIAL INSTITUTION (NOT REQUIRED): TELEPHONE NUMBER:

CDC 0.4433 (E), CDC Adobe Acrobat 9.0, S508 Electronic Version, January 2009

SMALL BUSINESS SUBCONTRACTING PLAN

DATE OF PLAN: _____

CONTRACTOR:
ADDRESS:

DUN & BRADSTREET NUMBER:
SOLICITATION OR CONTRACT NUMBER:
ITEM/SERVICE (Description):

TOTAL CONTRACT AMOUNT:$_____
Total contract or Base-Year, if options

$_____	$_____	$_____	$_____
Option #1 (if applicable)	Option #2 (if applicable)	Option #3 (if applicable)	Option #4 (if applicable)

TOTAL MODIFICATION AMOUNT, IF APPLICABLE $
TOTAL TASK ORDER AMOUNT, IF APPLICABLE $
PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year):

The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this outline has been designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable. It is not intended to replace any existing corporate plan that is more extensive. Failure to include the essential information of FAR Subpart 19.7 may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.

If assistance is needed to locate small business sources, contact the Office of Small and Disadvantaged Business Utilization (OSDBU) at 202.690.7300 or the OPDIV Small Business Specialist at _____. Sources may also be obtained from the Central Contractor Registration's (CCR) web site at http://www.ccr.gov.

For this procurement, HHS expects all proposed subcontracting plans to contain the following goals at a minimum: 34% for Small Business; 6.4% for Small Disadvantaged Business; 5.0% for Women-Owned Small Business; 3.0% for HUBZone Small Business; and 3.0% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business. These goals shall be expressed as percentages of the total estimated subcontracting dollars. **The offeror is required to include an explanation for a category that has zero as a goal.**

NOTE TO CONTRACTORS: Please provide your CCR number with your Dunn & Bradstreet number.

1. Type of Plan (check one)

[ ] ***Individual plan*** (all elements developed specifically for this contract and applicable for the full term of this contract).

[ ] ***Master plan*** (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.

[ ] ***Commercial products/service plan*** This plan is used when the contract sells products and services customarily used for non-government purposes. Plan/goals are negotiated with the initial agency on a company-wide basis rather than for individual contracts. The plan is effective only during the year approved. The contractor must provide a copy of the initial agency approval, and must submit an annual SF-295 to HHS with a breakout of subcontracting prorated for HHS (with an OPDIV breakdown, if possible).

2. Goals

State separate dollar and percentage goals for Small Business (SB), Small Disadvantaged Business (SDB), Woman-owned Small Business (WOSB), Historically Underutilized Business Zone (HUBZone) Small Business, Veteran-owned Small Business (VOSB), Service-Disabled Veteran-owned Small Business (SDVOSB) and "Other than small business" (Other) as subcontractors, for the base year and each option year, as specified in FAR 19.704. (Break out and append option year goals, if the contract contains option years or project annual subcontracting base and goals under commercial plans.)

a. Total estimated dollar value of ALL planned subcontracting, i.e., with ALL types of concerns under this contract is $_____ (b + h = a) (Base Year)

FY-_____(1st Option) FY-_____(2nd Option) FY-_____(3rd Option) FY-_____(4th Option)

$_____&_____% $_____&_____% $_____&_____% $_____&_____%)

b. Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES (including SDB, WOSB, HUBZone, VOSB, and SDVOSB):

(% of "a") $_____ and _____% (Base Year)

FY-_____(1st Option) FY-_____(2nd Option) FY-_____(3rd Option) FY-_____(4th Option)
$_____&_____% $_____&_____% $_____&_____% $_____&_____%)

c. Total estimated dollar and percent of planned subcontracting with SMALL DISADVANTAGED BUSINESSES: (% of "a") $_____ and _____% (Base Year)

FY-_____(1st Option) FY-_____(2nd Option) FY-_____(3rd Option) FY-_____(4th Option)
$_____&_____% $_____&_____% $_____&_____% $_____&_____%)

d. Total estimated dollar and percent of planned subcontracting with WOMEN-OWNED SMALL BUSINESSES: (% of "a") $_____ and _____% (Base Year)

FY-_____(1st Option) FY-_____(2nd Option) FY-_____(3rd Option) FY-_____(4th Option)
$_____&_____% $_____&_____% $_____&_____% $_____&_____%)

e. Total estimated dollar and percent of planned subcontracting with HUBZone SMALL BUSINESSES:

(% of "a") $_____ and _____% (Base Year)

FY-_____(1st Option) FY-_____(2nd Option) FY-_____(3rd Option) FY-_____(4th Option)
$_____&_____% $_____&_____% $_____&_____% $_____&_____%)

f. Total estimated dollar and percent of planned subcontracting with VETERAN SMALL BUSINESSES:

(% of "a") $_____ and _____% (Base Year)

FY-_____(1st Option) FY-_____(2nd Option) FY-_____(3rd Option) FY-_____(4th Option)
$_____&_____% $_____&_____% $_____&_____% $_____&_____%)

g. Total estimated dollar and percent of planned subcontracting with SERVICE-DISABLED VETERAN SMALL BUSINESSES:

(% of "a") $_____ and _____% (Base Year)

FY-_____(1st Option) FY-_____(2nd Option) FY-_____(3rd Option) FY-_____(4th Option)
$_____&_____% $_____&_____% $_____&_____% $_____&_____%)

h. Total estimated dollar and percent of planned subcontracting with "OTHER THAN SMALL BUSINESSES":

(% of "a") $_____ and _____% (Base Year)

FY-_____(1st Option) FY-_____(2nd Option) FY-_____(3rd Option) FY-_____(4th Option)
$_____&_____% $_____&_____% $_____&_____% $_____&_____%)

Notes:

1. Federal Prime contract goals

   SB equals 30.32%; SDB equals 11.12%; HUBZone equals 3.03%, WOSB equals 5.05% and SDVOSB equals 3%, VOSB equals 3% and can serve as objectives for subcontracting goal development.

2. SDB, WOSB, HUBZone, SDVOSB and VOSB goals are subsets of SB and should be counted and reported in multiple categories, as appropriate.

3. If any contract has more than four options, please attach additional sheets showing dollar amounts and percentages.

i. Provide a description of ALL the products and/or services to be subcontracted under this contract, and indicate the size and type of business supplying them (check all that apply).

Product/Service	Other	SB	SDB	WOSB	HUBZoneSB	VOSB	SDVOSB

j. Provide a description of the method used to develop the subcontracting goals for SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns and explain the method used to identify potential sources for solicitation purposes. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain how the areas to be subcontracted to SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns were determined, how the capabilities of these concerns were considered for subcontract opportunities and how such data comports with the cost proposal. Identify any source lists or other resources used in the determination process. (Attach additional sheets, if necessary.)

k. Indirect costs have [ ] have not [ ] been included in the dollar and percentage subcontracting goals above (check one).

l. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns.

3. Program Administrator:

NAME/TITLE:

ADDRESS:

TELEPHONE/E-MAIL:

Duties: Does the individual named above have general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans and perform the following duties:

[ ] yes [ ] no

(If NO is checked, please indicate who in the company performs those duties, or indicate why the duties are not performed in your company.)

a. Develops and promotes company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns; and assures that these concerns are included on the source lists for solicitations for products and services they are capable of providing; [ ] yes [ ] no

b. Develops and maintains bidder source lists of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns from all possible sources; [ ] yes [ ] no

c. Ensures periodic rotation of potential subcontractors on bidder's lists; [ ] yes [ ] no

d. Ensures that SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB businesses are included on the bidders' list for every subcontract solicitation for products and services that they are capable of providing; [ ] yes [ ] no

e. Ensures that Requests for Proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns; [ ] yes [ ] no

f. Reviews subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB participation; [ ] yes [ ] no

g. Accesses various sources for the identification of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns to include the Central Contractor Registration's (CCR) web site at (http://www.ccr.gov), the National Minority Purchasing Council Vendor Information Service, the Office of Minority Business Data Center in the Department of Commerce, local small business and minority associations, contact with local chambers of commerce and Federal agencies' Small Business Offices; [ ] yes [ ] no

h. Establishes and maintains contract and subcontract award records; [ ] yes [ ] no

i. Participates in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc; [ ] yes [ ] no

j. Ensures that SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company; [ ] yes [ ] no

k. Conducts or arranges for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended; [ ] yes [ ] no

l. Monitors the company's subcontracting program performance and makes any adjustments necessary to achieve the subcontract plan goals; [ ] yes [ ] no

m. Prepares and submits timely, required subcontract reports; [ ] yes [ ] no

n. Coordinates the company's activities during the conduct of compliance reviews by Federal agencies; [ ] yes [ ] no; and

o. Other duties:

4. Equitable Opportunity

Describe efforts the offeror will make to ensure that SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not limited to, the following activities:

a. Outreach efforts to obtain sources:

1. Contacting minority and small business trade associations; 2) contacting business development organizations and local chambers of commerce; 3) attending SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB procurement conferences and trade fairs; 4) requesting sources from the Central Contractor Registration's (CCR) web site at (hhtp://www.ccr.gov) and other SBA and Federal agency resources. Contractors may also conduct market surveys to identify new sources, to include, assessing the NIH e-Portals in Commerce, (e-PIC), (http://epic.od.nih.gov/). The NIH e-Portals in Commerce is not a mandatory source and may be used at the offeror's discretion.

b. Internal efforts to guide and encourage purchasing personnel:

1. Conducting workshops, seminars, and training programs;

2. Establishing, maintaining, and utilizing SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB source lists, guides, and other data for soliciting subcontractors; and

3. Monitoring activities to evaluate compliance with the subcontracting plan.

c. Additional efforts:

5. Flow Down Clause

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of $500,000 ($1,000,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." (Flow down is not applicable for commercial items/services as described in 52.212-5(e) and 52.244-6(c).)

6. Reporting and Cooperation

The contractor gives assurance of (1) cooperation in any studies or surveys that may be required; (2) submission of periodic reports which show compliance with the subcontracting plan; (3) submission of Standard Form (SF) 294, "Subcontracting Report for Individual Contracts," and attendant Optional Form 312, SDB Participation Report, if applicable, *(required only for contracts containing the clause 52.219-25)* and SF 295, "Summary Subcontract Report," in accordance with the instructions on the forms; and (4) ensuring that subcontractors agree to submit Standard Forms 294 and 295.

Reporting Period	Report Due	Due Date
Oct 1 – Mar 3	SF-294	4/30
Apr 1 – Sept 30	SF-294	10/30
Oct 1 – Sept 30	SF-295	10/30
Contract Completion	OF-312	30 days after completion

Special instructions for commercial plan: SF-295 Report is due on 10/30 each year for the previous fiscal year ending 9/30.

a. Submit SF-294 to cognizant Awarding Contracting Officer.

b. Submit Optional Form 312, (OF-312), if applicable, to cognizant Awarding Contracting Officer.

c. Submit SF-295 to cognizant Awarding Contracting Officer and to the:

Office of Small and Disadvantaged Business Utilization

Department of Health and Human Services

200 Independence Avenue, SW

Humphrey H. Building, Room 517-D

Washington, D.C. 20201

d. Submit "information" copy of the SF-295 and the SF-294 upon request to the SBA Commercial Market Representative (CMR); visit the SBA at http://www.sba.gov/gc and click on assistance directory to locate your nearest CMR.

7. Record keeping

In accordance with FAR 19.704(a)(11), the following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:

a. SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB source lists, guides and other data identifying such vendors;

b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB sources;

c. On a contract-by-contract basis, records on all subcontract solicitations over $100,000, which indicate for each solicitation (1) whether SB, SDB, WOSB, HUBZone, VOSB, and/or SDVOSB concerns were solicited, if not, why not and the reasons solicited concerns did not receive subcontract awards.

d. Records to support other outreach efforts, e.g., contacts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;

e. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program and requirements; and

f. On a contract-by-contract basis, records to support subcontract award data including the name, address, and business type and size of each subcontractor. (This item is not required on a *contract-by-contract basis* for company or division-wide commercial plans.)

g. Other records to support your compliance with the subcontracting plan: (Please describe)

8. Timely Payments to Subcontractors

FAR 19.702 requires your company to establish and use procedures to ensure the timely payment of amounts due pursuant to the terms of your subcontracts with small business concerns, small disadvantaged small business concerns, women-owned small business concerns, HUBZone small business concerns, veteran-owned small business concerns, and service-disabled veteran-owned small business concerns.

9. Description of Good Faith Effort

Maximum practicable utilization of small, small disadvantaged, women-owned, HUBZone, veteran-owned, and service-disabled veteran-owned small business concerns as subcontractors in Government contracts is a matter of national interest with both social and economic benefits. **When a contractor fails to make a good faith effort to comply with a subcontracting plan, these objectives are not achieved, and 15 U.S.C. 637(d)(4)(F) directs that liquidated damages shall be paid by the contractor.** In order to demonstrate your compliance with a good faith effort to achieve the small, small disadvantaged, women-owned, HUBZone, veteran-owned, and service-disabled veteran-owned small business subcontracting goals, outline the steps your company plans to take. These steps will be negotiated with the contracting officer prior to approval of the plan.

SIGNATURE PAGE

Signatures Required:

This subcontracting plan was submitted by:

Signature:
Typed Name:
Title:
Date:

This plan was reviewed by:

Signature:
Typed Name:
Title:
Date:

This plan was reviewed by:

Signature:
Typed Name:
Title:
Date:

This plan was reviewed by:

Signature:
Typed Name:
Title:
Date:

And is Accepted By:

Signature:
Typed Name:
Title:
Date:

Exhibit 10.5

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Asterisks denote omissions.

CONSULTING AGREEMENT

This Consulting Agreement ("***Agreement***"), effective as of September 6, 2011 ("***Effective Date***"), is made by and between Emergent BioSolutions Inc. ("***Emergent***"), with a principal office at 2273 Research Blvd. Suite 400 Rockville, MD 20850, and **Robert Kramer** ("***Consultant***"), with a principal office at 6872 Oleander Lane Portage, MI 49024. Emergent and Consultant are hereinafter referred to individually as "***Party***" or collectively as the "***Parties***". The Parties hereby agree as follows:

1. Services; Work Orders. Consultant agrees to perform certain services ("***Services***") for Emergent as mutually agreed from time to time in a fully-executed statement of work (each, a "***Work Order***"). The initial Work Order is attached hereto as Exhibit A. Each Work Order shall identify the Services to be performed, the person(s) providing Services, applicable milestones and deliverables, and the fees and total maximum compensation. If Consultant is requested or required to perform work beyond the Services necessarily contemplated by or specifically set forth in an applicable Work Order, any such additional work and an appropriate adjustment to amounts payable shall be negotiated in good faith and mutually agreed upon in writing prior to the performance thereof. If any Affiliate of Emergent enters into a Work Order with Consultant, for purposes of such Work Order and this Agreement "Emergent" shall mean and refer to such Affiliate, and "Parties" shall mean and refer to such Affiliate and Consultant. "***Affiliate***" shall mean any direct or indirect, current or future subsidiary of a Party, or any other entity controlled by, under common control with, or which controls such Party. "***Control***" shall mean direct or indirect possession of at least fifty percent (50%) of another entity's voting equity (or other comparable interest for a non-corporation), or the power to direct or cause the direction of the management or policies of such entity whether through ownership of securities, by contract or otherwise. Unless otherwise explicitly noted in a Work Order, this Agreement supersedes any provision of any Work Order or other document that is inconsistent with this Agreement.

2. **Federally-funded Services.** In the event that Emergent uses a Federal grant or contract as the source of funding for any Services, Emergent shall notify Consultant and may require, as a condition of such grant or contract and for continued eligibility for such federal funding, that the Parties comply with additional contract provisions, including certain clauses of the Federal Acquisitions Regulation, agency supplements, policy directives or other terms and conditions ("***Flowdown Provisions***"). Emergent shall have the right to include applicable Flowdown Provisions in the relevant Work Order, and Consultant shall comply with such Flowdown Provisions. If Flowdown Provisions require Emergent to submit detailed and certified cost or pricing data for Consultant's performance of Services, Consultant shall promptly provide and certify such non-proprietary data as is reasonably required to permit Emergent to comply with the Flowdown Provisions. Consultant shall also provide any other cost or pricing data as is required for Consultant to comply with the Flowdown Provisions. Notwithstanding any indemnification provision(s) of this Agreement to the contrary, unless otherwise specified in the applicable Work Order, Consultant shall indemnify and hold harmless Emergent for any cost or price reduction effected by the Federal Government, to the extent caused by (a) certified cost or pricing data submitted by Consultant or its permitted subcontractors that is not accurate, current or complete as certified by Consultant, or (b) the failure of Consultant or its permitted subcontractors to disclose and consistently follow applicable cost accounting practices and standards or otherwise comply with the Flowdown Provisions (including any regulations promulgated by the Cost Accounting Standards Board).

3. **Performance Standards.** Services shall be provided in accordance with the terms of this Agreement, specific requirements of the Work Order, and best industry standards applicable thereto. Consultant shall (a) provide the facilities and supplies necessary to perform Services unless otherwise specified in an applicable Work Order, (b) report to the authorized contact(s) identified in the applicable Work Order or such other person(s) as Emergent or its Affiliates may designate from time to time in writing, (c) provide Emergent with deliverables and reports described in the applicable Work Order or such other reports as Emergent or its Affiliates may from time to time request, and (d) not subcontract with or otherwise engage or consult any third party to provide Services or any part thereof without Emergent's prior written consent.

4. **Payment**. Emergent shall compensate Consultant for Services rendered based on invoices submitted by Consultant under the applicable Work Order and in accordance with the terms of this Agreement. All invoices shall reference the Emergent Accounting Codes designated in the applicable Work Order. Invoices shall be payable within twenty (20) days of receipt by Emergent. To protect against the possibility that the internal Revenue Service may deem Consultant's relationship with Emergent to be that of an "employee," Emergent will withhold and timely remit on behalf of Consultant federal and state income taxes at the applicable statutory rates. Consultant acknowledges that notwithstanding the withholding of taxes, Consultant is and remains an independent service provider. Consultant shall be fully responsible for payment of any other taxes or payment which may be due and owing by Consultant as the result of fees or amounts paid to it by Emergent under this Agreement, and Consultant shall indemnify and hold harmless Emergent from and against any such tax or payment. Payment of an invoice, net of applicable income taxes, shall be in full compensation for the corresponding Services performed unless expressly otherwise agreed in writing by the Parties. Consultant shall not receive employee benefits (such as paid vacation, sick leave or any insurance benefits) from Emergent even if Consultant is physically situated at Emergent's offices.

5. **Expenses**. Emergent shall pay for or reimburse Consultant for out-of-pocket expenses reasonably incurred in the performance of Services in addition to the compensation detailed in the applicable Work Order. Consultant shall submit monthly invoices detailing expenses incurred during the immediately preceding month by appropriate category and shall provide supporting documentation as is acceptable to Emergent in its reasonable discretion. Expenses shall not be marked up. All travel must be in accordance with the Emergent Corporate Travel, Food and Lodging Policy, a copy of which will be provided separately to Consultant. This Agreement relates to the provision of Services only. In the event Consultant deems it necessary to purchase equipment, goods, software or other tangible or intangible property for which it will seek reimbursement from Emergent, no such purchase shall be made and Emergent shall not be responsible for reimbursement to Consultant unless Consultant has received Emergent's express, prior written authorization.

6. **Confidential Information**. Consultant acknowledges that this Agreement creates a confidential relationship between the Parties, and that, in order to perform the Services, Consultant or its members, principals, directors, shareholders, officers, employees, agents, affiliates and advisors (collectively, "***Representatives***") may need to have access to certain commercially valuable, proprietary, and non-public information that Emergent considers to be Confidential Information. "***Confidential Information***" means any and all written, oral, electronic, graphic or other information relating directly or indirectly to Emergent or the business, products, markets, customers, suppliers, condition (financial or otherwise), operations, assets, liabilities, results of operations, cash flows or prospects of Emergent that is delivered, disclosed or furnished by or on behalf of Emergent to Consultant or its Representatives, whether before, on or after the Effective Date hereof, or which Consultant or its Representatives otherwise learns or obtains, through observation or through analysis of such information, and shall also be deemed to include all notes, analyses, compilations, studies, forecasts, interpretations or other documents prepared by Consultant or its Representatives to the extent such material contains, reflects or is directly based upon, in whole or in part, such information. Confidential Information may include, without limitation, technical information, business plans, identification or characterization of biological or other materials, results and/or design of experiments or preclinical or clinical testing, know-how, trade secrets, methods, methodologies, designs, specifications, clinical protocols, data, inventions, improvements, intellectual properties, devices, processes, procedures, financial analysis, accounting policies and procedures, employee staffing, employee compensation and benefits, manuals and marketing and advertising strategies disclosed directly or indirectly by Emergent to Consultant (whether prepared by Emergent, its advisors or otherwise). The existence, terms and conditions of this Agreement shall also be considered Confidential Information. Consultant agrees to keep confidential and not, without the prior written consent of Emergent, publish, disclose to any third party or use (except for purposes of performance under this Agreement) any Confidential Information. The obligations of this paragraph do not pertain to information which is generally known or hereafter becomes generally known to the public through no fault of Consultant or which is disclosed by Consultant with the written approval of Emergent. Consultant shall return all Confidential Information to Emergent upon completion of the corresponding Services hereunder or upon Emergent's request. Consultant shall be entitled to disclose Confidential Information as required by applicable law, regulation or court order only to the extent necessary to comply therewith; *provided, however*, Consultant shall, if reasonably practicable, provide Emergent an opportunity to seek to prevent disclosure of, or to obtain a protective order for, such Confidential Information by giving advance written notice of such required disclosure; *provided further*, that Consultant shall make such required disclosures in consultation with Emergent and shall cooperate with Emergent in connection with efforts to obtain any protective order or other remedy.

7. **Ownership of Work**. Consultant shall promptly disclose to Emergent in writing all data, information, documents, materials and inventions relating to or arising out of Services, and agrees that all right, title, and interest in and to the foregoing shall belong to and be the property of Emergent. Consultant hereby assigns all its rights in the foregoing to Emergent and agrees, without further payment by Emergent, to make any further assignments and execute all documents necessary to effect Emergent's title thereto in all countries of the world. All documents and materials prepared by Consultant in the performance of Services constitute works-for-hire and shall belong to and be the exclusive property of Emergent, and shall be surrendered by Consultant to Emergent upon request.

8. **Independent Contractor**. With respect to the subject matter hereof, the Parties are and remain independent contractors. This Agreement shall not be deemed to create an employer/employee relationship, joint venture, partnership, association, or agency between the Parties. Consultant is not authorized to incur or create any obligation (express or implied) on behalf of Emergent or to bind Emergent in any manner whatsoever.

9. **Term; Termination**. This Agreement is effective as of the Effective Date and shall continue in effect for 18 months thereafter or until the Agreement otherwise terminates under this Section ("***Term***"); *provided, however*, that in the event that any Work Order or amendment thereto is then pending, the Term shall be automatically extended until the Services to be provided thereunder are completed. This Agreement (or any Work Order, as applicable) shall terminate upon the expiration of the Term or the first to occur of (a) the date Emergent provides Consultant with written notice (setting out with particularity) that this Agreement is being terminated for "cause" where Consultant: (i) commits any act of embezzlement, theft or fraud against Emergent; (ii) is convicted of a felony or any crime involving moral turpitude, whether or not related to Services; (iii) commits any act of gross negligence or willful misconduct; or (iv) breaches the representations, warranties or covenants contained in this Agreement; or (b) the date either Party terminates the Agreement for convenience on not less than thirty (30) days' prior written notice. Upon termination of this Agreement, Emergent shall have no further liability other than for payment in accordance with the terms of this Agreement for Services provided prior to the termination date. If this Agreement is terminated by Emergent under the foregoing subsection (a)(iv), in the event that Consultant materially breaches the representations, warranties or covenants contained in Sections 10(a), 10(d), and 11, in addition to any other rights or remedies available at law or in equity, Consultant will surrender any claim for payment under the Agreement and will refund any payments received under this Agreement. The provisions of Sections 4 – 7, 9, 11 – 15, 16 (only for the applicable period following termination or expiration) and 17 shall survive the expiration or termination of this Agreement for any reason.

10. **Representations and Warranties**. In addition to any other representations and warranties set forth in this Agreement, Consultant represents and warrants that Consultant: (a) will perform Services in a competent, diligent and workmanlike manner consistent with the expected industry standards of professional conduct; (b) has not ever been debarred, and any Consultant representative who provides any portion of the Services has not been debarred, pursuant to the United States Food, Drug and Cosmetic Act, or been excluded from any federal health care program (including Medicare or Medicaid), and Consultant will notify Emergent immediately if any of the foregoing occurs; (c) will perform Services for Emergent and has been advised of the restrictions and obligations set forth in this Agreement, including without limitation, the requirements of confidentiality, compliance with laws and non-solicitation; (d) has full power to enter into and fully perform this Agreement and has the full and unrestricted right to disclose to Emergent any information Consultant makes available to Emergent under this Agreement; and (e) in the event Consultant is employed by a third party, Consultant has verified that the Services do not present a conflict with Consultant's primary employment and that Consultant has the right and authority to enter into this Agreement and to comply with the requirements of Section 7 (Ownership of Work).

11. **Compliance with Laws**. Consultant shall perform its duties and responsibilities hereunder in accordance with the highest standards of ethical business conduct and not engage in any acts or activities that are illegal or that may adversely affect or reflect upon the business, integrity or goodwill of Emergent. Consultant shall take no action that it believes might cause (or be construed as causing) Emergent to be in violation of international, federal, state or local laws or regulations, or Emergent's policies and procedures. Consultant further agrees, to the extent applicable to performance of the Services, to abide by the Emergent BioSolutions Code of Conduct and Business Ethics policy as posted from time to time on the company's website. Without limiting the generality of the foregoing, Consultant represents, warrants and agrees that Consultant will: (a) comply with all applicable laws, rules and regulations, including those governing employment practices (including employee recruiting and hiring), anti-bribery, anti-corruption and anti-gratuities laws or other similar laws; (b) comply with Emergent stated policies and procedures generally applicable to parties operating at Emergent's offices, including those governing safety, health, harassment, and discrimination; (c) prohibit its staff or any representatives from involvement with the payment or giving of anything of value, either directly or indirectly, to an official of any government, political party or official thereof, any candidate for foreign political office, or any official of an international organization, for the purpose of influencing an act or decision in its official capacity, or inducing that official to use influence with any government, to assist Emergent in obtaining or retaining business for or with, or directing business to, any person, or for obtaining an improper advantage; and (d) certify in writing, at such times as may be requested by Emergent, that Consultant and its Representatives understand, have complied with and are in compliance with the foregoing. Consultant will immediately advise Emergent if Consultant should learn of or have reason to believe that there has been a violation of any of the foregoing undertakings.

12. **Export Control Restrictions**. Each Party acknowledges that, in the course of exchanging Confidential Information, it may desire to have access to certain information about the production and/or development of materials that is subject to export controls by the U.S. Department of Commerce and requires a specific license from that agency before such technology can be transferred outside the United States or disclosed in the United States to nationals of other countries (unless such individuals have been granted U.S. citizenship, permanent residence, or asylee status) ("***Controlled Technology***"). Each Party agrees that Controlled Technology will not be transferred or "released" (as that term is defined in Title 15 CFR Sect. 734.2(b)(3)) to the other Party unless and until the disclosing Party notifies the prospective receiving Party that such information constitutes Controlled Technology and the prospective receiving Party agrees in writing to receive such Controlled Technology, and that any such ultimate disclosure or "release" shall be provided under a license or as may be otherwise authorized by the laws of the United States.

13. **Indemnification**. Consultant shall hold harmless and indemnify Emergent, its employees, agents and representatives, from and against any and all suits, demands, losses, damages, judgments, claims, costs (including reasonable attorneys' fees and costs) or other liabilities (including claims for personal injury or death) to the extent arising from or relating to the performance of Services under this Agreement, or the negligence, acts or omissions of Consultant or any of Consultant's Representatives.

14. **Dispute Resolution**. All disputes or claims arising hereunder that cannot be resolved by the Parties shall be submitted to non-binding mediation for a period of thirty (30) days, which may be extended by written agreement of the Parties. If such dispute is not resolved through mediation or otherwise within the specified period, either Party may pursue remedies available to it at law or in equity, subject to the terms of this Agreement.

15. Non-Solicitation. Consultant agrees that, during the Term and for a period of twelve (12) consecutive months after termination of the Agreement, Consultant will not knowingly (i) directly induce or attempt to induce or otherwise counsel, advise, solicit or encourage any employee to leave the employ of Emergent or accept employment with Consultant or any other person or entity, except for employees of Emergent that are being managed out an employment relationship with Emergent with the assistance of human resources, (ii) directly induce or attempt to induce or otherwise counsel, advise, solicit or encourage any person who at the time of such inducement, counseling, advice, solicitation or encouragement had left the employ of Emergent within the previous six (6) months to accept employment with any person or entity besides Emergent, except for employees of Emergent that are being managed out an employment relationship with Emergent with the assistance of human resources, or (iii) solicit, interfere with, or endeavor to cause any customer, client, or business partner of Emergent to cease or reduce its relationship with Emergent or induce or attempt to induce any such customer, client, or business partner to breach any agreement that such customer, client, or business partner may have with Emergent.

16. Restriction on Insider Trading. Emergent BioSolutions Inc. is a publicly traded company on the New York Stock Exchange. Consultant acknowledges the existence of laws and regulations prohibiting "insider trading," including the purchase or sale of securities of a company while in the possession of material information that has not been generally disclosed in the marketplace. Consultant acknowledges and agrees that it may have access to certain material nonpublic information of Emergent BioSolutions Inc. or its Affiliates as a result of the Services, and covenants and agrees that it will not engage in insider trading or disclose such information to any third parties.

17. Force Majeure. Neither Party shall be liable for delay or failure in the performance of any of its obligations under this Agreement if and to the extent such delay or failure is due to circumstances beyond the reasonable control of such Party, including but not limited to fires, floods, explosions, accidents, acts of God, war, riot, strike, lockout or other concerted acts of workers, acts of government and shortages of materials. The Party claiming force majeure shall use its commercially reasonable efforts to eliminate or prevent the cause so as to continue performing its obligations under this Agreement. During such time that the event of force majeure causes such a delay or failure of performance, this Agreement and the Parties' obligations and responsibilities under it shall be deemed suspended until the event of force majeure ceases.

18. Miscellaneous Provisions.

(a) Non-Waiver. No delay by or omission of any Party in exercising any right, power, privilege, or remedy shall impair such right, power, privilege, or remedy or be construed as a waiver thereof.

(b) Remedies. The rights and remedies provided in this Agreement are cumulative and are not exclusive of other rights or remedies provided by law.

(c) Notices. Any notice hereunder shall be given by first class mail, express mail, or facsimile (followed by confirmation), addressed to the Parties at the addresses given in the preamble of this Agreement, or to such other address as a Party may later designate in writing to the other Party. Notice of any legal action, claim or other legal matter given by Consultant to Emergent shall be directed to Emergent's General Counsel at 2273 Research Boulevard, Rockville, Maryland, USA 20850.

(d) Use of Name. Neither Party shall use the name, tradename or trademark of the other Party in a press release, advertising, publicity or promotional activity without the prior written consent of the other Party.

(e) Severability. In the event that any section or any part of a section of this Agreement should be declared void, invalid, or unenforceable by any court of law, for any reason, such a determination shall not render void, invalid, or unenforceable any other section or any part of any other section of this Agreement and the remainder of this Agreement shall remain in full force and effect.

(f) Headings. Headings and titles of parts and sections are for convenience only and have no interpretative significance.

(g) Assignability. This Agreement may not be assigned by Consultant without Emergent's prior, express written consent. Emergent may, without Consultant's written consent, assign and transfer this Agreement to any Affiliate, in which event Consultant agrees to continue to perform the duties and obligations according to the terms hereof to or for such assignee or transferee of this Agreement.

(h) Amendments. No modification or amendment to this Agreement or any Work Order shall be effected by or result from the receipt, acceptance, signing or acknowledgement of any purchase order, quotation, invoice, shipping document or other business form containing terms or conditions different from those set forth in this Agreement or any Work Order, and all such additional terms and conditions are hereby specifically rejected by both Parties.

(i) Governing Law and Jurisdiction. This Agreement and its interpretation shall be governed by the laws of Maryland without reference to its conflict of law or choice of law provisions. Any action commenced by a Party to enforce the terms of this Agreement must be brought in the courts of the jurisdiction where the Services were primarily delivered hereunder, and the Parties hereby irrevocably consent to the jurisdiction and venue of such courts to enforce the terms of this Agreement. **The Parties expressly waive any right that they have or may have to a jury trial of any dispute arising out of or in any way related to this Agreement, or any breach thereof**.

(j) Integration; Counterparts; Signatures. This Agreement and any Work Orders (including any corresponding Exhibits), constitute the entire agreement of the Parties, supersede all prior discussions, negotiations and understandings verbal and written, if any, and may only be amended or modified by a written agreement signed by both Parties. In the event of a conflict between the terms of this Agreement and the terms of any Work Order, Exhibit or attachment hereto, proposal, quotation or any Consultant documentation, the terms of this Agreement shall prevail. This Agreement may be signed in multiple identical copies, each of which shall be deemed to be an original copy, and each facsimile or electronic copy shall constitute a legally binding, enforceable document. Electronic signatures shall not be an acceptable means of execution unless both Parties have agreed in writing to the format and standard of such signature.

(k) Advice of Counsel. EACH PARTY ACKNOWLEDGES THAT, IN EXECUTING THIS AGREEMENT, SUCH PARTY HAS HAD THE OPPORTUNITY TO SEEK THE ADVICE OF INDEPENDENT LEGAL COUNSEL, AND HAS READ AND UNDERSTOOD ALL OF THE TERMS AND PROVISIONS OF THIS AGREEMENT. THIS AGREEMENT SHALL NOT BE CONSTRUED AGAINST ANY PARTY BY REASON OF THE DRAFTING OR PREPARATION HEREOF.

IN WITNESS WHEREOF, Emergent and Consultant have executed this Agreement to be effective as of the Effective Date.

Emergent BioSolutions Inc.	Robert Kramer
By: /s/ Daniel J. Abdun-Nabi	/s/ Robert Kramer
Name: Daniel J. Abdun-Nabi	
Title: President	
Date: September 9, 2011	

Exhibit A

Work Order

This Work Order, effective as of ***September 6, 2011*** ("***Effective Date***"), is made by and between **Emergent BioSolutions Inc.** ("***Emergent***") and **Robert Kramer** ("***Consultant***"), and is a "Work Order" under the Consulting Agreement dated as of **September 6, 2011**, between Emergent and Consultant ("***Agreement***"). Capitalized terms used but not defined herein shall have the meaning ascribed to such terms in the Agreement.

1. Description of Services:

[**]

2. Period of Performance: Up to 18 months

3. Person(s) providing Services: Robert Kramer

4. Reports: Consultant shall provide the Emergent Representative with such reports as requested by Emergent from time to time.

5. Fees and Maximum Compensation:

Fees: **Monthly payment of $37,500**
Maximum Compensation: $450,000 per year.
Based upon your individual performance, along with the Corporations' overall performance the company grant RSUs up to 20,000 shares, subject to Compensation Committee approval, at or near the completion of the twelfth month of the period of performance.

6. Invoicing and Payment: Invoices shall be sent to and payments made in accordance with the terms of the Agreement, and the following shall apply:

Manner/Location for Payments: First-class mail to Consultant business address

Accounting Codes (Must be noted on invoices for payment to be processed):

G/L No.: **650881** **Cost Center:** **10045**

Project Code (if applicable):

Emergent Address for Invoices: Emergent BioSolutions Inc.
300 Professional Drive, Suite 250
Gaithersburg, Maryland 20879
Attn: Accounts Payable

7. Expenses: Reimbursable in accordance with the terms of the Agreement.

8. Contacts: **Consultant Notices**: President & COO

Emergent Representative: General Counsel

Exhibit 10.6

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Asterisks denote omissions.

AMENDMENT TO
CONSULTING AGREEMENT

This **Amendment to Consulting Agreement** (the "**Amendment**") is effective as of January 1, 2012 (the "**Effective Date**") by and between Emergent BioSolutions Inc. ("**Emergent**"), with a principal office at 2273 Research Blvd. Suite 400 Rockville, MD 20850, and Robert Kramer ("**Consultant**"), with a principal office at 6872 Oleander Lane Portage, MI 49024.

WHEREAS, Emergent and Consultant executed a Consulting Agreement effective as of September 6, 2011 (the "**Agreement**"); and

WHEREAS, Emergent and Consultant desire to amend the Agreement as set forth herein; and

WHEREAS, the 2012 Project Focus set forth under the Description of Services on the Work Order attached to the Agreement as Exhibit A states that goals will be agreed by all parties; and

WHEREAS, Emergent and Consultant have now come to an agreement on the goals to be included in the 2012 Project Focus.

NOW THEREFORE, in consideration of the mutual covenants herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be bound, agree as follows:

1. Amendments.

a. The Description of Services set forth in the Work Order attached to the Agreement as Exhibit A be and hereby is amended to reflect the 2012 Project Focus set forth on Schedule 1 attached to this Amendment.

2. No further Amendments. Except for those amendments and modifications specifically set forth above, the Agreement is not being modified or amended in any way.

EMERGENT BIOSOLUTIONS INC.	Robert Kramer
By:/s/Daniel J. Abdun-Nabi Name:Daniel J. Abdun-Nabi Title:President and CEO	By:/s/Robert G. Kramer Name:Robert G. Kramer Title:_____

SCHEDULE 1

to
AMENDMENT TO CONSULTING AGREEMENT
between
EMERGENT BIOSOLUTIONS INC. AND ROBERT KRAMER

Description of Services:

[**]

EXHIBIT 31.1

CERTIFICATION

I, Daniel Abdun-Nabi 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: May 4, 2012

/s/Daniel Abdun-Nabi
Daniel Abdun-Nabi
Chief Executive Officer

EXHIBIT 31.2

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: May 4, 2012

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

EXHIBIT 32.1

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 three months ended March 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Daniel Abdun-Nabi, 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: May 4, 2012

/s/Daniel Abdun-Nabi
Daniel Abdun-Nabi
Chief Executive Officer

EXHIBIT 32.2

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 three months ended March 31, 2012 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: May 4, 2012

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