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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010

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). o 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 o Smal ler reporting company
(Do not check if a smaller reporting company)

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

As of October 29, 2010, the registrant had 34,720,191 shares of common stock outstanding.

Emergent BioSolutions Inc.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our ability to perform under our contract with the U.S. government for sales of BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, including the timing of deliveries;
- our ability to perform under our contract with the U.S. government to develop and obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55, our large-scale vaccine manufacturing facility in Lansing, Michigan;
- our ability to perform under our contract with the U.S. government to develop our recombinant protective antigen anthrax vaccine product candidate;
- our plans for future sales of BioThrax, including our ability to obtain new procurement and development contracts from the U.S. government;
- our efforts to pursue label expansions and improvements for BioThrax;
- our efforts to expand our manufacturing facilities and capabilities;
- the rate and degree of market acceptance and clinical utility of our products and product candidates;
- our ongoing and planned product development programs, preclinical studies and clinical trials;
- our ability to identify and acquire or in-license products and product candidates that satisfy our selection criteria;
- our ability to successfully integrate the operations, products, product candidates and personnel of any businesses that we may acquire, including Trubion Pharmaceuticals, Inc., which we acquired in October 2010;
- the potential benefits of our existing or planned collaborations;
- the timing of, and our ability to obtain and maintain, regulatory approvals for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property portfolio;
- our ability to sell two buildings classified on our balance sheet as assets held for sale; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

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

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

PART I. FINANCIAL INFORMATION

ITEM 1. ***FINANCIAL STATEMENTS***

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

	September 30, 2010	December 31, 2009
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 151,229	$ 102,924
Restricted cash	215	215
Accounts receivable	7,937	54,872
Inventories	17,320	13,521
Note receivable	10,000	10,000
Deferred tax assets, net	2,239	1,870
Income tax receivable, net	13,206	2,574
Prepaid expenses and other current assets	8,690	7,838
Total current assets	210,836	193,814
Property, plant and equipment, net	141,257	131,834
Assets held for sale	12,930	13,960
Deferred tax assets, net	86	3,894
Other assets	1,128	1,187
Total assets	$ 366,237	$ 344,689
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 22,518	$ 17,159
Accrued expenses and other current liabilities	1,300	1,570
Accrued compensation	13,749	14,926
Indebtedness under line of credit	-	15,000
Long-term indebtedness, current portion	12,038	5,791
Deferred revenue	253	255
Total current liabilities	49,858	54,701
Long-term indebtedness, net of current portion	36,225	44,927
Other liabilities	1,160	1,246
Total liabilities	87,243	100,874
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 31,350,209 and 30,831,360 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	31	31
Additional paid-in capital	130,832	120,492
Accumulated other comprehensive loss	(2,173)	(1,476)
Retained earnings	147,602	122,152
Total Emergent BioSolutions Inc. stockholders' equity	276,292	241,199
Noncontrolling interest in subsidiary	2,702	2,616
Total stockholders' equity	278,994	243,815
Total liabilities and stockholders' equity	$ 366,237	$ 344,689

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(Unaudited)		(Unaudited)	
Revenues:				
Product sales	$ 67,266	$ 39,004	$ 161,991	$ 170,012
Contracts and grants	6,720	4,268	20,933	10,970
Total revenues	73,986	43,272	182,924	180,982
Operating expenses:				
Cost of product sales	11,532	8,684	30,116	34,480
Research and development	21,156	18,772	59,680	55,362
Selling, general and administrative	20,693	19,767	54,534	55,115
Income (loss) from operations	20,605	(3,951)	38,594	36,025
Other income (expense):				
Interest income	38	426	802	1,031
Interest expense	-	(4)	-	(14)
Other income (expense), net	(1,003)	6	(1,012)	(28)
Total other income (expense)	(965)	428	(210)	989
Income (loss) before provision for (benefit from) income taxes	19,640	(3,523)	38,384	37,014
Provision for (benefit from) income taxes	7,696	(2,984)	15,088	14,130
Net income (loss)	11,944	(539)	23,296	22,884
Net loss attributable to noncontrolling interest	1,176	1,488	2,155	4,026
Net income attributable to Emergent BioSolutions Inc.	$ 13,120	$ 949	$ 25,451	$ 26,910
Earnings per share - basic	$ 0.42	$ 0.03	$ 0.82	$ 0.89
Earnings per share - diluted	$ 0.41	$ 0.03	$ 0.80	$ 0.86
Weighted-average number of shares - basic	31,301,796	30,506,661	31,094,616	30,321,873
Weighted-average number of shares - diluted	32,113,313	31,534,831	31,816,900	31,314,147

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

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

	Nine Months Ended September 30,	
	2010	2009
	(Unaudited)	
Cash flows from operating activities:		
Net income	$ 23,296	$ 22,884
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	5,206	3,645
Depreciation and amortization	4,020	3,677
Deferred income taxes	4,516	7,236
Non-cash development expenses from joint venture	2,241	6,026
(Gain) loss on disposal of property, plant and equipment	(31)	32
Provision for impairment of long-lived assets	1,029	3,818
Excess tax benefits from stock-based compensation	(1,077)	(1,555)
Changes in operating assets and liabilities:		
Accounts receivable	46,935	(858)
Inventories	(3,799)	5,156
Income taxes	(10,632)	(2,461)
Prepaid expenses and other assets	(794)	(1,031)
Accounts payable	5,990	4,372
Accrued compensation	(1,177)	2,783
Accrued expenses and other liabilities	(356)	51
Deferred revenue	(2)	23
Net cash provided by operating activities	75,365	53,798
Cash flows from investing activities:		
Purchases of property, plant and equipment	(14,042)	(14,376)
Net cash used in investing activities	(14,042)	(14,376)
Cash flows from financing activities:		
Proceeds from borrowings on line of credit	15,000	30,000
Principal payments on long-term indebtedness and line of credit	(32,454)	(47,596)
Issuance of common stock subject to exercise of stock options	4,056	4,193
Excess tax benefits from stock-based compensation	1,077	1,555
Net cash used in financing activities	(12,321)	(11,848)
Effect of exchange rate changes on cash and cash equivalents	(697)	(270)
Net increase in cash and cash equivalents	48,305	27,304
Cash and cash equivalents at beginning of period	102,924	91,473
Cash and cash equivalents at end of period	$ 151,229	$ 118,777

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

EMERGENT BIOSOLUTIONS INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Summary of significant accounting policies

Basis of presentation and consolidation

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

The unaudited consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with GAAP 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, 2009, as filed with the SEC.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of September 30, 2010, results of operations for the three and nine month periods ended September 30, 2010 and 2009, and cash flows for the nine month periods ended September 30, 2010 and 2009. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Earnings per share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except share and per share data)	**2010**	**2009**	**2010**	**2009**
Numerator:				
Net income attributable to Emergent BioSolutions Inc.	$ 13,120	$ 949	$ 25,451	$ 26,910
Denominator:				
Weighted-average number of shares - basic	31,301,796	30,506,661	31,094,616	30,321,873
Dilutive securities - stock options	811,517	1,028,170	722,284	992,274
Weighted-average number of shares - diluted	32,113,313	31,534,831	31,816,900	31,314,147
Earnings per share - basic	$ 0.42	$ 0.03	$ 0.82	$ 0.89
Earnings per share - diluted	$ 0.41	$ 0.03	$ 0.80	$ 0.86

Stock options with exercise prices in excess of the average per share closing price during the period are not considered in the calculation of fully diluted earnings per share. For the three month and nine month periods ended September 30, 2010, options to purchase approximately 1.3 million and 1.8 million shares of common stock, respectively, were excluded from this calculation. For the three and nine month periods ended September 30, 2009, options to purchase approximately 1.4 million and 1.3 million shares of common stock, respectively, were excluded from this calculation.

Accounting for stock-based compensation

As of September 30, 2010, the Company has two stock-based employee compensation plans, the Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan") and the Emergent BioSolutions Employee Stock Option Plan (the "2004 Plan" and together with the 2006 Plan, the "Emergent Plans"). The Company has granted options to purchase shares of common stock under each of the Emergent Plans, and has granted restricted stock units under the 2006 Plan.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	**2009**	**2010**	**2009**
Expected dividend yield	0%	0%	0%	0%
Expected volatility	55%	55%	55%	55%
Risk-free interest rate	0.82%	1.72%	0.82%-1.46%	1.32%-1.72%
Expected average life of options	3.29 years	3.0 years	3.41 years	3.35 years

- Expected dividend yield — the Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.
- Expected volatility — a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company analyzed the volatility of similar companies at a similar stage of development to estimate expected volatility. The volatility of these similar companies ranged from 38% to 77%, with an average estimated volatility of 55%. The Company used a rate of 55% for grants made in 2010, approximately the mid-point of this range.
- Risk-free interest rate — the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date on which the option is granted.
- Expected average life of options — the period of time that options granted are expected to remain outstanding, based primarily on the Company's expectation of optionee exercise behavior subsequent to vesting of options.

Fair value of financial instruments

The carrying amounts of the Company's short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair values due to their short maturities. The fair value of the Company's long-term indebtedness is estimated based on the current interest rates. The carrying value and fair value of long-term indebtedness at September 30, 2010 was $48.3 million and $48.1 million, respectively, and at September 30, 2009 was $39.6 million and $38.9 million, respectively.

Comprehensive income

Comprehensive income is comprised of net income and other changes in equity that are excluded from net income. The Company includes gains and losses on intercompany transactions with foreign subsidiaries that are considered to be long-term investments and translation gains and losses incurred when converting its subsidiaries' financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income. Comprehensive income for the three and nine months ended September 30, 2010 was $12.6 million and $24.8 million, respectively. Comprehensive income for the three and nine months ended September 30, 2009 was $1.0 million and $26.6 million, respectively.

Reclassifications

Certain amounts classified as inventory in the consolidated balance sheet as of September 30, 2009, and in the consolidated statement of cash flows for the nine months then ended have been reclassified as other current assets to conform with the current period presentation.

2. Inventories

Inventories consist of the following:

(in thousands)	September 30, 2010	December 31, 2009
Raw materials and supplies	$ 1,970	$ 1,565
Work-in-process	9,568	9,870
Finished goods	5,782	2,086
Total inventories	$ 17,320	$ 13,521

3. Note receivable

In 2008, the Company entered into a loan and security agreement with Protein Sciences Corporation (“PSC”) to loan PSC up to $10 million in conjunction with an agreement pursuant to which the Company would acquire substantially all of the assets of PSC. The loan is secured by substantially all of PSC’s assets, including PSC’s intellectual property. Under this loan agreement and a related promissory note, $10.0 million of principal is outstanding as of September 30, 2010, and the Company has recorded this as a note receivable. By its original terms, the note accrued interest at an annual rate of 8% and was due and payable no later than December 31, 2008. Thereafter, the note accrued interest at a default rate of 11%. In early 2009, the Company entered into a forbearance agreement with PSC, pursuant to which the note continued to accrue interest at an annual rate of 11%, and became due and payable on May 31, 2009. The Company also agreed not to foreclose on the collateral for the loan prior to May 31, 2009. Since the expiration of the forbearance agreement, the note has accrued interest at a default rate of 14%. As of September 30, 2010, the Company has recorded accrued interest on the note receivable of $1.5 million, included in prepaid expenses and other current assets.

On November 2, 2010, the Company and PSC executed a settlement agreement, whereby PSC paid the Company $11.5 million, consisting of full repayment of the original $10 million of principal plus $1.5 million in interest. In accordance with the terms of this agreement, all claims arising from the loan and security agreement and related promissory note, and from the original agreement to acquire the assets of PSC, were resolved (see Note 5, Litigation). In connection with this settlement, the Company recorded a charge of approximately $1.0 million in September 2010 to reduce the accrued interest due from PSC. This charge is reflected in the other income (expense) line in the Company’s statements of operations.

4. Stock options and restricted stock units

As of September 30, 2010, the Company has two stock-based employee compensation plans, the 2006 Plan and the 2004 Plan. The Company has granted options to purchase shares of common stock under the Emergent Plans and has granted restricted stock units under each of 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 September 30, 2010, an aggregate of 8,678,826 shares of common stock are authorized for issuance under the 2006 Plan, of which a total of 3,335,476 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 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. T he terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Emergent Plans are determined by the Company’s compensation committee, which administers the Emergent Plans. Each equity award granted under the Emergent Plans vests as specified in the relevant agreement and no 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, 2009	3,485,499	$ 12.72	130,082	$ 7.52	
Granted	804,053	15.86	-	-	
Exercised	(478,849)	8.23	(40,000)	3.50	
Forfeited	(133,732)	14.18	-	-	
Outstanding at September 30, 2010	3,676,971	$ 14.00	90,082	$ 9.30	$ 14,918,379
Exercisable at September 30, 2010	1,458,805	$ 12.05	90,082	$ 9.30	$ 9,026,708

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

	Number of Shares	Weighted-Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding at December 31, 2009	-	$ -	$ -
Granted	394,995	16.05	
Vested	-	-	
Forfeited	(7,990)	15.91	
Outstanding at September 30, 2010	387,005	$ 16.05	$ 6,679,706

5. Litigation

Litigation against Protein Sciences Corporation. Until reaching settlement with PSC on November 2, 2010, the Company had been pursuing several legal actions against PSC and its senior management arising out of a letter of intent, a loan and security agreement and related promissory note, and an asset purchase agreement between the Company and PSC that were entered into in 2008. On June 8, 2009, the Company initiated legal proceedings in the Superior Court of the State of Connecticut, Judicial District of New Haven, to acquire possession through disclosure of PSC's physical assets that secured the loan. On July 9, 2008, the Company initiated legal proceedings against PSC in the Supreme Court of the State of New York among other claims, claims for fraud, breach of contract, breach of the duty of good faith and fair dealing, unjust enrichment and unfair business practices. On October 3, 2008, the Company initiated legal proceedings in the United States District Court for the District of Connecticut against PSC's executive management team of Daniel D. Adams, PSC's Executive Chairman, and Manon M.J. Cox, PSC's President and Chief Executive Officer, alleging, among other things, that these individuals engaged in fraudulent conduct in connection with their efforts to obtain $10 million in bridge financing from the Company. On July 19, 2010, the Company filed a motion for summary judgment in lieu of complaint in the Supreme Court of the State of New York seeking repayment of its loan and interest.

On November 2, 2010, the Company and PSC entered into a settlement and mutual release of claims with respect to the letter of intent, the loan and security agreement and related promissory note and forbearance agreement, the asset purchase agreement and all other claims related thereto. Under the terms of the settlement, PSC paid the Company $11.5 million, consisting of full repayment of the original $10 million of principal plus $1.5 million in interest. At the time of this filing, the parties are in the process of filing stipulations with the relevant courts to dismiss all litigation with prejudice.

Patent Oppositions. The Company's live attenuated modified vaccinia Ankara virus ("MVA") platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based in part on rights to certain MVA-related materials and technology that the Company acquired from the Bavarian State Ministry of the Environment and Public Health. From 2006 to 2008, the Company filed patent oppositions in the European Patent Office against four of Bavarian Nordic's patents covering certain aspects of MVA technology. In each of the four pending opposition proceedings, the subject patents have also been opposed by one or more additional parties, including Sanofi Pasteu r, Transgene, Baxter, Virbac, and Innogenetics. The Company and the other opponents have alleged that the opposed patents should be revoked for failure to fulfill one or more of the patentability requirements of the European Patent Convention, such as the requirements for novelty and inventive step. In each opposition, the Company expects that a single hearing will be held before the Opposition Division of the European Patent Office, in which each opponent will present oral argument and Bavarian Nordic will present rebuttal arguments. The first of these hearings, which occurred in June 2010, resulted in the Bavarian Nordic patent under consideration being maintained but narrowed in scope. A time period has been set for all parties to file appeals, and the Company anticipates that all appeals will be filed by the due date of November 27, 2010. Hearings in two of the other pending oppositions occurred in October 2010. Bavarian Nordic introduced amended pat ent claims into the record, which claims were upheld strictly and expressly conditioned on such claims being interpreted within a narrowly-defined scope. The Opposition Division scheduled a hearing on the fourth pending opposition for January 2011. The Company routinely monitors the grant of further Bavarian Nordic European patents to determine whether any additional oppositions should be filed.

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

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

On October 8, 2010, the Defendants reached agreement in principle with the plaintiffs in the Actions regarding the settlement of the Actions. In connection with the settlement contemplated by that agreement in principle, the Actions will be stayed pending approval of the settlement of the State Action by the State Court. Thereafter, the State Action and all claims asserted therein will be dismissed with prejudice and counsel for the plaintiff in the Federal Action will take all necessary steps to dismiss the Federal Action and all claims asserted therein with prejudice. The terms of the settlement contemplated by that agreement in principle require that Trubion and the Company make certain additional disclosures related to the Acquisition, as set forth in the Company's Current Report on Form 8-K filed on October 8, 2010. The partie s also agreed that the plaintiffs in the Actions may seek attorneys' fees and costs in an aggregate amount up to $475,000, to be paid by Trubion if such fees and costs are approved by the State Court. There will be no other payment by Trubion, any of the members of the Trubion board of directors or the Company to the plaintiffs or their respective counsels in connection with the settlement and dismissal of the Actions. The agreement in principle further contemplates that the parties will enter into a stipulation of settlement, which will be subject to customary conditions, including State Court approval following notice to Trubion's shareholders. In the event that the parties enter into a stipulation of settlement, a hearing will be scheduled at which the State Court will consider the fairness, reasonableness and adequacy of the settlement. There can be no assurance that the parties will ultimately enter into a stipulation of settlement, that the State Court will approve any proposed settlement, or that any eventual settlement will be under the same terms as those contemplated by the agreement in principle.

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

6. Segment information

For financial reporting purposes, the Company reports financial information for two business segments: biodefense and commercial. In the biodefense segment, the Company develops, manufactures and commercializes vaccines and antibody therapies for use against biological agents that are potential weapons of bioterrorism or biowarfare. Revenues in this segment relate primarily to the Company's FDA-licensed product, BioThrax. In the commercial segment, the Company develops vaccines and antibody therapies for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. The "All Other" segment relates to the general operating costs of the Company and includes costs of the centralized services departments, whic h are not allocated to the other segments, as well as spending on product candidates or activities that are not classified as biodefense or commercial. The assets in this segment consist primarily of cash and fixed assets.

	Reportable Segments			
(in thousands)	**Biodefense**	**Commercial**	**All Other**	**Total**
Nine Months Ended September 30, 2010				
External revenue	$ 182,924	$ -	$ -	$ 182,924
Net income (loss) to Emergent BioSolutions Inc.	65,303	(32,378)	(7,474)	25,451
Assets	178,883	23,000	164,354	366,237
Nine Months Ended September 30, 2009				
External revenue	$ 180,770	$ 212	$ -	$ 180,982
Net income (loss) to Emergent BioSolutions Inc.	69,301	(32,506)	(9,885)	26,910
Assets	172,737	21,780	122,285	316,802

7. Related party transactions

The Company entered into an agreement in February 2009 with an entity controlled by family members of the Company's Chief Executive Officer to market and sell BioThrax. The agreement was effective as of November 2008 and requires payment based on a percentage of net sales of biodefense products of 17.5% in Saudi Arabia and 15% in Qatar and United Arab Emirates, and reimbursement of certain expenses. No payments under this agreement have been triggered for the nine months ended September 30, 2010 and 2009.

The Company entered into a severance agreement in April 2010 with the Company's former Senior Vice President, Legal Affairs and General Counsel, whose employment with the Company terminated in March 2010. Severance payments and other benefits under the agreement are substantially identical to those provided under the provisions of the Company's Severance Plan and Termination Protection Program. One-half of the amounts payable under the severance agreement was paid in September 2010, with the remaining amounts being paid in six equal monthly installments beginning in October 2010.

The Company entered into a consulting agreement in April 2010 with the Company's former Senior Vice President, Legal Affairs and General Counsel. The agreement, which was terminated in July 2010, provided for consulting and support services in connection with the Company's pending litigation with PSC. During the nine months ended September 30, 2010, the Company paid approximately $12,000 for services rendered under this agreement, of which no balance remained unpaid in accounts payable at September 30, 2010.

The Company entered into a consulting agreement in September 2010 with an entity controlled by the Company's former Senior Vice President, Corporate Affairs, who is also a family member of the Company's Chief Executive Officer. The agreement provides for consulting services in connection with special projects as assigned by the Company's President. During the nine months ended September 30, 2010, the Company paid approximately $5,000 for services rendered under this agreement, which is included in accounts payable at September 30, 2010.

The Company has entered into a transportation arrangement with an entity owned by the Company's Chief Executive Officer. For the nine months ended September 30, 2010 and 2009, the Company paid approximately $25,000 and $24,000, respectively, under this arrangement for transportation and logistical support, of which $4,000 remained in accounts payable at September 30, 2010.

The Company has entered into a consulting agreement with a member of the Company's Board of Directors. During each of the nine months ended September 30, 2010 and 2009, the Company paid approximately $135,000 under this agreement for strategic consultation and project support for the Company's marketing and communications group, of which no balance remained unpaid in accounts payable at September 30, 2010.

8. Oxford collaboration

In July 2008, the Company entered into a collaboration with the University of Oxford ("Oxford") and certain University of Oxford researchers to conduct clinical trials in the advancement of a vaccine product candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium ("OETC"). The Company has a 51% equity interest in OETC and controls the OETC Board of Directors. In addition, the Company has certain funding and services obligations of up to $20.3 million related to its investment. The Company has evaluated its variable interests in OETC and has determined that it is the primary beneficiary as it has the ability to direct the activities of OETC and will absorb the majority of expected losses. Accordingly, the Company consolidates the entity. As of Sept ember 30, 2010, assets of $229,000 and liabilities of $389,000 related to this entity are included within the Company's consolidated balance sheet. During the three and nine months ended September 30, 2010, the entity incurred net losses of $2.4 million and $4.4 million, respectively, of which $1.2 million and $2.2 million, respectively, is included in the Company's consolidated statement of operations.

In conjunction with the establishment of OETC, the Company granted a put option to Oxford and the Oxford researchers whereby the Company may be required to acquire all of the OETC shares held by Oxford and the Oxford researchers at fair market value of the underlying shares. This put option is contingent upon the satisfaction of a number of conditions that must exist or occur subsequent to the granting by the European Commission of marketing authorization for the OETC-sponsored vaccine product candidate for tuberculosis. The Company accounts for the put option in accordance with the accounting provisions related to derivatives and distinguishing liabilities from equity. In accordance with these provisions, the Company has determined that the put option has a de minimis fair value as of September 30, 2010.

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

(in thousands)	Emergent BioSolutions Inc.	Noncontrolling Interest	Total
Stockholders' equity at December 31, 2009	$ 241,199	$ 2,616	$ 243,815
Non-cash development expenses from joint venture	-	2,241	2,241
Net income (loss)	25,451	(2,155)	23,296
Other	9,642	-	9,642
Stockholders' equity at September 30, 2010	$ 276,292	$ 2,702	$ 278,994

9. Assets held for sale

The Company currently owns two buildings in Frederick, Maryland that it determined in 2009 would not be placed into service. Accordingly, the Company committed to a plan to sell the buildings, along with associated improvements. These buildings are classified on the Company's balance sheets as assets held for sale. Assets held for sale are recorded at the lower of the carrying amount or fair market value less costs to sell, and are no longer depreciated once classified as held for sale. The Company recorded the assets held for sale at fair market value, based on factors that include recent purchase offers less estimated selling costs, and recorded an impairment charge of $1.0 million for the nine months ended September 30, 2010. The charge is classified in the Company& #8217;s statement of operations as selling, general and administrative expense within the Company's commercial segment. The Company continues to actively seek to sell these buildings.

10. Subsequent Events

On October 28, 2010, the Company completed its acquisition of Trubion. As consideration for the acquisition, Emergent (i) paid an aggregate of $27.9 million in cash and issued an aggregate of 3,351,817 shares of the Company's common stock and 20,425,554 contingent value rights ("CVRs") to the holders of common stock of Trubion, and (ii) issued 1,677,827 CVRs to the holders of outstanding options to purchase Trubion common stock, which holders also received cash of approximately $3.9 million. Holders of CVRs are entitled to receive a pro rata portion of certain contingent payments following the achievement of future development milestones under collaboration agreements with Pfizer Inc. and a wholly-owned subsidiary of Abbott Laboratories. The Company has incurred transaction costs related to the acq uisition of approximately $1.3 million as of September 30, 2010, recorded in selling, general and administrative expenses in the Company's commercial segment. As of the date of this filing, the valuation of acquired intangible assets and other fair value adjustments are not complete, and as such the purchase price allocation for the transaction has not been completed.

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

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

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

Overview

Product Portfolio

We are a biopharmaceutical company focused on the development, manufacture and commercialization of vaccines and antibody therapies that assist the body's immune system to prevent or treat disease. For financial reporting purposes, we operate in two business segments, biodefense and commercial.

Our biodefense segment focuses on vaccines and antibody therapies for use against biological agents that are potential weapons of bioterrorism or biowarfare. Our products and product candidates in this segment are focused on anthrax. We manufacture and market BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. In addition to BioThrax, we are developing a recombinant protective antigen, or rPA, anthrax vaccine, an anthrax immune globulin therapeutic, an anthrax monoclonal antibody therapeutic, a next generation anthrax vaccine, and an advanced double mutant recombinant protective antigen anthrax vaccine.

Our commercial segment focuses on vaccines and antibody therapies for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. Our product candidates in this segment include a tuberculosis vaccine, a typhoid vaccine and an influenza vaccine. Additionally, through our recent acquisition of Trubion Pharmaceuticals, Inc., or Trubion, which we completed on October 28, 2010, we acquired certain clinical-stage product candidates focused on the targeted disease areas of oncology and autoimmunity and novel platform technologies for developing additional innovative therapeutic candidates. Specifically, the oncology product candidates include targeted treatments for chronic lymphocytic leukemia and non-Hodgkin's lymphoma, and the autoimmunity product candidates i nclude targeted treatments for rheumatoid arthritis and systemic lupus erythematosus.

Our biodefense segment has generated net income for each of the last five fiscal years. Over this timeframe, our commercial segment has generated revenue through development contracts and grant funding, but none of our commercial product candidates has received marketing approval and, therefore, our commercial segment has not generated any product sales revenues. As a result, our commercial 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. Department of Health and Human Services, or HHS, and the U.S. Department of Defense, or DoD, and 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 $162.0 million and $170.0 million for the nine months ended September 30, 2010 and 2009, 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 external funding awards for the following development programs:

- BioThrax post-exposure prophylaxis
- Next generation anthrax vaccine
- Large-scale manufacturing for BioThrax
- Recombinant protective antigen anthrax vaccine
- Anthrax immune globulin therapeutic
- Anthrax monoclonal antibody therapeutic
- Advanced double mutant recombinant protective antigen anthrax vaccine
- Recombinant botulinum vaccine
- Typhella™ (typhoid vaccine live oral ZH9)

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.

We continue to actively pursue additional government sponsored development contracts and grants and to 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. Prior to the award, we incurred costs of approximately $83 million for the building and associated capital e quipment, as well as for validation and qualification activities required for regulatory approval and initiation of commercial manufacture of BioThrax.

In November 2009, we purchased a building in Baltimore, Maryland for product development and manufacturing purposes, and have begun renovation and improvement of this facility. 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. As we proceed with this project, we expect the costs to be substantial and will likely seek external sources of funds to finance the project.

We also own two buildings in Frederick, Maryland that we currently expect to sell. Accordingly, we have classified these buildings as assets held for sale in our consolidated balance sheets. We recorded the assets held for sale at fair market value, based on factors that include recent purchase offers, less estimated selling costs, and recorded an impairment charge of approximately $1.0 million for the nine months ended September 30, 2010. We continue to actively seek to sell these buildings.

Critical Accounting Policies and Estimates

There have been no significant changes to our Critical Accounting Policies and Estimates during the nine months ended September 30, 2010. Refer to the Critical Accounting Policies and Estimates section in our Annual Report on Form 10-K for the year ended December 31, 2009 filed with the Securities and Exchange Commission, or SEC.

Financial Operations Overview

Revenues

On September 30, 2008, we entered into an agreement with HHS to supply up to 14.5 million doses of BioThrax for placement into the Strategic National Stockpile, or SNS. This agreement was amended in July 2010 to, among other things, allow us to accelerate the delivery of BioThrax doses into the SNS by approximately three months. The term of the agreement is from September 30, 2008 through September 30, 2011. Delivery of doses under the agreement commenced in September 2009 and will continue through June 2011. Funds for the procurement of these doses of BioThrax have been fully committed. The total purchase price for the 14.5 million doses will be up to approximately $400 million. Through September 30, 2010, we have delivered approximately 8.5 million doses under this agreement. We have agreed to provide all shipping services related to delivery of doses into the SNS over the term of the agreement, for which HHS has agreed to pay us approximately $1.9 million. We invoice under the agreement upon acceptance of each delivery of BioThrax doses to the SNS.

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

Product Candidate/Manufacturing	Funding Source	Award Date	Amount (Up to)	Performance Period
Anthrax immune globulin therapeutic	NIAID	9/2007	$9.5 million	9/2007 — 12/2011
Recombinant botulinum vaccine	NIAID	6/2008	$1.8 million	6/2008 — 5/2011
Next generation anthrax vaccine	NIAID	7/2008	$2.8 million	7/2008 — 6/2013
Anthrax monoclonal antibody therapeutic	NIAID/BARDA	9/2008	$24.3 million	9/2008 — 8/2012
Next generation anthrax vaccine	NIAID/BARDA	9/2008	$24.4 million	9/2008 — 9/2011
Advanced double mutant recombinant protective antigen anthrax vaccine	NIAID	9/2009	$4.9 million	9/2009 — 8/2011
Large-scale manufacturing for BioThrax	BARDA	7/2010	$107.0 million	7/2010 — 9/2014
Next generation anthrax vaccine	NIAID	8/2010	$28.7 million	8/2010 — 8/2014
Recombinant protective antigen anthrax vaccine	BARDA	9/2010	$186.6 million	9/2010 — 9/2015

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

Cost of Product Sales

The primary expense that we incur to deliver BioThrax to our customers is manufacturing costs, which are primarily fixed costs. These fixed manufacturing costs consist of facilities, utilities and salaries 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:

- salaries and related expenses for personnel;
- fees to professional service providers for, among other things, preclinical and analytical testing, independently monitoring 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, including those recently acquired through our acquisition of Trubion, and as we prepare for regulatory submissions and other regulatory activities. We expect that the magnitude of any increase in our research and development spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, continued participation of collaborative partners, the size, structure and duration of any follow-on clinical programs that we may initiate, costs associated with manufacturing our product candidates on a large-scale basis for later stage clinical trials, and our ability to use or rely on data generated by government agencies, such as studies with BioThrax conducted by the Centers for Disease Control and Prevention, or 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.

Total Other Income (Expense)

Total other income (expense) consists primarily of interest income and interest expense, and in 2010, a charge to reduce previously accrued interest income related to a settlement agreement with Protein Sciences Corporation, or PSC. We earn interest income on our cash, cash equivalents and a note receivable, and we incur interest expense on our indebtedness. We capitalize interest expense based on the cost of major ongoing projects which have not yet been placed in service, such as new manufacturing facilities. Some of our existing debt arrangements provide for increasing amortization of principal payments in future periods. See “Liquidity and Capital Resources — Debt Financing” for additional information.

Results of Operations

Quarter Ended September 30, 2010 Compared to Quarter Ended September 30, 2009

Revenues

Product sales revenues increased by $28.3 million, or 72%, to $67.3 million for the three months ended September 30, 2010 from $39.0 million for the three months ended September 30, 2009. This increase in product sales revenues was primarily due to a 46% increase in the number of doses of BioThrax delivered coupled with an 18% increase in the sales price per dose. Product sales revenues for the three months ended September 30, 2010 consisted of BioThrax sales to HHS of $67.2 million and aggregate other sales of $39,000. Product sales revenues for the three months ended September 30, 2009 consisted of BioThrax sales to HHS of $38.9 million and aggregate international and other sales of $117,000.

Contracts and grants revenues increased by $2.5 million, or 57%, to $6.7 million for the three months ended September 30, 2010 from $4.3 million for the three months ended September 30, 2009. The increase in contracts and grants revenue was primarily due to revenues from our recently awarded contract for development of large-scale manufacturing of BioThrax, along with increases in revenue from our advanced double mutant recombinant protective antigen anthrax vaccine and next generation anthrax vaccine development contracts. These increases were partially offset by a decrease in in revenues from our anthrax monoclonal antibody therapeutic development contract. All contracts and grants revenues for the three months ended September 30, 2010 and 2009 were from NIAID and BARDA.

Cost of Product Sales

Cost of product sales increased by $2.8 million, or 33%, to $11.5 million for the three months ended September 30, 2010 from $8.7 million for the three months ended September 30, 2009. This increase was primarily attributable to the 46% increase in the number of BioThrax doses sold, partially offset by a decrease in cost per dose sold associated with increased production yield in the period during which the doses sold were produced.

Research and Development Expense

Research and development expenses increased by $2.4 million, or 13%, to $21.2 million for the three months ended September 30, 2010 from $18.8 million for the three months ended September 30, 2009. This increase reflects higher contract service costs, and includes increased expenses of $509,000 on product candidates that are categorized in the biodefense segment and increased expenses of $2.0 million in other research and development, which are in support of technology platform development activities and central research and development activities. These increases were partially offset by decreased expenses of $105,000 on product candidates categorized in the commercial segment.

The increase in spending on biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials. The increase in spending for our next generation anthrax vaccine program was due to the preparation for and conduct of clinical and non-clinical studies. The increase in spending for our large-scale manufacturing for Biothrax program was primarily due to facility qualification and validation activities. The spending for BioThrax related programs was related to clinical and non-clinical studies to support applications for marketing approval of these programs. The decrease in spending for the rPA anthrax vaccine product candidate was primarily due to reduced spending while awaiting a development contract award from BARDA, which we received in September 2010. The increase in spending for our advanced double mutant recombinant protective antigen anthrax vaccine product candidate resulted from spending for process, formulation and assay development. The spending for our anthrax immune globulin therapeutic product candidate was primarily for clinical studies and model development. The decrease in spending for the anthrax monoclonal therapeutic product candidate was primarily due to the timing of process and formulation development. The 2009 spending for our botulinum vaccine product candidates resulted from conducting non-clinical studies. We expect that spending for our botulinum vaccine candidates will remain minimal in the future, due primarily to reduced interest from and funding by the U.S. government for these product candidates.

The decrease in spending on commercial product candidates, detailed in the table below, was primarily attributable to the timing of development efforts and to the termination or scaling back of certain programs. The spending for our tuberculosis vaccine product candidate is related to the costs incurred for the conduct of a Phase IIb clinical trial, which commenced in April 2009. The spending for Typhella was primarily due to stability and clinical studies. The increase in spending for our influenza vaccine product candidate is related to process and analytical development. The decrease in spending for our hepatitis B therapeutic vaccine product candidate was related to the cessation of the Phase II clinical trial in the United Kingdom and Serbia. We have significantly reduced ongoing spending with regard to this product c andidate while we investigate options to sell or outlicense the related technology, and expect that future spending will be reduced. We expect spending for other commercial vaccine product candidates, including group B streptococcus, chlamydia and meningitis B, will continue to be minimal in the future. In October 2010, we acquired Trubion Pharmaceuticals, Inc. and its development programs for product candidates to treat certain autoimmune diseases and cancer, including rheumatoid arthritis, systemic lupus erythematosus, chronic lymphocytic leukemia and non-Hodgkin’s lymphoma. We are currently evaluating the development requirements for these programs.

The increase in other research and development expenses was primarily attributable to spending associated with technology platform development activities and central research and development activities.

We continue to assess, and may alter, our future development plans for our products and product candidates based on a variety of factors, including the interest of the U.S. government or non-governmental and philanthropic organizations in providing funding for further development or procurement.

Our principal research and development expenses for the three months ended September 30, 2010 and 2009 are shown in the following table:

(in thousands)	Three Months Ended September 30, 2010	2009
Biodefense:		
Next generation anthrax vaccine	$ 2,423	$ 1,553
Large-scale manufacturing for BioThrax	2,607	290
BioThrax related programs	1,760	1,947
Recombinant protective antigen anthrax vaccine	840	2,359
Advanced double mutant recombinant protective antigen vaccine	1,378	72
Anthrax immune globulin therapeutic	1,104	860
Anthrax monoclonal antibody therapeutic	1,295	2,775
Botulinum vaccines	4	1,046
Total biodefense	11,411	10,902
Commercial:		
Tuberculosis vaccine	3,836	3,697
Typhella™	1,194	898
Influenza vaccine	999	599
Hepatitis B therapeutic vaccine	14	805
Other commercial vaccines	5	154
Total commercial	6,048	6,153
Other	3,697	1,717
Total	$ 21,156	$ 18,772

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $926,000, or 5%, to $20.7 million for the three months ended September 30, 2010 from $19.8 million for the three months ended September 30, 2009. This increase is primarily due to increased personnel and professional services to support the business, partially offset by lower legal service costs. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses increased by $1.0 million, or 8%, to $13.5 million for the three months ended September 30, 2010 from $12.5 million for the three months ended September 30, 2009. Selling, general and administrative expenses related to our commercial segment decreased by $81,000, or 1%, to $7.2 million for the three months ended September 30, 2010 from $7.3 milli on for the three months ended September 30, 2009.

Total Other Income (Expense)

Total other income (expense) decreased by $1.3 million to an expense of $965,000 for the three months ended September 30, 2010 from income of $428,000 for the three months ended September 30, 2009. The decrease was due primarily to a charge of approximately $1.0 million to reduce previously accrued interest income related to the settlement with PSC.

Income Taxes

Provision for (benefit from) income taxes increased by $10.7 million to a provision for income taxes of $7.7 million for the three months ended September 30, 2010 from a benefit from income taxes of $3.0 million for the three months ended September 30, 2009. The increase in income tax expense is due to a $22.9 million increase in income (loss) before provision for (benefit from) income taxes plus the loss attributable to noncontrolling interest, partially offset by the impact of utilization of foreign entity and research and development deductions during the third quarter of 2009.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest decreased by $312,000, or 21%, to $1.2 million for the three months ended September 30, 2010 from $1.5 million for the three months ended September 30, 2009. The decrease resulted from the timing of clinical and development activities and related expenses incurred by our joint venture with the University of Oxford. These amounts represent the portion of the loss incurred by the joint venture for the three months ended September 30, 2010 and 2009, respectively, that is attributable to the University of Oxford.

Nine Months Ended September 30, 2010 Compared to Nine Months Ended September 30, 2009

Revenues

Product sales revenues decreased by $8.0 million, or 5%, to $162.0 million for the nine months ended September 30, 2010 from $170.0 million for the nine months ended September 30, 2009. This decrease in product sales revenues was due to a 2% decrease in the number of doses of BioThrax delivered, along with 2009 payments from HHS of approximately $34.0 million related to the approval of four-year expiry dating for BioThrax. These deceases were partially offset by a 22% increase in the sales price per dose. Product sales revenues for the nine months ended September 30, 2010 consisted of BioThrax sales to HHS of $159.6 million and aggregate international and other sales of $2.4 million. Product sales revenues for the nine months ended September 30, 2009 consisted of BioThrax sales to HHS of $169.6 million, including approximately $34.0 mill ion related to the approval of four-year expiry dating for BioThrax, and aggregate international and other sales of $458,000.

Contracts and grants revenues increased by $10.0 million, or 91%, to $20.9 million for the nine months ended September 30, 2010 from $11.0 million for the nine months ended September 30, 2009. The increase in contracts and grants revenue was primarily due to increased revenues from development contracts for our next generation anthrax vaccine, our double mutant recombinant protective antigen anthrax vaccine, our anthrax monoclonal antibody therapeutic, and from our recently awarded contract for development of large-scale manufacturing of BioThrax. Contracts and grants revenues for the nine months ended September 30, 2010 consisted of $20.2 million in development contract and grant revenue from NIAID and BARDA and $750,000 from a milestone payment related to the 2008 sale of technology rights and related materials and documenta tion pertaining to our Pertussis technology. Contracts and grants revenues for the nine months ended September 30, 2009 consisted primarily of development contract and grant revenue from NIAID and BARDA.

Cost of Product Sales

Cost of product sales decreased by $4.4 million, or 13%, to $30.1 million for the nine months ended September 30, 2010 from $34.5 million for the nine months ended September 30, 2009. This decrease was primarily attributable to a decrease in the cost per dose sold associated with increased production yield in the period in which the doses were produced.

Research and Development Expense

Research and development expenses increased by $4.3 million, or 8%, to $59.7 million for the nine months ended September 30, 2010 from $55.4 million for the nine months ended September 30, 2009. This increase reflects higher contract service costs, and includes increased expenses of $6.3 million on product candidates that are categorized in the biodefense segment and increased expenses of $3.6 million in other research and development, which are in support of technology platform development activities and central research and development activities. These increases were partially offset by decreased expenses of $5.6 million on product candidates categorized in the commercial segment.

The increase in spending on biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials. The increase in spending for our next generation anthrax vaccine program was due to the preparation for and conduct of clinical and non-clinical studies. The increase in spending for our large-scale manufacturing of BioThrax program was primarily due to facility qualification and validation. The decrease in spending for BioThrax related programs was due to the timing of clinical and non-clinical studies to support applications for marketing approval of these programs. The decrease in spending for the rPA anthrax vaccine product candidate was primarily due to reduced spending whil e awaiting a development contract award from BARDA, which we received in September 2010. The increase in spending for our advanced double mutant recombinant protective antigen vaccine product candidate resulted from spending for process, formulation and assay development. The decrease in spending for our anthrax immune globulin therapeutic product candidate was primarily due to the timing of clinical and tolerability studies along with model development. The increase in spending for the anthrax monoclonal therapeutic product candidate was primarily due to the timing of process and assay development, stability studies and the conduct of non-clinical studies. The spending for our botulinum vaccine product candidates resulted from conducting non-clinical studies.

The decrease in spending on commercial product candidates was primarily attributable to the timing of development efforts and to the termination or scaling back of certain programs. The decrease in spending for our tuberculosis vaccine product candidate is related to the timing of costs incurred for the preparation, initiation, and conduct of a Phase IIb clinical trial, which commenced in April 2009. The decrease in spending for Typhella primarily resulted from the manufacture of clinical material and conduct of a Phase IIb clinical trial in the United States, both of which were substantially completed during 2009. The increase in spending for our influenza vaccine product candidate is related to process and analytical development. The decrease in spending for our hepatitis B therapeutic vaccine product candidate was rel ated to the cessation of the Phase II clinical trial in the United Kingdom and Serbia.

The increase in other research and development expenses was primarily attributable to spending associated with technology platform development activities and central research and development activities.

Our principal research and development expenses for the nine months ended September 30, 2010 and 2009 are shown in the following table:

	Nine Months Ended September 30,	
(in thousands)	**2010**	**2009**
Biodefense:		
Next generation anthrax vaccine	$ 6,975	$ 3,260
Large-scale manufacturing for BioThrax	6,022	1,505
BioThrax related programs	5,112	6,378
Recombinant protective antigen anthrax vaccine	2,290	6,173
Advanced double mutant recombinant protective antigen vaccine	4,470	292
Anthrax immune globulin therapeutic	4,994	5,407
Anthrax monoclonal antibody therapeutic	7,118	4,743
Botulinum vaccines	595	3,554
Total biodefense	37,576	31,312
Commercial:		
Tuberculosis vaccine	8,158	9,483
Typhella™	2,432	4,449
Influenza vaccine	2,588	1,731
Hepatitis B therapeutic vaccine	245	2,650
Other commercial vaccines	163	829
Total commercial	13,586	19,142
Other	8,518	4,908
Total	$ 59,680	$ 55,362

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $581,000, or 1%, to $54.5 million for the nine months ended September 30, 2010 from $55.1 million for the nine months ended September 30, 2009. This decrease is primarily due to a decrease of $2.8 million in the impairment charges associated with our Frederick, Maryland facilities and decrease in legal service costs, partially offset by increased personnel and professional services to support the business. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses increased by $2.4 million, or 7%, to $38.3 million for the nine months ended September 30, 2010 from $35.9 million for the nine months ended September 30, 2009. Selling, general and administrative expenses related to our commercial segment decreased by $3. 0 million, or 16%, to $16.2 million for the nine months ended September 30, 2010 from $19.2 million for the nine months ended September 30, 2009.

Total Other Income (Expense)

Total other income (expense) decreased by $1.2 million to an expense of $210,000 for the nine months ended September 30, 2010 from income of $989,000 for the nine months ended September 30, 2009. This decrease resulted primarily from a charge of approximately $1.0 million to reduce previously accrued interest income related to the settlement with PSC.

Income Taxes

Provision for income taxes increased by $958,000, or 7%, to $15.1 million for the nine months ended September 30, 2010 from $14.1 million for the nine months ended September 30, 2009. The estimated effective tax rate for the nine month periods ended September 30, 2010 and 2009 was 37% and 34%, respectively. The increase in the provision for income taxes was primarily due to the impact of the utilization of foreign entity and research and development deductions on our tax liability for the nine months ended September 30, 2009, partially offset by increased deductions for domestic manufacturing activities.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest decreased by $1.9 million, or 46%, to $2.2 million for the nine months ended September 30, 2010 from $4.0 million for the nine months ended September 30, 2009. The decrease resulted from the timing of clinical and development activities and related expenses incurred by our joint venture with the University of Oxford. These amounts represent the portion of the loss incurred by the joint venture for the nine months ended September 30, 2010 and 2009, respectively, that is attributable to the University of Oxford.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our cash requirements from inception through September 30, 2010 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, 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, 2009 and for the nine months ended September 30, 2010.

As of September 30, 2010, we had cash and cash equivalents of $151.2 million. Additionally, at September 30, 2010 our accounts receivable balance was $7.9 million.

The acquisition of Trubion in October 2010 resulted in a payment of approximately $27.9 million by us to Trubion stockholders. As a result of the acquisition, we acquired approximately $20 million of cash, cash equivalents, and investments held by Trubion at the time of the acquisition.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2010 and 2009:

(in thousands)	Nine Months Ended September 30, 2010	2009
Net cash provided by (used in):		
Operating activities(1)	$ 74,668	$ 53,528
Investing activities	(14,042)	(14,376)
Financing activities	(12,321)	(11,848)
Total net cash provided by (used in)	$ 48,305	$ 27,304

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

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

Net cash provided by operating activities of $53.5 million for the nine months ended September 30, 2009 was due principally to our net income attributable to Emergent BioSolutions Inc. of $26.9 million, a decrease in inventories of $3.9 million reflecting the value of BioThrax lots delivered, an increase in accounts payable of $4.4 million related to the timing of payment of invoices, and a net increase in income taxes related to timing differences of $4.8 million, coupled with non-cash charges of $6.0 million for development expenses from our joint venture, $3.8 million related to the impairment of our Frederick facilities, $3.7 million for depreciation and amortization and $3.6 million for stock-based compensation.

Net cash used in investing activities for the nine months ended September 30, 2010 and 2009 of $14.0 million and $14.4 million, respectively, resulted principally from the construction and related costs for Building 55, our large-scale manufacturing facility in Lansing, Michigan, and infrastructure investments and other equipment.

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

Net cash provided by financing activities of $11.8 million for the nine months ended September 30, 2009 resulted primarily from $30.0 million in proceeds from borrowings under our revolving line of credit with Fifth Third Bank, $4.2 million in proceeds from stock option exercises and $1.6 million related to excess tax benefits from the exercise of stock options, partially offset by $47.6 million in principal payments on indebtedness, including $45.0 million in payments on our revolving line of credit with Fifth Third Bank

Debt Financing

As of September 30, 2010, we had $48.3 million principal amount of debt outstanding, comprised primarily of the following:

- $2.5 million outstanding under a loan from the Department of Business and Economic Development of the State of Maryland used to finance eligible costs incurred to purchase our first facility in Frederick, Maryland;
- $5.8 million outstanding under a mortgage loan from PNC Bank used to finance the remaining portion of the purchase price for our first Frederick facility;
- $6.8 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance a portion of the purchase price for our second facility on the Frederick site;

- $21.7 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;
- $6.6 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance a portion of the purchase price of our facility in Baltimore, Maryland; and
- $4.9 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance a portion of the purchase price of our facility in Gaithersburg, Maryland.

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures and debt service requirements from existing cash and cash equivalents, revenues from BioThrax product sales, development contract and grant funding, and our existing line of credit. 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 debt 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 new facilities, and capital improvements to new or existing facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to Building 55, our large-scale manufacturing facility in Lansing, Michigan, the build out of our new facility in Baltimore, Maryland, and any other new facilities;
- our ability to sell two buildings classified on our balance sheet as assets held for sale;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the level of participation of our collaborative partners in our development programs, including those recently acquired in the acquisition of Trubion;
- 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 extent to which we lend money to, and are able to obtain repayment from, third parties;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- the extent to which we acquire or invest in companies, businesses, products and technologies;
- the extent to which we become obligated to make cash payments related to the contingent value rights issued to former holders of Trubion common stock in connection with our acquisition of Trubion that are not offset by corresponding cash inflows from our collaborative partners; and
- our ability to establish and maintain collaborations.

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 r educe our planned commercialization efforts.

Our ability to borrow additional amounts under our revolving line of credit agreement is 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 an d licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

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

Our exposure to market risk is currently confined to our cash and cash equivalents and restricted cash that have maturities of less than three months, and our long-term indebtedness. We currently do not hedge interest rate exposure or foreign currency exchange exposure, and the movement of interest rates and 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 do not believe that an increase in market rates would have a significant impact on the realized value of our investments, but would likely increase the interest cost associated with our debt.

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2010. 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 co mpany in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2010, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the quarter ended September 30, 2010 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***

Litigation Against Protein Sciences Corporation. Until reaching settlement with Protein Sciences Corporation, or PSC, on November 2, 2010, we had been pursuing several legal actions against PSC and its senior management arising out of a letter of intent, a loan and security agreement and related promissory note, and an asset purchase agreement between us and PSC that were entered into in 2008. On June 8, 2009, we initiated legal proceedings in the Superior Court of the State of Connecticut, Judicial District of New Haven, to acquire possession through foreclosure of PSC's physical assets that secure the loan. On July 9, 2008, we initiated legal proceedings against PSC in the Supreme Court of the State of New York including, among other claims, claims for fraud, breach of contract, breach of the duty of good faith and fair dealing, unjust enrichment and unfair business practices. On October 3, 2008, we initiated legal proceedings in the United States District Court for the District of Connecticut against PSC's executive management team of Daniel D. Adams, PSC's Executive Chairman, and Manon M.J. Cox, PSC's President and Chief Executive Officer alleging, among other things, that these individuals engaged in fraudulent conduct in connection with their efforts to obtain $10 million in bridge financing from us. On July 19, 2010, the Company filed a motion for summary judgment in lieu of complaint in the Supreme Court of the State of New York seeking repayment of its loan and interest.

On November 2, 2010, weand PSC entered into a settlement and mutual release of claims with respect to the letter of intent, the loan and security agreement and related promissory note and forbearance agreement, the asset purchase agreement and all other claims related thereto. Under the terms of the settlement, PSC paid us $11.5 million, consisting of full repayment of the original $10 million of principal plus $1.5 million in interest. At the time of this filing, the parties are in the process of filing stipulations with the relevant courts to dismiss all litigation with prejudice.

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

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

On October 8, 2010, the Defendants reached agreement in principle with the plaintiffs in the Actions regarding the settlement of the Actions. In connection with the settlement contemplated by that agreement in principle, the Actions will be stayed pending approval of the settlement of the State Action by the State Court. Thereafter, the State Action and all claims asserted therein will be dismissed with prejudice and counsel for the plaintiff in the Federal Action will take all necessary steps to dismiss the Federal Action and all claims asserted therein with prejudice. The terms of the settlement contemplated by that agreement in principle require that Trubion and we make certain additional disclosures related to the Acquisition, as set forth in our Current Report on Form 8-K filed on October 8, 2010. The parties also agreed that the pl aintiffs in the Actions may seek attorneys' fees and costs in an aggregate amount up to $475,000, to be paid by Trubion if such fees and costs are approved by the State Court. There will be no other payment by Trubion, any of the members of the Trubion board of directors or us to the plaintiffs or their respective counsels in connection with the settlement and dismissal of the Actions. The agreement in principle further contemplates that the parties will enter into a stipulation of settlement, which will be subject to customary conditions, including State Court approval following notice to Trubion's shareholders. In the event that the parties enter into a stipulation of settlement, a hearing will be scheduled at which the State Court will consider the fairness, reasonableness and adequacy of the settlement. There can be no assurance that the parties will ultimately enter into a stipulation of settlement, that the State Court will approve any proposed settlement, or that any eventual settlement wi ll be under the same terms as those contemplated by the agreement in principle.

Patent Oppositions. Our live attenuated modified vaccinia Ankara virus, or MVA, platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based in part on rights to certain MVA-related materials and technology that we acquired from the Bavarian State Ministry of the Environment and Public Health. From 2006 to 2008, we filed patent oppositions in the European Patent Office against four of Bavarian Nordic's patents covering certain aspects of MVA technology. In each of the four pending opposition proceedings, the subject patents have also been opposed by one or more additional parties, including Sanofi Pasteur, Transgene, Baxter, Virbac, and Innogenetics.&# 160; We and the other opponents have alleged that the opposed patents should be revoked for failure to fulfill one or more of the patentability requirements of the European Patent Convention, such as the requirements for novelty and inventive step. In each opposition, we expect that a single hearing will be held before the Opposition Division of the European Patent Office, in which each opponent will present oral argument and Bavarian Nordic will present rebuttal arguments. The first of these hearings, which occurred in June 2010, resulted in the Bavarian Nordic patent under consideration being maintained but narrowed in scope. A time period has been set for all parties to file appeals, and we anticipate that all appeals will be filed by the due date of November 27, 2010. Hearings in two of the other pending oppositions occurred in October 2010. Bavarian Nordic introduced amended patent claims into the record, which claims were upheld strictly and expressly co nditioned on such claims being interpreted within a narrowly-defined scope. The Opposition Division scheduled a hearing on the fourth pending opposition for January 2011. We routinely monitor the grant of further Bavarian Nordic European patents to determine whether any additional oppositions should be filed.

Other. We are, and may in the future become, subject to other legal proceedings, claims and litigation arising in the ordinary course of our business in connection with the manufacture, distribution and use of our products and product candidates. For example, Emergent BioDefense Operations Lansing Inc., or EBOL, was a defendant, along with many other vaccine manufacturers, in a series of lawsuits that have been filed in various state and federal courts in the United States alleging that thimerosal, a mercury-containing preservative allegedly used by the defendants in the manufacture of some vaccines, caused personal injuries, including brain damage, central nervous system damage and autism. The last of the lawsuits in which EBOL was named a defendant, which were pending in Californ ia, were dismissed without prejudice in July 2010.

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 HHS or the DoD. If HHS or DoD 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 U.S. Department of Health and Human Services, or HHS, to supply doses of BioThrax for placement into the Strategic National Stockpile, or SNS. We are not currently party to a procurement contract with the U.S. Department of Defense, or DoD, which currently procures doses of BioThrax directly from the SNS. If the SNS priorities change, or if the DoD dose requirements from the SNS are reduced, our revenues could be substantially reduced.

Our existing and prior contracts with HHS and the DoD do not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government. 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, a competitive bidding process that involves risks and requirements not present in commercial contracting.

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

- the commitment of substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- the possibility that we may be ineligible to respond to a request for proposal issued by the government;
- the submission by third parties of protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- if our competitors protest or challenge contract awards made to us pursuant to competitive bidding, the potential that we may incur or could suffer 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, or 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. For example, in December 2009, the Biomedical Advanced Research and Development Authority, or BARDA, cancelled a previously issued request for proposal for development and procurement of a recombinant protective antigen, or rPA, anthrax vaccine for the SNS for which we had submitted a proposal. BARDA subsequently issued a Broad Agency Announcement, or BAA, solely for the development of an rPA anthrax vaccine under which we were awarded a development contract in September 2010. 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 such contract awards, our growth strategy and our business, financial condition and operating results could be materially adversely affected.

Our U.S. government contracts require ongoing funding decisions by the 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 of some government programs is subject to Congressional appropriations, generally made on a fiscal year basis even though a program may continue for several years. Our government customers are subject to stringent budgetary constraints and political considerations. For example, the sale of most of the doses of BioThrax supplied under our most recent procurement contract with HHS was subject to the annual appropriations process. Additionally, our government-funded development cont racts typically consist of a base period of performance followed by successive option periods for performance of certain future activities. The value of these optional services, which options are in the sole discretion of the government, may constitute the majority of the total value of the underlying contract. 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, our business, revenues and operating results may suffer.

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

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

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

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

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

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

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

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

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

Generally, government contracts, including our HHS contracts for BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the government's convenience. Under general principles of government contracting law, if the government terminates a contract for convenience, the other party to that contract may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination.

If the government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source.

One or more of our government contracts could be terminated under these circumstances. Some government contracts grant the government the right to use, for or on behalf of the U.S. government, any technologies developed by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the government.

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

Legal proceedings could be costly to defend, and the results could reduce demand for BioThrax by the U.S. government. For example, a group of unnamed military personnel filed a lawsuit in 2003 seeking to enjoin the DoD from administering BioThrax on a mandatory basis without informed consent of the recipient or a Presidential waiver, and a federal court issued the requested injunction in 2004. In 2005, the FDA issued an order affirming the BioThrax license and, as a result, an appellate court ruled in February 2006 that the injunction was dissolved. In October 2006, the DoD announced that it was resuming a mandatory vaccination program for BioThrax for designated personnel and contractors. In December 2006, the same counsel who brought the prior lawsuit filed a new lawsuit contending that the FDA's 2005 Final Order should be s et aside and that BioThrax is not properly approved for use in the DoD's vaccination program. In February 2008, the federal district court in which that case was pending dismissed the action, concluding that the FDA did not make a clear error of judgment in reaffirming the safety and efficacy of BioThrax. On September 29, 2009, the United States Court of Appeals for the District of Columbia Circuit issued its opinion in *Rempfer v. Torti*, affirming the February 29, 2008 finding of the District Court that the FDA did not violate the Administrative Procedure Act in connection with its December 19, 2005 Final Order classifying BioThrax as safe and effective. The plaintiffs' petition for writ of certiorari in the United States Supreme Court was denied on March 1, 2010.

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

Risks Related to Our Financial Position and Need for Additional Financing

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

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

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

As of September 30, 2010, we had $48.3 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;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

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

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

We expect our development expenses to increase in connection with our ongoing activities, particularly as we conduct additional and later stage clinical trials for our product candidates. We also expect our commercialization expenses to increase in the future as we seek to broaden the market for BioThrax and if we receive marketing approval for additional products. We also may undertake additional facility projects in the future.

As of September 30, 2010, we had $151.2 million of cash and cash equivalents. 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 new facility in Baltimore, Maryland, and any other new facilities;
- the level of participation of our collaborative partners in our development programs, including those recently acquired in the acquisition of Trubion;
- 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 extent to which we lend money to, and are able to obtain repayment from, third parties;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- the extent to which we acquire or invest in companies, businesses, products and technologies;
- the extent to which we become obligated to make cash payments related to the contingent value rights issued to former holders of Trubion Pharmaceuticals, Inc., or Trubion, common stock in connection with our acquisition of Trubion that are not offset by corresponding cash inflows from our collaborative partners; and
- our ability to establish and maintain collaborations.

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 p lanned commercialization efforts.

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

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

Risks Related to Manufacturing and Manufacturing Facilities

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

We continually evaluate alternatives for the manufacture of BioThrax and our various product candidates. We may seek to acquire one or more additional facilities or sign agreements with contract manufacturing organizations. We have constructed Building 55, a large-scale manufacturing facility on our Lansing, Michigan campus for which we received an award from BARDA in July 2010 for scale-up, qualification and validation to manufacture BioThrax. Additionally, in 2009, we acquired a facility in Baltimore, Maryland that we expect to utilize for certain product development or manufacturing projects. In order to do so, we anticipate that we will be required to make certain capital expenditures to upgrade and maintain this facility.

Constructing, preparing and maintaining a facility for manufacturing purposes is a significant project. For example, the process for qualifying and validating Building 55 for FDA licensure will be costly and time consuming, may result in unanticipated delays and may cost more than expected due to a number of factors, including regulatory requirements. The costs and time required to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements for sales of our products outside the U.S. may be significant. If our qualification and validation activities are delayed, we may not be able to meet our obligations to our customers, which may limit our opportunities for growth. Costs associated with constructing, qualifying and validating manufacturing facilities could require us to raise additional fund s 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 banks and preventing drift, obtaining materials, seed 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 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.

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

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.

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

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

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

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

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

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

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

We have outsourced the operation for filling BioThrax into vials to a single company. Our contract with this company expires on December 31, 2010, and we are negotiating a new filling agreement with this Company that we expect to execute in the fourth quarter of 2010. We have not established internal redundancy for our filling functions; however, we have identified and contracted with an additional provider that we believe can handle our filling needs. Before this additional provider can perform filling services for us, it must be qualified and licensed by the FDA. Such qualification and licensure may require use of a significant number of doses of BioThrax for consistency lots and stability testing that we may not be able to sell in the future once testing is complete. If our existing BioThrax filler is unable to perform filling se rvices for us, we would need to obtain FDA approval of our potential substitute filler, engage, qualify and license an alternative filling company or develop our own filling capabilities. Any new contract filling company or filling capabilities that we acquire or develop will need to be approved by the FDA. Identifying and engaging a new contract filling company or developing our own filling capabilities and obtaining FDA approval could involve significant time and cost. As a result, we might not be able to deliver BioThrax orders on a timely basis and our revenues could decrease.

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 may not be able to scale-up manufacturing processes for our product candidates to allow production of commercial quantities at a reasonable cost or at all. Furthermore, if we overestimate customer demand, or choose to commercialize products for which the market is smaller than we anticipate, we could incur significant unrecoverable costs from creating excess capacity. In addition, if we do not successfully develop and commercialize any of our product candidates, we may never utilize the production capacity that we expect to have available.

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

We currently rely, or plan to rely, on third parties to manufacture the supplies of some or all of our vaccine and therapeutic product candidates that we require for preclinical and clinical development, including the product candidates from our recently-completed acquisition of Trubion. For example, through a prior agreement between Trubion and Pfizer, Inc., or Pfizer, we now depend on Pfizer for the supply of SBI-087, a next generation CD20-directed product candidate targeted for treatment of rheumatoid arthritis, or RA. 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 our anthrax monoclonal antibody therapeutic product candidate informed us it was discontinuing contract manufacturing operations and we were forced to secure alternative manufacturing resources to continue development of this product candidate.

In addition, we expect that we will rely on third parties for a portion of the manufacturing process for commercial supplies of product candidates that we successfully develop, including fermentation for some of our vaccine product candidates, plasma fractionation and purification and contract fill and finish operations, and we rely on those manufacturers to comply with a wide variety of rules and regulations. If our contract manufacturers are unable to scale-up production to generate enough materials for commercial launch, if manufacturing is of insufficient quality, 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.

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

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

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

If, as a result of regulatory requirements or otherwise, we or third parties are unable to manufacture our product candidates at an acceptable cost, our product candidates may not be commercially viable.

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

Our development and manufacturing processes involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we are subject to federal, state, local and foreign laws and regulations governing the use, manufacture, distribution, storage, handling, disposal and recordkeeping of these materials. We are also subject to a variety of environmental laws in Michigan 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 Centers for Disease Control and Prevention, or CDC, HHS and the DoD.

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

We also are subject to export control regulations governing the export of BioThrax and technology and materials used to develop and manufacture BioThrax and our product candidates. These laws and regulations may limit the countries in which we may conduct development and manufacturing activities. If we fail to comply with environmental, occupational health and safety, biosafety and export control laws, we could be held liable for fines, penalties and damages that result, and any such liability could exceed our assets and resources. In addition, we could be required to cease immediately all use of a select agent or toxin, and we could be prohibited from exporting our products, technology and materials or we could be suspended from the right to do business with the U.S. government.

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

We hold a number of insurance policies in an effort to protect ourselves against extraordinary or unanticipated costs. Our general liability and excess insurance policies provide for coverage up to annual aggregate limits of $12 million, with coverage of $1 million per occurrence and $2 million in the aggregate for general liability and $10 million per occurrence and in the aggregate for excess liability. Both policies exclude coverage for liabilities relating to the release of pollutants. We do not currently hold insurance policies expressly providing for coverage relating to our use of hazardous materials other than storage tank liability insurance for our Lansing facility with coverage of $1 million per occurrence and $2 million annual aggregate limit and a $25,000 per claim deductible. We hold product liabili ty 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. Circumstances may arise where we face liabilities that are not covered by these 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 Our Acquisition of Trubion Pharmaceuticals

We will be subject to continued risks of product development, regulatory approvals and commercialization with respect to the product candidates we acquired as a result of our acquisition of Trubion.

Our recently-acquired Trubion product candidates are subject to the same risks that affected our product candidates prior to the Trubion acquisition. For example, TRU-016, a CD37-targeted therapy for the treatment of B-cell malignancies, is being developed with a wholly owned subsidiary of Abbott Laboratories, or Abbott, for patients with chronic lymphocytic leukemia, or CLL. A Phase I clinical trial of TRU-016 in this indication is underway. We and Abbott will be responsible for completing the clinical development of, seeking regulatory approval for and commercializing this product candidate. The results of the ongoing clinical trial for TRU-016 may not be sufficient to support an application for marketing approval. If the efficacy of this product candidate cannot be confirmed in pivotal clinical trials, we may be forced to delay or cease development efforts. Our product development costs will increase if we experience delays in clinical trials or in seeking marketing approval. Significant delays could impair our ability to commercialize TRU-016 or any of the other product candidates we acquired through the Trubion acquisition. If we are unable to complete the development of, obtain regulatory approvals for and commercialize these product candidates, we will not realize the anticipated benefits of our acquisition of Trubion.

Our commercial success depends in significant part on the success of the partnered clinical product candidates we recently acquired from Trubion. We cannot be certain that the collaborative partners for those product candidates will continue development, or that those product candidates will be safe or effective, complete clinical trials, receive regulatory approval or be successfully commercialized.

In June 2010, Pfizer decided to discontinue development of TRU-015, an investigational drug in Phase II evaluation for the treatment of RA that was developed under Trubion's CD20 collaboration with Pfizer. Accordingly, the lead commercial product candidate that we acquired through our acquisition of Trubion is SBI-087, a second generation anti-CD20 product candidate. SBI-087 is earlier in development than TRU-015 and is currently the subject of an ongoing Phase II trial. Patient dosing in the Phase II SBI-087 RA trial commenced in December 2009 and final data is not anticipated until the end of 2011. Because SBI-087 is at an earlier stage in clinical development, the decision by Pfizer to develop SBI-087 instead of TRU-015 is likely to delay the potential commercialization of any product candidate under our c ollaboration with Pfizer, which could adversely affect our business.

Initial clinical testing of TRU-016 and SBI-087 commenced in 2008. Even if we and our collaborative partners for those product candidates determine to proceed with further clinical testing, a number of additional clinical trials will be required before a Biologics License Application, or BLA, can be submitted to the FDA for product approval. Clinical trials required for FDA approval of SBI-087 for RA or systemic lupus erythematosus, or SLE, and TRU-016 for CLL and non-Hodgkin’s lymphoma, or NHL, may not be successfully completed. If required clinical trials are not completed or their results do not meet safety and efficacy thresholds required by the FDA, these product candidates will likely not receive regulatory approval. The regulatory approval process can take many years and require the expenditure of substantial resources. Even if any of these product candidates receive regulatory approval, the approved product candidate may never be successfully commercialized. If these product candidates do not receive regulatory approval or are not successfully commercialized, we may not realize the anticipated benefits of our acquisition of Trubion.

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

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

In June 2010 Pfizer decided to discontinue development of TRU-015. We cannot predict how or whether Pfizer will proceed with the collaboration or the development of any of the remaining collaboration product candidates, including SBI-087 and other therapeutics directed to CD20, as well as certain other product candidates directed to a small number of targets other than CD20 that have been established pursuant to the agreement. Our ability to receive any significant revenue from our product candidates covered by the collaboration agreement depends on the efforts of Pfizer and on our ability to collaborate effectively. Any future payments, including royalties to us, will depend on the extent to which we and Pfizer advance product candidates through development and commercialization. Pfizer may terminate the collaboration relationship, in whole or in part, without cause, by giving 90 days' written notice to us. Pfizer also has the right to terminate the agreement, on a target-by-target basis, upon 60 days' written notice, if any safety or regulatory issue arises that would have a material adverse effect on Pfizer's ability to develop, manufacture, or commercialize one or more product candidates.

With respect to control over decisions and responsibilities, the collaboration agreement provides for a research committee and a CD20-directed therapy development committee consisting of representatives of Pfizer and us. Ultimate decision-making authority as to most matters within the collaboration, including development plans and timelines, however, is vested in Pfizer.

In August 2009, Trubion entered into a collaboration agreement with Facet Biotech, or Facet, for the joint worldwide development and commercialization of TRU-016, a product candidate in Phase I clinical development for CLL and other CD37-directed protein therapeutics. Facet became a wholly-owned subsidiary of Abbott on April 21, 2010. Under the terms of the collaboration agreement, neither we nor Abbott have the right to develop or commercialize protein therapeutics directed to CD37 outside of the collaboration. Our ability to receive funding for TRU-016 under the collaboration depends on our ability to collaborate effectively with Abbott. Any future payments, including milestones payable to us, will depend on the extent to which we and Abbott advance TRU-016 through development and commercialization. Abbott may terminate the collaboration agreement without cause, and would not be obligated to pay us a termination fee if such a termination were to occur after February 27, 2011. Abbott also has the right upon 90 days' written notice to terminate the agreement for any uncured material breach by us, and has the right to opt out of the collaboration during the six-month period following a change in control of Trubion, which includes the right to opt out of the collaboration as a result of our acquisition until April 28, 2011. With respect to control over decisions and responsibilities, the collaboration agreement provides for a joint steering committee that must make decisions by consensus. Failure to reach consensus on material aspects of the development or commercialization of TRU-016 would lead to dispute resolution by our respective designated officers, and potentially arbitration, any of which may delay the development of TRU-016, which may harm our business.

Under certain circumstances, the parties have the right to opt-out of the collaboration or may be deemed to have opted-out of the collaboration. If Abbott opts-out of the collaboration with respect to a product, then we would become responsible for all development and commercialization costs for that product and be obligated to pay Abbott certain royalty payments upon the sale of that product. We are currently the lead manufacturing party for TRU-016 and if we opt-out of the collaboration as allowed under the collaboration agreement, and are the lead TRU-016 manufacturing party at that time, we would be obligated to continue to supply TRU-016 to Abbott for up to 18 months.

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. In addition to BioThrax sales, our ability to generate near term revenue is dependent on the success of our development programs, on the U.S. government's interest in providing development funding for or procuring certain of our product candidates, on the interest of non-governmental organizations in providing grant funding for development of certain of our product candidates and on the commercial viability of those product candidates. The commercial success of our product candidates will depend on many factors, including accomplishing the following in an economical manner:

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

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

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 must conduct extensive preclinical studies and clinical trials to establish proof of concept, safety and efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete, and the outcome of such trials is uncertain. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. For example, in December 2008, we and Sanofi Pasteur determined that the joint efforts of our collaboration related to our meningitis B product development program had not identified a viable product can didate, which effectively ended most development activities under this collaboration.

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

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

- regulators or institutional review boards may not authorize us 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;
- 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;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

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

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

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

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

Under the Project BioShield Act, the Secretary of HHS can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the Secretary of HHS 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.

Risks Related to Commercialization

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

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

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

Government regulations may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, many foreign governments require licensure of BioThrax in their jurisdiction before they will consider procuring doses. Additionally, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of BioThrax and related technology, the U.S. government may decide, particularly in the current environment of elevated concerns about global terrorism, to increase the scope of export prohibitions. These prohibitions could limit our sales of BioThrax to foreign governments and other foreign customers. In addition, U.S. government demand for an anthrax vaccine may limit supplies of BioThrax available f or 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 potential increased demand that develops for sales of BioThrax to customers other than the U.S. government depends on our available production capacity. We use substantially all of our current production capacity at our FDA-approved manufacturing facility in Lansing, Michigan to manufacture BioThrax for current sales to U.S. government customers. Additionally, we have constructed Building 55, a large-scale manufacturing facility at our Lansing campus that is available for large-scale production of BioThrax, subject to final qualification and validation activities. To prepare for the event that we obtain significant orders for BioThrax from customers other than the U.S. government that cannot be accommodated by our existing facilities, we may explore additional manufacturing alternatives that would e nable us to increase our manufacturing capacity and, as a result, allow us to increase sales of BioThrax to customers other than the U.S. government. If we are successful in this effort, it could be several years until a facility is qualified and validated and able to produce saleable vaccine. If we are unsuccessful in this effort, our opportunities for growth could be limited.

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

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

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

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. China is an example of one jurisdiction in which we are contemplating future expansion where we will need to exercise caution to ensure our compliance with the FCPA.

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 expanding presence outside of the United States will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

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

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

Any products that we bring to the market may not gain or maintain market acceptance by potential government customers, physicians, patients, healthcare payors and others in the medical community. In particular, our biodefense vaccine and therapeutic products and product candidates are subject to the product criteria that may be specified by potential U.S. government customers. The product specifications in any government procurement request may prohibit or preclude us from participating in the government program if our products or product candidates do not satisfy the stated criteria.

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

The use of vaccines carries a risk of adverse health effects. The adverse reactions that have been associated with the administration of BioThrax include local reactions, such as redness, swelling and temporary limitation of motion in the inoculated arm, and systemic reactions, such as headache, fever, chills, nausea and general body aches. In addition, some serious adverse events have been reported to the vaccine adverse event reporting system database maintained by the CDC and the FDA with respect to BioThrax, including diabetes, heart attacks, autoimmune diseases, including Guillian 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.

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:

- the prevalence and severity of any side effects;
- the efficacy and potential advantages over alternative 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; and
- the sufficiency of coverage or reimbursement by third parties.

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

Products developed to treat diseases caused by or to combat the threat of bioterrorism are subject to changing political and social environments. The political and social responses to bioterrorism have been highly charged and unpredictable. 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 publici ty 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 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. However, to increase our sales of BioThrax to state and local governments and foreign governments and create an infrastructure for future sales of other biodefense products to these customers, we plan to expand our sales and marketing organization, which will be expensive and time consuming.

We may not be able to attract, hire, train and retain qualified sales and marketing personnel to build a significant or effective sales and marketing force for sales of biodefense product candidates to customers other than the U.S. government or for sales of our commercial product candidates. If we are not successful in our efforts to expand our internal sales and marketing capability, our ability to independently market and sell BioThrax and any other product candidates that we successfully develop will be impaired. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed as a result of FDA requirements or other reasons, we would incur related expenses too early relative to the product launch. This may be costly, and our investment would be lost if we cannot retain our sales and marketing personnel.

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

Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. We believe that our most significant competitors in the area of vaccine and therapeutics are a number of pharmaceutical companies that have vaccine programs, including Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Pfizer, and Novartis, as well as smaller more focused companies engaged in vaccine and therapeutic development, such as Aeras, Crucell, Cangene, Human Genome Sciences, Soligenix, Dynport Vaccine Company, Elusys, Bavarian Nordic and PharmAthene.

Any vaccine and therapeutic product candidate that we successfully develop and commercialize is likely to compete with currently marketed products, including antibiotics and antiviral drugs, and with other product candidates that are in development for the same indications. In many cases, the currently marketed products have well known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. In addition, we are aware of product candidates of third parties that are in development, which, if approved, would compete against product candidates for which we intend to seek marketing approval.

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

Numerous companies have vaccine product candidates in development that would compete with any of our commercial product candidates for which we are seeking to obtain marketing approval. One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the U.S. and Europe. The Aeras Global Tuberculosis Vaccine Foundation is developing or supporting the development of five tuberculosis vaccine product candidates in addition to ours, any of which could present competitive risks. If approved for the treatment of RA, we anticipate that some of our commercial product candidates would compete with other marketed protein therapeutics for the treatment of RA, including: Enbrel ® (Amgen, Pfizer and Takeda), Remicade ® (Centocor Ortho Biotech, Merck and Mitsubishi Tanabe), Hu mira ® (Abbott and Eisai), Orencia ® (BMS), Cimzia ® (UCB and Otsuka), Simponi ® (Centocor Ortho Biotech and Merck), Actemra ® (Roche and Chugai) and Rituxan ® (Genentech, Roche and Biogen Idec). If approved for the treatment of SLE, our product candidates will compete with other therapies. If approved for the treatment of CLL, NHL, or other B-cell malignancies, we anticipate that our product candidates would compete with other B-cell depleting therapies. While we are not aware of any CD37- directed therapeutics in development or on the market, other biologic therapies are marketed for the treatment of NHL or CLL or both, such as Rituxan/Mabthera ® (Genentech, Roche and Biogen Idec), Zevalin ® (Spectrum Pharmaceuticals, Inc. and Bayer Schering AG), Bexxar ® (GSK), Campath ® (Genzyme and Bayer Schering AG), Treanda ® (Cephalon Oncology) and Arzerra ® (GSK and Genmab).

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early stage companies may also prove to be significant competitors, particularly through competing for government funding and through collaborative arrangements with large and established companies. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring products, product candidates and technologies complementary to, or necessary for, our programs or advantageous to our business.

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

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

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

In August 2006, the Department of Homeland Security approved our application under the Support Anti-Terrorism by Fostering Effective Technology Act, or SAFETY Act, enacted by the U.S. Congress in 2002 for liability protection for sales of BioThrax. The SAFETY Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. In addition, the SAFETY Act provides a process by which an anti-terrorism technology may be certified as an "approved product" by the Department of Homeland Security and therefore entitled to a rebuttable presumption that the government contractor defense applies to sales of the product. The government contractor defense, under specified circumstances, extends the sovereign immunity of the U.S. to government contractors who manufacture a product for the government. Specifically, for the government contractor defense to apply, the government must approve reasonably precise specifications, the product must conform to those specifications and the supplier must warn the government about known dangers arising from the use of the product. Although we are entitled to the benefits of the SAFETY Act, it may not provide adequate protection from any claims made against us.

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

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

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

BioThrax is currently identified as a covered countermeasure under a PREP Act declaration issued in October 2008, which provides us with immunity with respect to the manufacture, administration or use of BioThrax. Under our prior BioThrax contracts with the DoD and HHS, the U.S. government agreed to indemnify us against claims by third parties for death, personal injury and other damages related to BioThrax, including reasonable litigation and settlement costs, to the extent that the claim or loss results from specified risks not covered by insurance or caused by our grossly negligent or criminal behavior. As required under our prior BioThrax contracts, we have notified the DoD of personal injury claims that have been filed against us as a result of the vaccination of U.S. military personnel with BioThrax and are seeking reimbu rsement from the DoD for uninsured costs incurred in defending these claims. The collection process can be lengthy and complicated, and there is no guarantee that we will be able to recover these amounts from the U.S. government.

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 will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

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

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

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 commercial 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.

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, generally is intended to expand health care coverage to currently uninsured Americans and to limit the rate of increase in health care spending. The legislation 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 bios imilar 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, 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.

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 capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by health care providers. If third party payors do not provide adequate coverage or reimbursement for any products we may develop, it could have a negative effect on our revenues and results of operations.

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

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

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

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

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

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

In addition, our growth will require us to hire a significant number of qualified scientific and commercial personnel, including clinical development, regulatory, marketing and sales executives and field sales personnel, as well as additional administrative 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.

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

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

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

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

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

Risks Related to Regulatory Approvals

If we 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 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, informat ion 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 to the FDA a BLA. 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. 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 can didates cannot be demonstrated in humans, but instead must be demonstrated, in part, by utilizing animal models before they can be approved for marketing. This is known as the FDA's "animal rule".

We intend to use the animal rule in pursuit of FDA approval for BioThrax as a post-exposure prophylaxis, our anthrax immune globulin therapeutic, our rPA anthrax vaccine, our anthrax monoclonal antibody therapeutic, our next generation anthrax vaccine, and our double mutant rPA vaccine. 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.

After we acquired BioThrax and related vaccine manufacturing facilities in Lansing, Michigan in 1998 from the Michigan Biologic Products Institute, we spent significant amounts of time and money renovating those facilities before the FDA approved a supplement to our manufacturing facility license in December 2001. The State of Michigan had initiated renovations after the FDA issued a notice of intent to revoke the FDA license to manufacture BioThrax in 1997. The notice of intent to revoke cited significant deviations by the Michigan Biologic Products Institute from cGMP requirements, including quality control failures. In March 2007, the FDA notified us that our manufacturing facility license is no longer subject to the notice of intent to revoke.

After approving the renovated Lansing facilities in December 2001, the FDA conducted routine, biannual inspections of the Lansing facilities in September 2002, May 2004, May 2006, March 2008 and December 2009. 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 each of those inspections were successfully closed out. In December 2005, the FDA stated in its final order on BioThrax that at that time we were in substantial compliance with all regulatory requirements related to the manufacture of BioThrax and that the FDA would continue to evaluate the production of BioThrax to assure comp liance with federal standards and regulations. If in connection with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, or if the FDA is not satisfied with the corrective actions we take in connection with any such inspection, the FDA may undertake enforcement action against us.

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

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

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

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

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

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

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

We intend to have some or all of our products marketed outside the United States. To market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. With respect to some of our product candidates, we expect that a future collaborator will have responsibility to obtain regulatory approvals outside the United States, and we will depend on our collaborators to obtain these approvals. The approval procedure varies among countries and can involve additional testing. 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. 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. We and our collaborators may not be able to obtain regulatory approvals to commercialize our products in any market.

Risks Related to Our Dependence on Third Parties

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

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

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

Any collaboration that we enter into may not be successful. For example, based on preclinical studies performed under a license agreement that we entered into with Sanofi Pasteur, both parties determined that the joint efforts had not identified a promising meningitis B vaccine product candidate and we mutually terminated the collaboration. Additionally, the success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. It is likely that our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations.

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

- our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach by us;
- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not do so, our ability to maintain and defend our intellectual property rights may be compromised by our collaborators' acts or omissions;
- our collaborators may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability; or
- our collaborators may decide not to continue to work with us in the development of product candidates.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Such terminations or expirations could adversely affect us financially and could harm our business reputation.

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 independent clinical investigators, contract research organizations and other third party service providers to conduct the clinical and non-clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical and non-clinical trials, but do not exercise day-to-day control over their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the r esults 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. 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, we encourage government entities and non-government organizations to conduct studies of, and pursue other development efforts for, our product candidates.

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

Risks Related to Our Intellectual Property

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

Our success, particularly with respect to our commercial 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 and products. 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, 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 pro duct 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.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not do so, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties.

For example, we licensed an oligonucleotide adjuvant, CpG 7909, for use in our double mutant rPA product candidate and our next generation anthrax vaccine product candidate from Coley Pharmaceutical Group, Inc., or Coley. Coley which was subsequently acquired by Pfizer Inc., is responsible for prosecuting, maintaining and defending these licensed patent rights. Coley notified us that a patent interference had been declared in the U.S. Patent and Trademark Office between our licensed patent and a third party patent application, which could result in revocation of the patent we have licensed. We may not know the outcome for a considerable period of time.

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

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

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

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

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

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

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

As a result of patent infringement or other similar claims, or to avoid potential claims, we or our collaborators may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms or if an injunction is granted against us. This 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, 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. The Acambis strain has a distinct lineage from the strains used by us. 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 Oxford BioMedica strain also has a distinct lineage from the strain used by us. The lawsuit was settled in January 2010 by agreement between the parties. While the terms of the settlement have not been published, the parties have announced that Oxford BioMedica received a license for TroVax under Bavarian Nordic's MVA patents, and in return Bavarian Nordic received a license under Oxford BioMedica's patents on heterologous prime boost technology and a sublicense under certain patents licensed by Sanofi to Oxford BioMedica. Typically, patent infringement settlements are structured to specifically cover the alleged infringing product, and the settlement has no direct im pact on other products in the field. We have licensed from StMUG rights to materials and technology related to MVA. Our MVA platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based in part on these rights.

Our MVA platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based in part on rights to certain MVA-related materials and technology that we acquired from the Bavarian State Ministry of the Environment and Public Health. From 2006 to 2008, we filed patent oppositions in the European Patent Office against four of Bavarian Nordic's patents covering certain aspects of MVA technology. In each of the four pending opposition proceedings, the subject patents have also been opposed by one or more additional parties, including Sanofi Pasteur, Transgene, Baxter, Virbac, and Innogenetics. We and the other opponents have alleged that the opposed patents should be revoked for failure to fulfill one or more o f the patentability requirements of the European Patent Convention, such as the requirements for novelty and inventive step. In each opposition, we expect that a single hearing will be held before the Opposition Division of the European Patent Office, in which each opponent will present oral argument and Bavarian Nordic will present rebuttal arguments. The first of these hearings, which occurred in June 2010, resulted in the Bavarian Nordic patent under consideration being maintained but narrowed in scope. A time period has been set for all parties to file appeals, and we anticipate all appeals to be filed by the due date of November 27, 2010. Hearings in two of the other pending oppositions occurred in October 2010. Bavarian Nordic introduced amended patent claims into the record, which claims were upheld strictly and expressly conditioned on such claims being interpreted within a narrowly-defined scope. The Opposition Division scheduled a hearing on th e fourth pending opposition for January 2011. We routinely monitor the grant of further Bavarian Nordic European patents to determine whether any additional oppositions should be filed.

Risks Related to Our Acquisition Strategy

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

Since our inception we have pursued a strategy of growing our business through licensing and acquisition. We commenced operations in September 1998 through an acquisition of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how, all from the Michigan Biologic Products Institute. We acquired a portion of our pipeline of vaccine and therapeutic product candidates through our acquisition of Microscience Limited in a share exchange in 2005 and our acquisitions of substantially all of the assets, for cash, of Antex Biologics, Inc. in 2003 and of ViVacs GmbH in 2006. More recently, we acquired additional pipeline product candidates as a result of our acquisition of Trubion, which we completed in Octobe r 2010.

In the future, we may be unable to license or acquire suitable products or product candidates from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical and biological products is a competitive area. A number of more established companies are also pursuing strategies to license or acquire products in the vaccine and therapeutic field. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. 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.

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. If we are unable to successfully obtain rights to suitable products and product candidates, including through the acquisition of Trubion, our business, financial condition and prospects for growth could suffer.

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

As part of our business strategy, we 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, including the Trubion acquisition, 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;
- large write-offs and difficulties in assessing the relative percentages of in-process research and development expense that can be immediately written off as compared to the amount that must be amortized over the appropriate life of the asset; and
- amortization expenses related to other intangible assets.

Operational risks that could harm our existing operations or prevent realization of anticipated benefits from these transactions include:

- challenges associated with managing an increasingly diversified business;
- prioritizing product portfolios;
- disruption of our ongoing business;
- difficulty and expense in assimilating and integrating the operations, products, technology, information systems or personnel of the acquired company;
- diversion of management's time and attention from other business concerns;
- inability to maintain uniform standards, controls, procedures and policies;
- the assumption of known and unknown liabilities of the acquired company, including intellectual property claims;
- challenges and costs associated with reductions in work force; and
- subsequent loss of key personnel.

If we are unable to successfully manage and integrate our acquisitions, our ability to develop new products and continue to expand our product pipeline may be limited.

Risks Related to Our Common Stock

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

Mr. El-Hibri has the ability to control the election of the members of our Board of Directors through his ownership interests among our significant stockholders. As of October 29, 2010, Mr. El-Hibri was the beneficial owner of approximately 32% 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 i nfluencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

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

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

These provisions include:

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

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

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

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

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

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

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

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through October 29, 2010, 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 for 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;
- 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;
- 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; and
- the other factors described in this "Risk Factors" section.

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 total outstanding shares may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. For example, we have filed a registration statement that would permit us to issue up to $100 million in common stock. Moreover, holders of an aggregate of approximately 10.0 million shares of our common stock outstanding as of October 29, 2010 have the right to require us to register these shares of common stock under specified circumstances.

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

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

Not applicable.

Purchases of Equity Securities

Not applicable.

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

Not applicable.

ITEM 4. ***REMOVED AND RESERVED***

ITEM 5. ***OTHER INFORMATION***

On November 3, 2010, we and the contract manufacturer of our anthrax immune globulin therapeutic product candidate, Talecris Biotherapeutics, Inc., or Talecris, agreed to extend the commencement date of the commercial manufacturing term for that product candidate to July 31, 2011. In the event that we request Talecris to produce any quantities of the product candidate before or after commencement of the commercial term, the parties are required to negotiate in good faith as to the timing, price, quantity and support, among other terms, of such production, subject to Talecris' right to delay or refuse such specific request.

ITEM 6.

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

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

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

Date: November 4, 2010

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

Date: November 4, 2010

EXHIBIT INDEX

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated August 12, 2010, among the Registrant, Trubion Pharmaceuticals, Inc., 35406 LLC, and 30333 Inc. (Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on August 13, 2010)
2.2	Amendment No. 1 to Agreement and Plan of Merger, dated September 29, 2010, among the Registrant, Trubion Pharmaceuticals, Inc., 35406 LLC, and 30333 Inc. (Incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on September 30, 2010)
10.1	Contingent Value Rights Agreement, dated August 12, 2010, among the Registrant, Trubion Pharmaceuticals, Inc. and Mellon Investor Services LLC, as rights agent (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on August 13, 2010)
10.2	Form of Support Agreement, dated August 12, 2010, between the Registrant and certain former holders of common stock of Trubion Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on August 13, 2010)
10.3	Form of Lock-up Agreement, dated August 12, 2010, between the Registrant and certain former holders of common stock of Trubion Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on August 13, 2010)
10.4 #†	Contract No. HHSO100201000034C, dated July 13, 2010, between Emergent BioDefense Operations Lansing Inc. and the Department of Health and Human Services
10.5 #†	Modification No. 9 to Contract No. 200-2009-30162, dated July 16, 2010, between Emergent BioDefense Operations Lansing Inc. and the Centers for Disease Control and Prevention
10.6 #†	Contract No. HHSO100201000059C, dated September 17, 2010, between Emergent Product Development Gaithersburg Inc. and the Department of Health and Human Services
10.7 #	Modification No. 7 to Contract No. HHSO100200700037C, dated September 22, 2010, between Emergent BioDefense Operations Lansing Inc. and the Department of Health and Human Services
10.8 #	Amendment No. 5 to Product Supply Agreement, dated November 3, 2010, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics, Inc.
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

Filed herewith
† Confidential treatment requested. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

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

Exhibit 10.4

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)	RATING N/A	PAGE 1 OF PAGES 45
2. CONTRACT (Proc. Inst. Ident.) NO. HHSO100201000034c	3. EFFECTIVE DATE See Block 20C.	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. OS41620	

5. ISSUED BY	CODE N/A	6. ADMINISTERED BY (If other than Item 5)	CODE N/A
HHS/OS/ASPR/BARDA 330 INDEPENDENCE AVE S.W., RMG640 WASHINGTON, D.C. 20201		See Block 5.	

7. NAME AND ADDRESS OF CONTRACTOR (No., street, country, State and ZIP Code)	8. DELIVERY
Emergent BioDefense Operations Lansing 3500 N. Martin Luther King, Jr. Blvd. Lansing, MI 48906 DUNS# 026489018	See Section F.2.
	9. DISCOUNT FOR PROMPT PAYMENT N/A
FACILITY CODE N/A	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: ITEM See Section G.

11. SHIP TO/MARK FOR	CODE N/A	12. PAYMENT WILL BE MADE BY	CODE N/A
See Block 5.		See Block 5.	

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253(c)( )	Appropriate; Object Class: 25329 CAN# 1990087 FY 2010 $54,586,376

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
See Section B.					$

15G. TOTAL AMOUNT OF CONTRACT $54,586,376

16. TABLE OF CONTENTS

(✓)	SEC.	DESCRIPTION	PAGE(S)	(✓)	SEC.	DESCRIPTION	PAGE(S)
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required to sign this document and return 2 copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☐ AWARD *(Contractor is not required to sign this document.)* Your offer on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual documentation is necessary.

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
Daniel J. Abdun-Nabi, Vice President	Ethan J. Mueller

19B. Emergent BioDefense Operations Lansing	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
/s/ Daniel J. Abdun-Nabi (Signature of person authorized to sign)	7/13/10	BY /s/ Ethan J. Mueller (Signature of Contracting Officer)	7/13/10

PART I - THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of the contract is the development and FDA licensure of a large-scale manufacturing process for BioThrax®.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The total estimated cost of the base period of performance contract is $[**].

b. The total fixed fee for the base period of performance contract is $[**]. The fixed fee shall be paid in accordance with and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1 of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The total amount of the contract, represented by the sum of the total estimated cost plus fixed fee is $54,586,376.

d. It is estimated that the amount currently allotted will cover performance of the contract through July 18, 2012.

CONTRACT LINE ITEM NUMBERS (CLINs)

BASE PERIOD

CLIN	PERIOD OF PERFORM.	SUPPLIES/SERVICES	TOTAL ESTIMATED COST	FIXED FEE	TOTAL ESTIMATED COST PLUS FIXED
0001	7/19/2010-7/18/2012	[**]	[**]	[**]	$54,586,376

ARTICLE B.3. OPTION PRICES

a. Unless the Government exercises its option pursuant to the option clause referenced in ARTICLE I.1., the contract consists only of the Base Period specified in the Statement of Work as defined in SECTIONS C and F, for the price set forth in ARTICLE B.2. of the contract.

b. Pursuant to H. 13. EXERCISE OF OPTIONS and **Option for Increased Quantity (FAR Clause 52.217-7)** the Government may, by unilateral contract modification, require the Contractor to perform the Option(s) specified in the Statement of Work as defined in SECTIONS C and F of this contract. If the Government exercises this/these option(s), notice must be given before the expiration date of the contract. Specific information regarding the time frame for this notice is set forth in the OPTION CLAUSE Article in SECTION H of this contract. The estimated cost of the contract will be increased as set forth below:

CONTRACT OPTION PERIODS

Option Period 1 (CLIN 0003)
Option Period 2 (CLIN 0004)
Option Period 3 (CLIN 0005)
Option to Conduct Feasibility Studies for Long-Term Storage of Frozen Bulk Drug Substance Year 1 (CLIN 0006)
Option to Conduct Feasibility Studies for Long-Term Storage of Frozen Bulk Drug Substance Year 2 (CLIN 0007)
Option to Conduct Feasibility Studies for Long-Term Storage of Frozen Bulk Drug Substance Year 3 (CLIN 0008)

OPTION CLIN	PERIOD OF PERFORM.	SUPPLIES/SERVICES	TOTAL ESTIMATED COST	FIXED FEE	TOTAL ESTIMATED COST PLUS FIXED
0002		RESERVED.			
0003	7/19/2012- 7/18/2013	[**]	[**]	[**]	$25,981,420
0004	7/19/2013-7/18/2014	[**]	[**]	[**]	$13,461,557
0005	7/19/2014-7/18/2015	[**]	[**]	[**]	$10,847,991
0006	10/1/2011- 9/30/2012	[**]	[**]	[**]	$1,302,527
0007	10/1/2012- 9/30/2013	[**]	[**]	[**]	$622,257
0008	10/1/2013- 9/30/2014	[**]	[**]	[**]	$62,219

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable

Notwithstanding the clause, ALLOWABLE COST AND PAYMENT, incorporated in the contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

1. Acquisition, by purchase or lease, of any interest in real property;

2. Special rearrangement or alteration of facilities;

3. Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

4. Travel to attend general scientific meetings;

5. Foreign travel - See subparagraph b below;

6. Consultant costs;

7. Subcontracts;

8. Research patient care costs − See Attachment 1;

9. Accountable Government property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and “sensitive items” (defined and listed in the Contractor’s Guide for Control of Government Property, see Article G.10), regardless of acquisition value.

10. Printing Costs (as defined in the Government Printing and Binding Regulations).

11. Light Refreshment and Meal Expenditures. Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Project Officer, with a copy to the Contracting Officer, at least six (6) weeks in advance of the event. The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provided; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshment and/or meal costs; and (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals. It is unlikely that BARD A will approve these requests since circumstances are very limited under which appropriated funds can be used for these costs.

b. Travel Costs

1. Domestic Travel

   a. Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed $30,000 during the base period (7/19/2010-7/18/2012) without the prior written approval of the Contracting Officer.

   b. Subject to the annual dollar limitation specified under B.4.b.l.a. above the Contractor shall invoice and be reimbursed for all travel costs in accordance with FAR Subpart 31.2 contracts with Commercial Organizations and FAR § 31.205-46 Travel Costs

2. Foreign Travel

   Requests for foreign travel must be submitted at least six weeks in advance and shall contain the following: (a) meeting(s) and place(s) to be visited, with costs and dates; (b) name(s) and title(s) of Contractor personnel to travel and their functions in the contract project; (c) contract purposes to be served by the travel; (d) how travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of AMCG contract funds; (e) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and (f) what additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

ARTICLE B.5. ADVANCE UNDERSTANDINGS

a. Man-in-Plant

With 7 days advance notice to the Contractor via in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor’s facility and shall be subject to the Contractor’s polices and procedures as well as security and facility access procedures at all times while in the Contractor’s facility. The man-in-plant is restricted to observing, verifying, and surveying the Contractor’s performance under the contract.

b. Security Plan

The Contractor agrees to provide an updated Security Plan, if requested by the Contracting Officer, and within fifteen (15) working days after receipt of the request.

The Contractor agrees to provide data generated from this contract to the Contracting Officer upon request either in the form of an email attachment or via delivery to a secured Government eRoom.

c. Subcontracts and Consultants

Award of any subcontract or consulting agreement shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

d. Site Visits and Inspections

At the discretion of the U.S. Government and independent of activities conducted by the Contractor, within ten (10) business days notice to the Contractor via written notification from the Contracting Officer, the U.S. Government reserves the right to conduct site visits and inspections on an as needed basis, including collection of samples limited to [**] vials of Final Drug Product and samples of key intermediates held at the Contractor’s or Subcontractor’s site, provided that the Government’s collection of such samples should not frustrate the Contractor’s ability to perform under the contract.

e. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

   a. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.

   b. Fringe Benefits - Cite rate and amount

   c. Overhead - Cite rate and amount

d. Materials & Supplies - Include detailed breakdown when total amount is over $1,000.

e. Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.

f. Consultant Fees - Identify individuals and amounts.

g. Subcontracts - Attach sub-Contractor invoice(s).

h. Equipment - Cite authorization and amount.

i. G&A - Cite rate and amount.

j. Total Cost

k. Fixed Fee

l. Total CPFF

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

f. Confidential Treatment of Sensitive Information

The Contractor shall guarantee strict confidentiality of any information/data of a sensitive nature that is generated by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of information/data that is sensitive in nature, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer. (See also HHSAR clause 352.224-70).

Notwithstanding the foregoing, such information/data shall not be deemed of a sensitive nature with respect to the Contractor for purposes of this contract if such information/data: (a) was already known to the Contractor; (b) was generally available or known, or was otherwise part of the public domain, at the time of its disclosure to the Contractor; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to the information/data by, the Contractor through no fault of the Contractor; (d) was disclosed to the Contractor, other than under an obligation of confidentiality or non-use, by a third party who had no obligation to the Government that controls such information/data not to disclose such information/data to others; or (e) was independently discovered or developed by the Contractor, as evidenced by its written records, without the use of information/data belonging to the Government.

Contractor may disclose information/data of a sensitive nature provided by the Government to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the Contractor shall first have given notice to the Government and give the Government a reasonable opportunity to quash such order and to obtain a protective order requiring that the information/data of a sensitive nature that is the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the information/data disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order; (b) otherwise required by law, in the opinion of legal counsel to the Contractor as expressed in an opinion letter in form and substance reasonably satisfactory to the Government, which shall be provided to the Government at least two (2) business days prior to the Contractor's disclosure of the information/data; or (c) made by the Contractor to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, ho wever, that reasonable measures shall be taken to assure confidential treatment of such information/data.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work dated 5 May 2010 set forth in SECTION J-List of Attachments, attached hereto and made a part of the contract.

ARTICLE C.2. REPORTING REQUIREMENTS

Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this contract and in SECTION J-List of Attachments, attached hereto and made a part of the contract.

1. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;

SECTION I-An introduction covering the purpose and scope of the contract effort;

SECTION II-PROGRESS

SECTION II Part A: OVERALL PROGRESS-A description of overall progress;

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE-A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating, and managing subcontractor performance);

SECTION II Part C: TECHNICAL PROGRESS-For each activity, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and sc ientific evaluation of data accumulated to date under the project;

SECTION II Part D; PROPOSED WORK-A summary of work proposed for the next reporting period and preprints/reprints of papers and abstracts.

A Monthly Progress Report will not be required in the same month that the Quarterly or Annual Technical Progress Report is submitted.

2. Quarterly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full quarter of performance plus any fractional part of the initial quarter. Thereafter, the reporting period shall consist of each calendar quarter.

The Contractor shall submit a Quarterly Progress Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;

SECTION I-An introduction covering the purpose and scope of the contract effort;

SECTION II-PROGRESS

SECTION II Part A: OVERALL PROGRESS-A description of overall progress;

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE-A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating, and managing subcontractor performance);

SECTION II Part C: TECHNICAL PROGRESS-For each activity, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and sc ientific evaluation of data accumulated to date under the project;

SECTION II Part D; PROPOSED WORK- A summary of work proposed for the next reporting period; and preprints/reprints of papers, abstracts and a current GANTT chart. A Quarterly Progress Report will not be required in the same month that the Annual Progress Report is submitted.

3. Annual Progress Report

This report shall include a summation of the results of the entire contract work for the period covered. An Annual Technical Progress Report will not be required for the period when the Final Technical Progress Report is due. Monthly and Quarterly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due.

The first Annual Progress Report shall be due on or before the 15th Calendar day following the last day of the reporting period. Each Annual Progress Report shall include:

a) A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;

b) SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period;

c) SECTION II: PROGRESS

i) SECTION II Part A: OVERALL PROGRESS-A description of overall progress;

ii) SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE-A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating, and managing subcontractor performance; regulatory compliance audits);

iii) SECTION II Part C: TECHNICAL PROGRESS-A detailed description of the work performed structured to follow the activities and decision gates outlined in the approved Strategic Staged Product Development Plan. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved;

iv) SECTION II Part D; PROPOSED WORK-A summary of work proposed for the next year period.

a) Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and

b) A summary of any inventions developed during the course of the contract. (See also FAR Clause 52.227-11)

4. Draft Final Technical Progress Report and Final Technical Progress Report

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Technical Progress Report will not be required for the period when the Final Technical Progress Report is due. The Draft Final Technical Progress Report shall be submitted one hundred twenty (120) calendar days before completion date of the contract and the Final Technical Progress Report shall be submitted on or before the completion date of the contract. The report shall conform to the following format:

(a) Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date;

(b) SECTION I: EXECUTIVE SUMMARY-Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

(c) SECTION II: RESULTS-A detailed description of the work performed, the results obtained, and the impact of the results on the scientific and/or public health community, including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance, and a summary of all inventions.

Draft Final Technical Progress Report: The Contractor is required to submit the Draft Final Technical Progress Report to the Contracting Officer's Technical Representative and Contracting Officer. This report is due 120 calendar days before the completion date of the contract. The Contracting Officer's Technical Representative and Contracting Officer will review the Draft Final Technical Progress Report and provide the Contractor with comments within 45 calendar days after receipt.

Final Technical Progress Report: The Contractor will deliver the final version of the Final Technical Progress Report on or before the completion date of the contract. The final version shall include or address the Contracting Officer's Technical Representative comments and Contracting Officer comments on the draft report.

5. Summary of Salient Results

The Contractor shall submit, with the Final Technical Progress Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

6. Other Technical Progress Reports

a. Draft Report for Clinical and Non-Clinical Studies and Final Report for Clinical and Non-Clinical Studies

· The non-clinical and clinical trial reports shall follow the format of International Conference on Harmonization document ICH E3 "Guidelines on Structure and Content of Clinical Study Reports" (http://www.pharmacontract.ch/support/su_ich_liste.htm).

· Draft Final Report for Clinical and Non-Clinical Studies will be submitted to the Contracting Officer's Technical Representative and Contracting Officer (CO) for review and comment no later than 15 working days after completion of analysis of study data.

· The Contracting Officer shall provide written comments within 30 working days after the submission of the Draft Final Report for Clinical and Non-Clinical Studies.

· The comprehensive Final Report for Clinical and Non-Clinical Studies will be submitted to the Contracting Officer and the Contracting Officer's Technical Representative within 30 calendar days after receiving comments on the Draft Final Report for Clinical and Non-Clinical Studies from the Contracting Officer. The final version shall include or address the Contracting Officer's Technical Representative comments and Contracting Officer comments on the draft report

b. Audit Reports

Within thirty (30) calendar days of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, or GCP guidelines, as it relates to performance under this contract where the results will adversely impact contract performance, the Contractor shall provide the Contracting Officer's Technical Representative and the Contracting Officer with copies of the audit report and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

c. Clinical Trial Protocols

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf), the Contractor shall develop a protocol for each clinical trial and submit all protocols and protocol amendments for approval by the BARDA Contracting Officer's Technical Representative. Important information regarding performing human subjects research is available at http://www3.nia.id.nih.gov/healthscience/clinicalstudies/.

Any updates to technical reports are to be addressed in the Monthly, Quarterly and Annual Progress Reports. The Contractor shall advise the Contracting Officer's Technical Representative or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

7. Other Reports/Deliverables

a. **Copies of FDA Correspondence and Meeting Summaries**

1. For any formal meeting with the FDA, the Contractor shall forward initial draft minutes and subsequently final meeting minutes within thirty (30) calendar days of receipt from the FDA to the BARDA Contracting Officer's Technical Representative.

2. The Contractor shall forward the final draft minutes of any informal meeting with the FDA to BARDA.

3. The Contractor shall forward the dates and times of any meeting with the FDA to BARDA at least 30 days prior to the meeting and make arrangements for appropriate BARDA staff to attend FDA meetings.

4. The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA. The Contractor shall provide BARDA with five (5) business days in which to review and provide comments back to the Contractor.

b. **Technology Transfer**

Animal Models and other technology packages developed under the contract that include complete protocols and critical reagents for animal models developed and/or improved with contract funding must be submitted at the request of the BARDA Contracting Officer's Technical Representative. See FAR clause 52.227-11 (Patent Rights-Ownership by the Contractor).

c. **Institutional Biosafety Approval**

The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments at the request of the BARDA Contracting Officer's Technical Representative.

d. **Data**

The Contractor shall provide raw data or specific analysis of data generated with contract funding at the request of the BARDA Contracting Officer's Technical Representative. See FAR clause 52.227-14 (Rights in Data-General).

e. **Meeting Minutes**

The Contractor shall provide an electronic copy of conference call meeting minutes/summaries to the BARDA Contracting Officer's Technical Representative and Contracting Officer within seven (7) calendar days after the conference call is held.

f. **Audits/Site Visits**

BARDA/AMCG Audits

The United States Government (USG) reserves the right to conduct an audit of the Contractor with five (5) business days notice. The USG reserves the right to accompany the Contractor on routine and for-cause site-visits/audits of subcontractors. At the discretion of the USG and independent of testing conducted by the Contractor, BARDA reserves the right to conduct site visits/audits.

ARTICLE C.3. SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 2207, MSC 7987, Bethesda, Maryland 20892-7987 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract. See also FAR clause 52.227-11 (Patent Rights-Ownership by the Contractor).

Reports and documentation submitted to the Contracting Officer shall be sent to the following address:

Contracting Officer
Ethan J. Mueller
Office of Acquisitions Management, Contracts, and Grants (AMCG)
330 Independence Avenue, S.W.
Room G640
Washington, D.C. 20201

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, "Interagency Edison," an electronic invention reporting system has been developed. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedisop.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

ARTICLE C.4. TWICE MONTHLY CONFERENCE CALLS

A conference call between the Contracting Officer's Technical Representative and the principal investigator shall occur bi-monthly or as directed by the Contracting Officer's Technical Representative. During this call the principal investigator will discuss the activities during the reporting period, any problems that have arisen and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. The principal investigator may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Technical Representative.

ARTICLE C.5. PROJECT MEETINGS

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Technical Representative. These meetings may include face-to-face meetings with BARDA/AMCG in Washington, D.C. and at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts and USG personnel as required by the Contract ing Officer's Technical Representative in order to facilitate review of contract activities.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

Report Deliverables

Unless otherwise specified by the Contracting Officer, delivery of reports to be furnished to the Government under this contract (including invoices), shall be addressed as follows:

Dr. Eric Espeland, Contracting Officer's Technical Representative (COTR)
DHHS/OS/ASPR/BARDA
330 Independence Avenue, S.W.
Room 640G
Washington, D.C. 20201
E-mail: Eric.Espeland@hhs.gov

Francine L. Hemphill, Contracting Specialist
DHHS/OS/ASPR/AMCG
330 Independence Avenue, S.W.
Room 640G
Washington, D.C. 2020
E-mail: Francine.Hemphill@hhs.gov

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided under this contract.

b. For the purpose of this SECTION, the designated Contracting Officer's Technical Representative (COTR) is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:

Biomedical Advanced Research and Development Authority

Office of the Assistant Secretary for Preparedness and Response

U.S. Department of Health and Human Services

330 Independence Avenue, S.W., Room G644

Washington, D.C. 20201

d. The contract incorporates the following clause by reference with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause 52.246-8, Inspection of Research and Development - Cost-Reimbursement (May 2001). (Note: Work is deemed acceptable 90 days after delivery.)

SECTION F - DELIVERIES OR PERFORMANCE

Deliveries and performance under these Contract Line Item Numbers (CLINs) and Option CLINs shall be as follows:

ARTICLE F.1. PERIOD OF PERFORMANCE

a. Under CLIN 0001, the base period of performance of this contract shall be from 7/19/2010-7/18/2012.

b. If the Government exercises its options pursuant to the OPTION CLAUSE Article in Section H of the contract, the period of performance will be increased as listed below:

OPTION CLIN	PERIOD OF PERFORM.	SUPPLIES/SERVICES
0002		RESERVED.
0003	[**]	[**]
0004	[**]	[**]
0005	[**]	[**]
0006	[**]	[**]
0007	[**]	[**]
0008	[**]	[**]

ARTICLE F.2. REPORTING REQUIREMENTS AND DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work dated 5 May 2010 set forth in SECTION J-List of Attachments of this contract and upon delivery and acceptance, as required by the Statement of Work, by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract and the Statement of Work dated 5 May 2010 set forth in SECTION J-List of Attachments will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract:

1. Other Contract Deliverables

Item	Deliverable	Quantity	Due Date
1.	Risk Management Plan	1 Electronic Copy Project Officer (PO)	Quarterly on the 15th day of the month due or as

1 Hard Copy - PO 1 Electronic Copy - Contracting Officer (CO) 1 Hard Copy - CO	Determined by the Project Officer.

2. WBS Milestones/Deliverables and Technical Deliverables as contained in the Statement of Work dated 5 May 2010 set forth in SECTION J-List of Attachments.

The above items shall be addressed and delivered to:

Contracting Officer's address:	AMCG 330 Independence Avenue, S.W. Room G640 Washington, D.C. 20201 E-mail: Ethan.Mueller@hhs.gov
Contracting Officer's Technical Representative's address:	BARDA 330 Independence Avenue, S.W. Room G644 Washington, D.C. 20201 E-mail: Eric.EspelandAhhs,gov

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

The contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER

The following Contracting Officer will represent the Government for the purpose of this contract:

Ethan J. Mueller, Contracting Officer

DHHS/OS/ASPR/AMCG

330 Independence Avenue, S.W.

Room 640G

Washington, D.C. 2020

E-mail: Ethan.Mueller@hhs.gov

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.

2) The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimburse to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.

3) 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 US Government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.

4) The Government may unilaterally change its COTR designation.

ARTICLE G.2. CONTRACTING OFFICER'S TECHNICAL REPRESENTATIVE (COTR)

The following COTR will represent the Government for the purpose of this contract:

1. Dr. Eric Espeland, COTR

DHHS/OS/ASPR/BARDA

330 Independence Avenue, S.W.

Room 640G

Washington, D.C. 20201

E-mail: Eric.Espeland@hhs.gov

The COTR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical

evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

ARTICLE G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:

#	NAME	ORGANIZATION	B55 SCALE-UP ROLE
1	[**]	EBOL	Program Manager
2	[**]	EBOL	Vice President Quality Assurance
3	[**]	EBSI	Senior Director Regulatory Affairs
4	[**]	EBSI	Non-Clinical Development Lead
5	[**]	EBSI	Senior Director Clinical Development
6	[**]	EBOL	Manufacturing Development Lead

The key personnel specified in this contract are considered to be essential to work performance. At least 30 business days prior to diverting any of the specified individuals to other programs or contracts, including an instance when an individual must be replaced as a result of leaving the employ of the Contractor, the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

ARTICLE G.4. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Financial Report of Individual Project/Contract shall be submitted by the Contractor in accordance with the instructions for completing this form, which accompany the form, in an original and two copies, not later than the 30th business day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in that part of the instructions for completing this form, entitled "**PREPARATION INSTRUCTIONS** ," all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated within the Attachment entitled, "Financial Report of Individual Project/Contract," located in SECTION J and made a part of this contract.

f. The Government may unilaterally revise the "Financial Report of Individual Project/Contract" to reflect the allotment of additional funds.

ARTICLE G.5. INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING

1) The Contractor shall submit an electronic copy of monthly contract invoices/financial reports to the address shown below:

DHHS/OS/ASPR/AMCG

Attn: Francine L. Hemphill, Contract Specialist

330 Independence Ave., S.W.

Room G640

Washington, D.C. 20201

2) Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting made a part of the contract in Section J.

3) Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

4) The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Cost (FAR 52.232-20) clause in the contract.

5) All invoice submissions shall be in accordance with FAR Clause 52.232-25 in Section I of this contract.

ARTICLE G.6. REIMBURSEMENT OF COST

1) The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with the clause entitled Allowable Cost and Payment in Section I, Contract Clauses, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

a) All direct materials and supplies that are used in the performing of the work provided for under the contract, including those purchased for

subcontracts and purchase orders.

b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

d) Special expenditures which, upon request from the Contractor, the Contracting Officer approves as being an allowable cost under this contract, such as purchase or lease of office furniture or equipment, etc.

e) All travel costs plus per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract. These costs will be in accordance with the Contractor's policy and subject to the following:

(i) Air travel shall be by the most direct route using "air coach" or "air tourist" (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

(ii) Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.

(iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).

(iv) Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

ARTICLE G.7. INDIRECT COST RATES

The following rates will be utilized for billing purposes during the base period. Fringe benefits at [**]%, development overhead at [**]% applied to a base of sum of total direct labor plus fringe benefits, and G&A at [**]% applied to a modified base that excludes subcontracts and equipment. The billing rates for each option period will be based on the incurred cost submission for the previous calendar year, subject to Government audit adjustments. Final rate proposals must be sent to the Contractor's cognizant audit agency, NIH Division of Financial Advisory Services, as well as a copy to the Contracting Officer, within 6 months subsequent to the fiscal year end.

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

1. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted June 29, 2012.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

2. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

ARTICLE G.9. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

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

ARTICLE G.10. GOVERNMENT PROPERTY

1. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at:

http://www.hhs.gov/oamp/policies/contractors_guidefor_control_of^govproperty.pdf .

Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

2. Notwithstanding the provisions outlined in the HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated in this contract in paragraph a. above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

3. Title will vest in the Government for equipment purchased as a direct cost.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-8(b) (January 2006)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Office of Public Health and Science (OPHS). The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings an d the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(c) If at any time during the performance of this contract, the Contracting Officer determines, in consultation with the OHRP, OPHS, ASH, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OHRP, OPHS, ASH, terminate this contract in a whole or in part, and the Contractor's name may be removed form the list of those contractors with approved Health and Human Services Human Subject Assurances.

ARTICLE H.2. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

ARTICLE H.3. RESEARCH INVOLVING HUMAN FETAL TISSUE

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-l and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grantsl.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-l(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

ARTICLE H.4. NEEDLE EXCHANGE

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.5. PRESS RELEASES

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.6. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-9(b) (January 2006)

(a) Before undertaking performance of any contract involving animal related activities, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

(b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 through 2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1 - 4). In case of conflict between standards, the more stringent standard shall be used.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved PFIS Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

(End of Clause)

ARTICLE H.7. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:

http ://grants 1.nih.gov/grants/olaw/references/phspol.htm .

ARTICLE H.8. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL:

http://wwwl.od.nih.gov/oma/manualchapters/intramural/3044-2/

ARTICLE H.9. PUBLICATION AND PUBLICITY

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer Technical Representative.

In addition to the requirements set forth in HHSAR Clause **352.270-6, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, under Contract No. _____"

ARTICLE H.10. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is Htips@os.dlihs.gov and the mailing address is:

Office of Inspector General

Department of Health and Human Services

TIPS HOTLINE

P.O. Box 23489

Washington, D.C. 20026

ARTICLE H.11. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST

ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 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.

ARTICLE H.12. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions, which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

ARTICLE H.13. EXERCISE OF OPTIONS

Unless the Government exercises its option pursuant to the Option Clause set forth in Section I, Article I.I, the contract will consist only of **CLIN 0001** of the Statement of Work, Deliverables and Requirements as defined in Sections C, F and J of the contract. Pursuant to FAR Clause **52.217-7 (Option for Increased Quantity)** set forth in Section I of this contract, under Article I.I., the Government may, by unilateral contract modification, require the Contractor to perform **any of the additional CLIN's listed in Section B, Article B.3.,** and as also defined in Sections C, F and J of this contract. If the Government exercises an option, notice must b e given at least 60 days prior to the expiration date of this contract. The amount of the contract will then be increased as set forth in Section B, Article B.3

ARTICLE H.14. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.270-10 ANTI-LOBBYING (Jan 2006)

The Contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United Stated Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person 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 any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, as set forth in HHSAR 352.270-10 "Anti-Lobbying" (January 2006), the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

ARTICLE H.15. PRIVACY ACT APPLICABILITY (Apr 2000)

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://www.gpoaccess.gov/cfr/index.html

2) The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

3) The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

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

ARTICLE H.16. 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.

ARTICLE H.17. DISSEMINATION OF INFORMATION (May 1998)

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer.

ARTICLE H.18. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will 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 directly related to and/or generated under 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.

ARTICLE H.19. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

Registration with the U. S. Dept. of Agriculture (USD A) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), http://www.nal.usda.gov/awic/legislat/awa.htm.

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) http://grants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS Policy http://grants2.mh.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U.S. Public Health Service.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* http://www.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 CFR, Subchapter A) http://www.nal.usda.gov/awic/legislat/usdalegl.htm issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the *Guide* as their primary evaluation tool. They also use the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching*. It is published by the Federated of Animal Science Societies http://www.fass.org.

ARTICLE H.20. REQUIREMENTS FOR ADEQUATE ASSURANCE OF PROTECTION OF VERTEBRATE ANIMAL SUBJECTS

The PHS Policy on Humane Care and Use of Laboratory Animals requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS Policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. Also, the PHS policy defines "animal" as "any live, vertebrate animal used, or intended for use, in research, research training, experimentation, biological testing or for related purposes." This Policy implements an d supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires that institutions use the Guide for the Care and Use of Laboratory Animals as a basis for developing and implementing an institutional animal care and use program. This Policy does not

affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et. seq.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163. See http://grants.nih.gov/grants/olaw/olaw.htm.

No PHS supported work for research involving vertebrate animals will be conducted by an organization, unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the institution for further review in the case of apparent or potential violations of the PHS Policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. Foreign applicant organizations are not required to submit IACUC approval, but should provide information that is satisfactory to the Government to provide assurances for the humane care of such animals.

ARTICLE H.21. APPROVAL OF REQUIRED ASSURANCE BY OLAW

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the Contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and indepen dent from those activities that do involve live vertebrate animals) may be conducted by the Contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants2.nih.gov/grants/olaw/references/phspol.htm.

ARTICLE H.22. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.eov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulat ions and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http ://www.cdc.gov/od/sap/.

ARTICLE H.23. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

ARTICLE H.24. ACKNOWLEDGMENT OF FEDERAL FUNDING

A. Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money, and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

B. Publication and Publicity

Publications: Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted for BARD A Project Officer review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. A “publication” is defined as an issue of printed material offered for distribution or any communication or oral presentation of information.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an

acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201000034C."

C. Press Releases

a. Pursuant to Section 508 of Public Law 105-78, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b. The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The Contractor shall ensure that the Project Officer has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

ARTICLE H.25. MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP)(21 CFR Parts 210-211) and regulations pertaining to biological products (21 CFR Part 600) and regulations pertaining to diagnostic products (21 CFR Part 860) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery 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 the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the USG Project Officer, or fails to provide a remediation plan that is acceptable to the Project Officer, then the contract may be terminated.

ARTICLE H.26. EXPORT CONTROL NOTIFICATION

Offerors are responsible for ensuring compliance with all export control laws and regulations that maybe applicable to the export of and foreign access to their proposed technologies. Offerors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CRF Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CRF Parts 730-774).

ARTICLE H.27. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

1. The Small Business Subcontracting Plan, dated 5 May 2010 is attached hereto and made a part of this contract.

2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages- Subcontracting Plan."

b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov .

a. Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

October 30th

April 30th

Expiration Date of Contract

b. Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

April 30th

For both the Individual and Summary Subcontract Reports, the Contract Specialist shall be included as a contact for notification purposes at the following e-mail address:

Francine L. Hemphill, Contracting Specialist

DHHS/OS/ASPR/BARDA

E-mail: Francine.Hemphill@hhs.gov

ARTICLE H.28. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research

funded under BARDA contracts) will not be biased by any conflicting financial interest. For the purposes of this part relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children. 45 CFR Part 94 is available at the following Web site:

htlp://ecfr.gpoaccess.gov/cgi/ I/text/ texl-idx?c=ecfr;sid=9fl30b6d2d48bb73803ca91ce943be3a:rgn-div5;view=text:node=45%3A1.0.1.1,53;idno=45;cc =ecfr

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

ARTICLE H.29. HUMAN MATERIALS

It is understood that the acquisition and supply of all human specimen material (including fetal material) used under this contract will be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States and that no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.30. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.eov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regula tions and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

PART II - PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.I. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at these addresses: http://www.arnet.gov

General Clauses for Cost-Reimbursement Research and Development

(1) FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Jul 2004	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Sep 2007	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.203-13	Apr 2010	Contractor Code of Business Ethics and Conduct
52.203-14	Dec 2007	Display of Hotline Poster
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.204-7	Apr 2008	Central Contractor Registration
52.209-6	Sep 2006	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000) Audit and Records - Negotiation (Over $100,000)
52.215-2	Mar 2009	Order of Precedence - Uniform Contract Format Price Reduction for Defective Cost or Pricing Data Subcontractor Cost or Pricing Data (Over $500,000) Integrity of Unit Prices (Over $100,000) Pension Adjustments and Asset Reversions
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost of Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Date (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Oct 2004	Pension Adjustments and Asset Reversions
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment (Note: the following language is included in this clause - "(3) The designated payment office will make interim payments for contract financing on the 30th day after the designated billing office receives a proper payment request..."
52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Apr 2008	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-19	Aug 2009	Child Labor - Cooperation with Authorities and Remedies
52.222-3	Jun 2003	Convict Labor
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Mar 2007	Equal Opportunity
52.222-35	Sep 2006	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities

52.222-37	Sep 2006	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-50	Feb 2009	Combating Trafficking in Persons
52.222-54	Jan 2009	Employment Eligibility Verification
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
52.224-1	April 1984	Privacy Act Notification
52.224-2	April 1984	Privacy Act
52.225-1	Feb 2009	Buy American Act - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Dec 2007	Patent Rights - Ownership by the Contractor
52.227-14	Dec 2007	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Oct 2008	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Oct 2008	Prompt Payment
52.232-33	Oct 2003	Payment by Electronic Funds Transfer-Central Contractor Registration
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (June 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.242-15	Apr 1989	Stop Work Order. Alt I (Aug 1984)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	June 2007	Subcontracts
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.244-6	Apr 2010	Subcontracts for Commercial Items
52.245-1	June 2007	Government Property
52.245-9	Jun 2007	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	May 2004	Termination (Cost-Reimbursement)
52-249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

(2) DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2006	Definitions - with Alternate paragraph (h) (Jan 2001)

		Additional Cost Principles
352.216-72	Jan 2006	
		Insurance - Liability to Third Persons
352.228-7	Dec 1991	
		Withholding of Contract Payments
352.232-9	Jan 2006	
		Litigation and Claims
352.233-70	Jan 2006	
		Final Decisions on Audit Findings
352.242-71	Apr 1984	
		Key Personnel
352.270-5	Jan 2006	
		Pricing of adjustments.
352.270-4	Jan. 2001	
		Publications and Publicity
352.270-6	Jan 2006	
		Care of Live Vertebrate Animals
352.270-9	Jan 2006	
		Anti-Lobbying
352.270-10	Jan 2006	

ARTICLE 1.2. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).

2. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program-- Disadvantaged Status and Reporting** (April 2008).

3. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause **352.223-70, Safety and Health** (January 2006).

2. HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).

3. HHSAR Clause **352.270-7, Paperwork Reduction Act** (January 2006).

4. HHSAR Clause **352.270-8 (b), Protection of Human Subjects** (January 2006).

ARTICLE 1.3. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1)CLAUSES:

a. FAR Clause **52.219-28, Post-Award Small Business Program Representation** (April 2009).

(a) *Definitions*. As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is “not dominant in its field of operation” when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, own ership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall represent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts—

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall represent its size status in accordance with the size standard in effect at the time of this representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/contractmgopportiinities/officials/size/index.html.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the time frames specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the representation was completed:

The Contractor represents that it [ ] is, [ ] is not a small business concern under NAICS Code assigned to contract number.

[Contractor to sign and date and insert authorized signer's name and title].

b. FAR **Clause 52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees** (December 2004)

(a) *Definition.* As used in this clause –

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended

(45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board

Division of Information

1099 14th Street, N.W

Washington, DC 20570

1-866-667-6572

1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov .

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B -- Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to **–**

(l) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for Contractors covered by the Railway Labor Act and a second for all other Contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov ; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States. (End of Clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work

Statement of Work, dated 5 May 2010.

2. Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for BARD A Cost- Reimbursement Type Contracts,

Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for BARDA Cost-Reimbursement Type Contracts, 5 pages.

3. Financial Report of Individual Project/Contract, 1 page

4. Instructions for Completing Financial Report of Individual Project/Contract, 3 pages

5. Inclusion Enrollment Report

Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01), 1 page.

6. Research Patient Care Costs Research Patient Care Costs, 1 page.

7. Report of Government Owned, Contractor Held Property

Report of Government Owned, Contractor Held Property, dated 12/2/09, 1 page. Located at: http://rcb.cancer.gov/rcb-iuternet/lbrms/Govt-Owned-Prop.pdf **(Not Attached)**

8. Small Business Subcontracting Plan

Small Business Subcontracting Plan, dated 5 May 2010.

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following documents are incorporated by reference in this contract:

1) Annual Representations and Certifications completed at the Online Representations Applications (ORCA) website.

2) Representations & Certifications dated 5 May 2010.

3) Human Subjects Assurance Identification Number FSW00007296, Type F

4) Animal Welfare Assurance Number A3034-01

- -

ATTACHMENT 1 - Statement of Work, dated 5 May 2010.

3.0 STATEMENT OF WORK BROAD AGENCY ANNOUNCEMENT (BAA)

BARDA 09-34

Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures Statement of Work

Development of a Large-Scale Manufacturing Process for BioThrax Preamble

(TG2) Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work (SOW) submitted in response to Broad Agency Announcement (BAA) BARDA 09-34.

The Government reserves the right to modify the milestones, progress, schedule, budget, or product to add or delete products, process, or schedule as need may arise. Because of the nature of the (R&D) contract and complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made. In any event the Government reserves the right to change product, process, schedule, or event to add or delete part or all of these elements as the need arises.

1.0 SCOPE

The scope of work for this contract includes development activities that fall into the following areas: process and assay development, qualification and validation, manufacturing, clinical, animal study, and all other BLA-enabling activities.

2.0 OBJECTIVE

The objective of this SOW is to license Building 55 on Emergent BioDefense

Operations Lansing Inc.'s campus for large-scale manufacturing of BioThrax.

3.0 TECHNICAL APPROACH

This section identifies representative tasks and sub-tasks for achieving the objective. We organize tasks and subtasks by year, Figure 27.

SOW Task #	WBS#	Base Years	Opt. Yr1	Opt. Yr2	Opt. Yr3
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
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[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]

Figure 27. We organized the representative tasks and sub-tasks of the SOW by the years in which they will occur.

3.1 (WBS [**]**) Development Approach:**

3.1.1 (WBS [**]**) Non-Clinical Research and Development**

Non-clinical activities delineated in the Integrated Product Development Plan include:

3.1.1.1 (WBS [**]

Evaluate [**]

3.1.1.2 (WBS [**]

Evaluate [**].

3.1.1.3 (WBS [**]

Evaluate [**].

Additional non-clinical activities required for licensure of BioThrax in Building 55 may be identified in the course of development.

Studies evaluating the safety, comparability, immunogenicity, toxicity, efficacy, formulation, dose, route and schedule of BioThrax using both in vitro and animal models following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations 21 CFR Part §58) may need to be conducted as and when appropriate to achieve the contract objective.

3.1.2 (WBS [**]**) Development**

Activities delineated in the Integrated Product Development Plan include:

3.1.2.1 (WBS [**]**) Process Development and Validation**

3.1.2.2 (WBS [**]**) Assay Development and Validation**

3.1.2.2.1 (WBS [**]

– [**]

3.1.2.2.2 (WBS [**]

– [**]

3.1.2.2.3 [**]

3.1.2.2.4 (WBS [**]

3.1.2.2.5 [**]

3.1.2.3.1 (WBS [**]

– [**]

3.1.2.3.2 (WBS [**]

– [**]

3.1.2.3.3 (WBS [**]

– [**]

3.1.2.3.4 (WBS [**]

– [**]

3.1.2.4 (WBS [**]

3.1.2.4.1 (WBS [**]

– [**]

3.1.2.4.2 (WBS [**]

– [**]

3.1.2.4.3 (WBS [**]

– [**]

Additional process development, formulation and manufacturing development studies may be identified in the course of development to meet the requirements for FDA licensure of BioThrax in Building 55.

3.1.3 (WBS [**]) Clinical Development

Activities include:

3.1.3.1 (WBS [**]

In accordance with all Federal regulations and GCP guidelines as required for BioThrax licensure in Building 55. [**]

[**]

Additional requirements [**] may be identified in the course of development to meet the requirements for FDA licensure of BioThrax in Building 55.

3.1.4 (WBS [**]) Regulatory Affairs Management

Activities delineated in the Integrated Product Development Plan include:

[**]

An EVM System shall be implemented within days of contract award to meet the requirements of a Tier 2 EVM implementation as outlined in the BARDA Tier 2 EVM System Implementation Intent Guide.

For the purposes of this contract, EBOL shall use EVMS in the management of this contract to meet the Seven Principles of Earned Value Management as follows:

a) Plan all work scope for the program to completion.

b) Break down the program work scope into finite pieces that can be as signed to a responsible person or organization for control of technical, schedule, and cost objectives.

c) Integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured. Control Changes to the base line.

d) Use actual cost incurred and re corded in accomplishing the work per formed.

e) Objectively assess accomplishments at the work performance level.

f) Analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed..

g) Use earned value information in the company's management processes specific to this contract.

EVMS shall be applied to CLIN [**] as part of the Integrated Master Project Plan, EBOL shall submit a written summary of the management procedures that it will establish, maintain and use to comply with EVMS requirements.

3.2.2 Integrated Product Development Plan (IPDP)

The IPDP shall contain the following elements:

a) Activities and stages of product development that Emergent is proposing to per-form under contract funding in a project plan that indicates the base period and option period activities and includes all of the functional areas of development listed below.

b) A detailed description of the experimental design, including the rationale for experimental approaches, and a description of alternative approaches to be employed if these methods do not achieve the defined goals.

c) Distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the IPDP.

d) The qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.

e) Milestones and timelines for the initiation, conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.

f) A listing of key personnel (including proposed consultants) who possess the necessary education, training, and experience to successfully perform the work identified in the technical proposal and their resumes.

g) A staffing plan that indicates personnel (in house and contracted) resources and the percentage of time to be dedicated to perform the work.

h) A clear and comprehensive regulatory master plan that focuses on the crucial pathway integrating all products, risk evaluation and mitigation at all development stages, non-clinical and clinical testing, manufacturing activities using the most current and available information, and documented and time-relevant FDA consultation.

i) Establishment and filing of regulatory submissions to the relevant FDA center.

j) A plan for additional studies to support future filing for FDA-approval/ clearance.

k) Summary of any prior communication with the FDA relevant to the product development; summary of audits and inspections.

l) Tentative schedule of regulatory milestones.

m) Potential Plan for consideration of an Emergency Use Authorization (EUA) of a medical product.

n) A work breakdown structure (WBS) that is discernable and consistent. It may include data at the cost account level or at the work package level or at a lower level if there is significant complexity and risk associated with the task.

o) An approach for tracking milestones, costs, risks, subcontractor effort (if applicable), deliverables and proposed internal procedures for assuring timely responses to the Government's needs on any resulting contract.

p) An approach for performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both prime- and sub-contractors on a real time basis.

q) A table matrix capturing all program activities that will generate data and the documents that will be generated from each activity.

3.2.1.1 Updated IPDP

Within fourteen (14) days of the effective date of the BAA award and prior to the contract kickoff meeting, which will occur within thirty (30) days of the effective date of the BAA award, EBOL shall submit an updated draft IPDP which shall be approved by the Project Officer and the Contracting Officer prior to initiation of any activities related to their implementation. The final IPDP is due within ten (10) days of the contract kickoff meeting. During the course of contract performance, in response to a need to change the IPDP,

Emergent shall submit a Deviation Report. This report shall request a change in the agreed-upon Plan and timelines. This report shall include:

a) Discussion of the justification/ rationale for the proposed change.

b) Options for addressing the needed changes from the approved timelines, including a cost-benefit analysis of each option.

c) Recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development pro gram, timelines, and budget.

d) Emergent shall carry out activities within the contract SOW only as requested and approved by the Contracting Officer, and may not conduct work on the contract without prior approval from the Contracting Officer, including initiating work that deviates from the agreed-upon IPDP.

3.2.2 Target Product Profile (TPP):

a) The intended use or indication of the proposed medical countermeasure.

b) The intended product profile (strength, quality, purity and identity) noting the performance specifications and features of the medical countermeasure that provide benefit.

c) A description of the medical counter measure as it is currently configured.

d) A description of the manufacturing process including expected formulation (configuration) of the final product.

e) A description and developmental status of the assays for product release which provide characterization, strength, identity, and purity, as well as any needed assays for product activity and efficacy.

f) Discussions with appropriate FDA reviewers that is relevant to development activities for the proposed medical countermeasure, including plans for generating data to support an Investigational New

Drug (IND) or Biologies License Application (BLA): summary of any prior, time-relevant communication with FDA relevant to the product development for the indication noted; summary of audits and inspections relative to the current development or proposed manufacturing (including at key sub-contractors) of the intended product.

3.2.3 Contractor Provided Facilities, Infrastructure, and Other Resources

This includes but is not limited to:

a) Current facility design including quality control labs for testing and release, laboratory areas supporting formulation and assay development, manufacturing process flow, and animal studies.

b) Major equipment and layout (preliminary piping/ instrumentation drawing).

c) Validation master plan for key equipment, analytical methods and manufacturing process.

3.2.4 Security Plan

This includes but is not limited to:

a) Security administration, as an element of the security program that address threat and risk assessments and related policies and procedures for personnel security, physical security, information security, information technology.

b) Security management, as an element of the security program that de scribe each element of security: physical, operations, personnel, information, information technology, transportation; and related training, auditing, and reporting requirements.

3.2.5 (WBS [**]

[**]

Contract Period	MSTN #	Milestones	Deliverables Summary (Details as specified in the Deliverable section)	Quantity	Date
Base	01	[**]	[**]	1 Electronic Copy Project Officer (PO) 1 Hard Copy - PO 1 Electronic Copy -Contracting Officer (CO) 1 Hard Copy - CO	[**]
	02	[**]	[**]	see above	[**]
Base	03	[**]	[**]	see above	[**]
	04	[**]	[**]	see above	[**]
	05	[**]	[**]	see above	[**]
	06	[**]	[**]	see above	[**]
	07	[**]	[**]	see above	[**]
	08	[**]	[**]	see above	[**]
Option Year 1	09	[**]	[**]	see above	[**]
	10	[**]	[**]	see above	[**]
Option Year 2	11	[**]	[**]	see above	[**]
	12	[**]	[**]	see above	[**]
	13	[**]	[**]	see above	[**]
	14	[**]	[**]	see above	[**]
Option Year 3	15	[**]	[**]	see above	[**]
	16	[**]	[**]	see above	[**]
	17	[**]	[**]	see above	[**]
	18	[**]	[**]	see above	[**]

	MSTN #	Milestones	Deliverables Summary (Details as specified in the Deliverable section)	Quantity	Date
[**] Option	01	[**]	[**]	1 Electronic Copy Project Officer (PO) 1 Hard Copy - PO 1 Electronic Copy -Contracting Officer (CO) 1 Hard Copy - CO	[**]
	02	[**]	[**]	see above	[**]
	03	[**]	[**]	see above	[**]

CDRL#	Deliverable	Deliverable Description	Quantity	Due Date
01	Kickoff Meeting/Status Update Meetings	The contractor shall complete a Kickoff meeting after contract award and shall hold recurring Program Review Meetings.	N/A	Within a month of contract award, but after submission of a draft PDP, for Kick Off meeting (Final IPDP revision to be submitted per Deliverable #9). Program Review Meetings shall occur semi-annually or as negotiated by all Parties during contract period of Performance.
02	Biweekly Teleconference	The Contractor shall participate in biweekly teleconferences with BARDA to discuss the performance of the contract. The Contractor shall record, maintain and provide draft meeting minutes to the Project Officer for approval within three (3) days after teleconference. The Project Officer will approve the draft version within two (2) business days after receipt. The Contractor shall distribute the final approved version duly marked as final within 3 business days after receipt of BARDA approval.	1 Electronic Copy Project Officer (PO) 1 Electronic Copy - Contracting Officer (CO)	Biweekly or as negotiated by all parties
03	Monthly & Annual Technical Progress Report	The Monthly and Annual Technical Progress report shall address each of the below items and be cross-referenced to the WBS in the Gantt chart and IPDP. 1. An Executive Summary in MS PowerPoint format, highlighting the progress, issues, and relevant activities in manufacturing, non-clinical, clinical, and regulatory. The Executive Summary should be limited to a few slides and also highlight only critical issues for that reporting period and resolution approach 2. Progress in meeting contract milestones - broken out by subtasks within each milestone, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned progress and actual progress during the period covered, explaining occurrences of any differences between the two, and the corrective steps and actions are planned, if behind schedule. 3. The reports shall also include a three month rolling forecast of key planned activities, referencing the WBS/IPDP. 4. A tracking log of progress on regulatory submissions with the FDA submission number, description of submission, date of submission, status of submission, and next steps 5. Estimated and Actual Expenses a. This report shall also contain a narrative statement as to whether there is any discrepancy at this time between the % of work completed and the cumulative costs incurred to date. This section of the report shall also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. These shall be listed for each subcontractor. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.	1 Electronic Copy Project Officer (PO) 1 Hard Copy - PO 1 Electronic Copy — Contracting Officer (CO) 1 Hard Copy - CO	Monthly Reports shall be submitted on the 15th day of each month for the previous calender month with an Annual Report submitted on the 15th day of the final month of each contract year for the previous twelve calender months. Monthly progress reports are not required for the periods when the Annual Report(s) and Final Report is due.
04	Technical Documents	The contractor shall provide complete technical documents for BARDA review and approval. All documents shall be duly marked as either 'Draft' or 'Final'. These technical documents shall include, but shall not be limited to, the following: [**]	For Draft Documents: 1 Electronic Copy Project Officer (PO) 1 Electronic Copy -Contracting Officer (CO) For Final Documents: 1 Electronic Copy Project Officer (PO) 1 Hard Copy - PO 1 Electronic Copy — Contracting Officer (CO) 1 Hard Copy - CO	Draft documents shall be submitted to BARDA for review and comment. BARDA will provide feedback within 5 business days. Contractor shall submit all final technical documents within 5 calendar days of completion or as mutually agreed to during the program execution with the Project Officer.
05	Draft Final Contract Report	A draft Final Contract Report containing a summation of the work performed and the results obtained for the entire contract period of performance. The draft report shall be duly marked as 'Draft'.	1 Electronic Copy Project Officer (PO) 1 Hard Copy - PO 1 Electronic Copy -Contracting Officer (CO) 1 Hard Copy - CO	Due 90 days prior to the completion date of the contract.
06	Final Contract Report	The Final Contract Report incorporating the feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire	see above	Due on/before the completion of the

		contract period of performance. The final report shall be duly marked as 'Final'. The Contractor shall submit one (1) copy of a comprehensive final report to the Contracting Officer and two (2) copies (one electronically on a CD) to the Project Officer. This final report shall detail, document and summarize the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved under all milestones.		contract
07	Milestone Reports	The Contractor shall provide a Milestone Report with final versions of key project documentation, after the completion of each Milestone unless otherwise agreed upon by the Project Officer and the Contracting Officer. All documents related to Milestone deliverables shall be submitted to BARDA in draft form for review and comments prior to submittal in final form in the final Milestone Report. All documents shall be duly marked as either 'Draft' or 'Final'. Milestone reports and monthly reports may be combined if agreed by the Project Officer and the Contracting Officer	see above	Draft Milestone report shall be submitted within 15 calendar days after completion of Milestone. 3ARDA will provide comments on :he Draft Milestone Report within 5 business days after receipt. Final Milestone Report shall be submitted within 15 calender days from receipt of BARDA comments.
08	Standard Operating Procedures	The contractor shall make internal and subcontractor Standard Operating Procedures (SOPs) available for review electronically.	N/A	Upon request from the project officer/contracting officer
09	IPDP	The Contractor shall be required to update the IPDP and include within the IPDP a table matrix capturing all program activities that will generate data and the documents that will be generated from each activity. In response to a need to change the IPDP, the contractor shall provide a deviation report identifying the reason for the deviation and request for change in the agreed upon plan and timelines.	1 Electronic Copy Project Officer (PO) 1 Hard Copy - PO 1 Electronic Copy -Contracting Officer (CO) 1 Hard Copy - CO	Within 10 business days after the contract kick off -meeting and following any revisions to the IPDP that occur during the contract Period of Performance. A deviation report shall be submitted as soon as the Contractor has sufficient data to support the need for a change from the approved IPDP.
10	FDA Correspondence and Mtgs Summaries	The contractor shall forward initial contractor and CBER-issued draft minutes and final minutes of any meeting with the FDA to BARDA. All documents shall be duly marked as either 'Draft' or 'Final'.	see above	Within 5 business days of each meeting for contractor's minutes and upon receipt of minutes from CBER
11	FDA Meetings	The contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (Project Officer, Contracting Officer, and up to 2 subject matter experts).	N/A	As and when scheduled during the contract period of performance
12	FDA Submissions	The contractor shall provide BARDA the opportunity to review and comment upon all draft regulatory documents before submission to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either 'Draff or 'Final'.	1 Electronic Copy Project Officer (PO) 1 Electronic Copy -Contracting Officer (CO)	BARDA shall provide comment within 10 business days after receipt. BARDA reserves the right to request more than 10 business days for review of any regulatory submission that is of significant length. The contractor shall inform BARDA of the anticipated submission length so BARDA can make a determination if more than 10 business days will be needed to complete its review of the document. Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of its submission to CBER.
13	FDA Audits	The Contractor shall notify the Project Officer and Contracting Officer within 24 hours of all FDA's arrival to conduct site visits/audits by any regulatory agency. In the event of an FDA inspection which occurs as a result of this contract and for this product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted; of the FDA Form 483, and the Establishment Inspection Report (EIR). The contractor shall provide the Project Officer and Contracting Officer copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution, and a copy of all final responses to the FDA. 0; The Contractor	1 Electronic Copy Project Officer (PO) 1 Hard Copy - PO 1 Electronic Copy - Contracting Officer (CO) 1 Hard Copy - CO	Within 24 hours of receipt from Regulatory Agency or Subcontractor.

		shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.		
14	Contractor Audit/Site Visits	The contractor shall inform the Project Officer and Contracting Officer in advance of upcoming audits/site visits of subcontractors as part of the biweekly communications, including goals and agenda. Upon completion of the audit/site visit the contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, details concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution	1 Electronic Copy Project Officer (PO) 1 Electronic Copy — Contracting Officer (CO)	Within 5 business days of report completion.
15	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to BARDA for review prior to submission	see above	Within 30 calendar days for manuscripts and 15 calendar days for abstracts
16	Press Releases	The contractor agrees to accurately and factually represent the work conducted under this contract in all press releases	1 Electronic Copy - Contracting Officer (CO)	The contractor shall ensure that the Contracting Officer has received and approved an advanced copy of any press release to this contract not less than 4 business days prior to the issuance of the press release
17	Security Reporting	The contractor shall report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products	1 Electronic Copy Project Officer (PO) 1 Electronic Copy -Contracting Officer (CO)	within 24 hours after occurrence of activity or incident
18	Contract Performance report Format 1	A monthly Contract Performance Report Format at an agreed upon reporting level using the BARDA provided Work Breakdown Structure	see above	Due 20 days after the end of the Emergent Accounting Calendar
19	Format 5 Variance Analysis Report	A Format 5 Variance Analysis Report for each WBS reporting level that exceeds the agreed upon variance reporting threshold	see above	Due 20 days after the month-end of the Emergent accounting calendar
20	Program Integrated Master Schedule	A program Integrated Master Schedule with monthly status updates (e.g. % complete for program tasks)	see above	Initial IMS due 30 days after award. Monthly status updates are due 10 days after the month-end of the Emergent accounting calendar
21	Performance Measure Baseline	Provide EVM documentation to BARDA, providing proof of a Performance Measurement Baseline 90 days after contract award. This submission EVM documentation shall include: a description of the work scope through control account Work Authorization Documents (WADs); Integrated Master Schedule (IMS) with the inclusion of agreed major milestones and control account plans (CAP) for all control accounts; baseline revision documentation and program logs (s) risk register. BARDA will review documentation and provide written comments and questions to Contractor. A follow-on meeting or telecom will be scheduled no later than 10 business days after receipt from BARDA	Electronic Copy of Project Officer (PO) 1 Hard Copy - PO 1 Electronic Copy -Contracting Officer (CO) 1 Hard Copy - CO	Due 90 days after contract award. BARDA will provide comments to the draft no later than 20 business days. Final Performance Measurement Baseline due to BARDA 10 business days following follow-on meeting or telecon.

ATTACHMENT 2

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING

INSTRUCTIONS FOR BARDA COST-REIMBURSEMENT TYPE CONTRACTS

Format: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All BARDA contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, which are not set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

Invoice/Financing Request Identification: Each payment request shall be identified as either.

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number: Show** the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i .e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee**: Insert the total fixed-fee (where applicable). For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract.

For Level of Effort contracts only, the Contractor shall provide the following information on a separate sheet of paper attached to the payment request:

- hours or percentage of effort and cost by labor category (as specified in the Level of Effort Article in Section F of the contract) for the current billing period, and

- hours or percentage of effort and cost by labor category from contract inception through the current billing period. (NOTE: The Contracting Officer may require the Contractor to provide additional breakdown for direct labor, such as position title, employee name, and salary or hourly rate.)

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect cost.

(3) **Accountable Personal Property:** Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS Contractor's Guide for Control of Government Property). Show permanent research equipment separate from general purpose equipment.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. An asterisk (*) shall precede the item if the equipment is below the $1,000 approval level. Include reference to the following (as applicable):

- item number for the specific piece of equipment listed in the Property Schedule, and

- COA number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

(4) Materials and Supplies: Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) Premium Pay: List remuneration in excess of the basic hourly rate.

(6) Consultant Fee: List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) Travel: Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) Subcontract Costs: List subcontractor(s) by name and amount billed.

(9) Other: List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(q) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(t) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(u) **Grand Totals**

(v) **Certification of Salary Rate Limitation**: If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

The Contracting Officer may require the Contractor to submit detailed support for costs claimed on one or more interim payment requests.

FINANCIAL REPORTING INSTRUCTIONS:

These instructions are keyed to the Columns on the sample invoice/financing request.

Column A - Expenditure Category: Enter the expenditure categories required by the contract.

Column B - Cumulative Percentage of Effort/Hrs. - Negotiated: Enter the percentage of effort or number of hours agreed to for each employee or labor category listed in Column A.

Column C - Cumulative Percentage of Effort/Hrs. - Actual: Enter the percentage of effort or number of hours worked by each employee or labor category listed in Column A.

Column D - Amount Billed - Current: Enter amounts billed during the current period. Column E - Amount Billed - Cumulative: Enter the cumulative amounts to date.

Column F - Cost at Completion: Enter data only when the Contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column G - Contract Amount: Enter the costs agreed to for all expenditure categories listed in Column A.

Column H - Variance (Over or Under): Show the difference between the estimated costs at completion (Column F) and negotiated costs (Column G) when entries have been made in Column F. This column need not be filled in when Column F is blank. When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column F by Column G, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications: Any modification in the amount negotiated for an item since the preceding report should be listed in the appropriate cost category.

Expenditures Not Negotiated: An expenditure for an item for which no amount was negotiated (e.g., at the discretion of the Contractor in performance of its contract) should be listed in the appropriate cost category and all columns filled in, except for G. Column H will of course show a 100 percent variance and will be explained along with those identified under H above.

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a)Designated Billing Office Name and Address:
DHHS/OS/ASPR/BARDA
Attn: Contracting Officer
330 Independence Ave., S.W.
Room G644
Washington, D.C. 20201

(b)Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:

ABC CORPORATION 100 Main Street Anywhere, USA Zip Code

Name, Title, Phone Number, and E-mail Address of person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent.

(c)Invoice/Financing Request No.:
(d)Date Invoice Prepared:
(e)Contract No. and Order No. (if applicable): _____
(f)Effective Date:
(g)Total Estimated Cost of Contract/Order:
(h)Total Fixed-Fee (if applicable):
(i)Two-Way Match:
Three-Way Match:
(j)Office of Acquisitions:
(k)Central Point of Distribution:

VIN:
DUNS or DUNS+4:
(l) This invoice/financing request represents reimbursable costs for the period from _____ to

	Cumulative Percentage of Effort/Hrs.		Amount Billed				
Expenditure Category*	Negotiated	Actual	(m) Current	(n) Cumulative	Cost at Completion	Contract Amount	Variance
A	B	C	D	E	F	G	H
(o) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(p) Cost of Money							
(q) Indirect Costs							
(r) Fixed Fee							
(s) Total Amount Claimed							
(t) Adjustments							
(u) Grand Totals							

I certify that all payments are for appropriate purposes and in accordance with the contract.

(Name of Official) (Title)
* Attach details as specified in the contract

ATTACHMENT 3

FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT Note: Complete this Form in Accordance with Accompanying Instructions.	Project Task:	Contract No.:	Date of Report:	0990-0134 0990-0131
	Reporting Period:	Contractor Name and Address:		

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost-Current Period	Cumulative Cost to Date (D + E)	Estimated Cost to Complete	Estimated Cost at Completion (F + G)	Negotiated Contract Amount	Variance (Over or Under) (I -H)
	Negotiated	Actual							
A	B	C	D	E	F	G	H	1	J

ATTACHMENT 4

INSTRUCTIONS FOR COMPLETING "FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. This Quarterly Financial Report is designed to: (1) provide a management tool for use by be BARDA in monitoring the application of financial and personnel resources to the BARDA contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the Contracting Officer's Technical Representative.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate quarterly report, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing the Quarterly Report. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel-Other.** List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property".

(5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care**. Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.

(9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.

(10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts.** List each subcontract by name and amount billed.

(12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expense**. Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) **Fee.** Cite the fee earned, if any.

(16) **Total Costs to the Government.**

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on the Quarterly Report.

Column A-Expenditure Category. Enter the expenditure categories required by the contract.

Column B-Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C-Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D-Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E-lncurred Cost-Current Period. Enter the costs which were incurred during the current period. Column F-Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G-Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I-Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

Attachment 5

INCLUSION ENROLLMENT REPORT

This report format should NOT be used for data collection from study participants

Study Title:

Total Enrollment: **Protocol Number:**

Contract Number:

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				

PART B. HISPANIC ENROLLMENT REPORT: **Number of Hispanics or Latinos Enrolled to Date (Cumulative)**

Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				

*These totals must agree
**These totals must agree

ATTACHMENT 6

Research Patient Care Costs

(1) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(2) Research patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine research patient care costs. Research patient care rates or amounts shall be established by the Secretary of HHS or his/her duly authorized representative.

(3) Prior to submitting an invoice for research patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for research patient care.

(4) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(5) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

ATTACHMENT 8 - Small Business Subcontracting Plan, dated 5 May 2010.

DHHS SUBCONTRACTING PLAN REVIEW FORM

SB No: B09-005	MULTIPLE AWARD	Yes	No	(if yes, identify subcontracting plans)

MOD No. (if applicable)	1. Solicitation/Contract No.	2. Title of Acquisition
	BAA-BARDA-09-34	Development of a Large-Scale Manufacturing Process for Bio-Thrax

3. Contractor's Name	4. Period of Performance (base & options)	5. Total Contract Amount (including opinions)
Emergent Biodefense Operations Lansing, Inc.	7/19/10 through 6/14/15	$ 106,864,347 Total MOD Amt (if applicable) $ [**] Base Year (if there are options) $ 54,586,376

6. Option #1 (if applicable)	Option #2 (if applicable	Option #3 (if applicable)	Option #4 (if applicable)
$[**]	$[**]	$[**]	$

7. Contracting Officer/Specialist Name, Bldg., Room, Phone, Fax, & Email:	8. Date Received by SBS for Review:
Ethan J. Mueller, 409 3rd Street, SW, Washington, D.C. 20204, Phone: 202-205-4657, e-mail: Ethan.Mueller@HHS.Gov.	

1. SUBCONTRACTING PLAN TYPE: (check one)	Individual:	ü	Master:	Commercial:

SUBCONTRACTING PLAN REQUIREMENTS	CO		SBS		SBA/PCR	
2. Subcontracting Goal Data	A	U	A	U	A	U
a. Total Subcontracting Dollars [(bi-g), except when subcontracting baseline equals contract value) [**]	ü		ü			
b. Total Subcontracting Dollars & Percentage with Small Businesses (incl. SDB, WOSB, HUBZone, SDVOSB) – [Percentage of 2.n.] $[**] and [**]%	ü		ü			
c. Total Subcontracting Dollars & Percentage with Small Disadvantaged Businesses – [Percentage of 2.n.] $[**] and [**]%	ü			ü		
d. Total Subcontracting Dollars & Percentage with Women-owned Small Businesses – [Percentage of 2.n.] $[**] and [**]%	ü		ü			
e. Total Subcontracting Dollars & Percentage with HUBZone Small Businesses – [Percentage of 2.n.] $[**] and [**]%	ü			ü		
f. Total Subcontracting Dollars & Percentage with Service-Disabled Veteran Small Businesses – [Percentage of 2.n.] $[**] and [**]%	ü			ü		
g. Total Subcontracting Dollars & Percentage with "Other" than Small Businesses – [Percentage of 2.n.] $[**] and [**]%	ü		ü			
h. Subcontracting Opportunities (description of all principal products/services to be subcontracted to all types of concerns)	ü		ü			
i.j.k. Metholodlogy used to develop goals & identify sources (e.g. historical trends, information on technical and competitive bidding, formula for calculating goals, etc.)	ü		ü			

OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION

SMALL BUSINESS SUBCONTRACTING PLAN

The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by the Federal Acquisition Regulations (FAR) Subpart 19.7. The U.S. Department of Health and Human Services (HHS), Office of Small and Disadvantaged Business Utilization (OSDBU) recommend offerors use the following format to submit proposed Individual Subcontracting Plan, including modifications. It is not intended to replace any existing Corporate/Commercial Plan that is more extensive. A subcontracting Plan is required. If the estimated cost of the contract ***may exceed $550,000*** *(small businesses are excluded). Questions should be forwarded to the Contracting Officer or Teneshia Alston, S enior Small Business Analyst (Teneshia.Alston@HHS.GOV).*

HHS Operating Division (OPDIV): BARDA 0;

SOLICITATION OR CONTRACT NUMBER: BAA-BARDA-09-34

DATE OF PLAN: May 5, 2010 ;

CONTRACTOR: Emergent Biodefense Operations Lansing Inc. ;

ADDRESS: 3500 N. Martin Luther King Jr. Blvd. 60;

STATE/ZIP CODE: Lansing, MI 48906 60;

DUNN & BRADSTREET NUMBER: [**] & #160;

ITEM/SERVICE (Description): Development of a Large-Scale Manufacturing Process

for Bio.Thrax®

NEW/INITIAL CONTRACT

PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year): 7/9/10 – 6/14/15
;

Base Years 1 & 2	$ 54,586,376	Performance Period/Quantity	2 years
Option 1: Year 3	$ [**]	Performance Period/Quantity	1 year
Option 2: Year 4	$ [**]	Performance Period/Quantity	1 year
Option 3: Year 5	$ [**]	Performance Period/Quantity	1 year
CLIN 006: Year 1	$ [**]	Performance Period/Quantity	1 year
CLIN 0007 Year 22	$ [**]	Performance Period/Quantity	1 year
CLIN 0008: Year 3	$ [**]	Performance Period/Quantity	1 month
	$ 106,864,347	Total Contract Cost	

CONTRACT MODIFICATION (if applicable)

NEW PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year): ;

Original/Base	$	Performance Period/Quantity	
Modification	$	Performance Period/Quantity	
Task Order	$	Performance Period/Quantity	
	$	Modified Total Contract Cost	

Failure to include the essential information of FAR Subpart 19.7 may 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 requesting supplies or services required for performance of the contract or subcontract.

If assistance is needed to locate small business sources, contact the Small Business Specialist (SBS) supporting the OPDIV. SBS contact information is located on the OSDBU website (http://www.hhs.gov/osdbu/staff.html) or you may contact the OSDBU headquarters at (202) 690-7300.

HHS current subcontracting goal is **39.9%** for small business, including 8(a) Program Participants (hereafter referred to as SB), **5.00%** for Small Disadvantaged Business, including Alaska Native Corporations (ANC) and Indian Tribes (hereafter referred to as SDB), **5.00%** for women-owned business and economically disadvantges women-owned business (hereafter referred to as WOSB), **3.00%** HubZone business (HUBZone) and **3.00%** service disabled veteran-owned small business (SDVOSB) concerns for **Fiscal Year (FY) 2008**. ; For this procurement, HHS expects all proposed subcontracting plans to contain at a minimum the aforementioned percentages. These percentages shall be expressed as percentages of the total estimated subcontracting dollars. Zero goal statement removed.

1. Type of Plan (check one)

__X__ ***Individual plan*** (all elements developed specifically for this contract and applicable for the full term of this contract).

__X__ ***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 end contractor must provide copy of lead agency approval.

__X__ ***Commercial products/service plan*** (goals are negotiated with the initial agency on a company-wide basis rather than for individual contracts) this plan applies to the entire production of commercial service or items or a portion thereof. The contractor sells commercial products and services customarily used for non-government purposes. The plan is effective during the offeror's fiscal year (attach a copy). ***The Summary Subcontracting Report (SSR) must include a breakout of subcontracting prorated for HHS and other Federal agencies).***

2. Goals

Below indicate the dollar and percentage goals for Small Business, Small Disadvantaged (SDB) including Alaska Native Corporations and Indian Tribes, Woman-owned and Economically Disadvantaged Women-Owned (WOSB), Historically Underutilized Business Zone (HUBZone), Service Disabled Veteran-owned (SDVOSB) small businesses and "Other than small business" (Other) as subcontractors. Indicate the base year and each option year, as specified in FAR 19.704 or project annual subcontracting base and goals under commercial plans. If any contract has more four options, please attach additional sheets which illustrate dollar amounts and percentages.

a. **Total estimated dollar value of ALL planned subcontracting**, i.e., with ALL types of concerns under this contract is $[**] (Base Year 1).

FY 11 (Base)	Year 2	FY 12 (Option 1)	Year 3	FY 13 (Option 2)	Year 4	FY 15 (Option 3)	Year 5
[**]		[**]		[**]		[**]	

b. **Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES** (including SDB, WOSB, HUBz and SDVOSB): (% of "a")

$ [**] and [**]% (Base Year 1)

FY 11 (Base)	Year 2	FY 12 (Option 1)	Year 3	FY 13 (Option 2)	Year 4	FY 15 (Option 3)	Year 5
[**]		[**]		[**]		[**]	

c. Total estimated dollar value and percent of planned subcontracting with **SMALL DISADVANTAGED BUSINESSES**: (% of "a") $[**] and [**]% (Base Year 1)

FY 11 (Base)	Year 2	FY 12 (Option 1)	Year 3	FY 13 (Option 2)	Year 4	FY 15 (Option 3)	Year 5
[**]		[**]		[**]		[**]	

d. Total estimated dollar value and percent of planned subcontracting with **WOMAN-OWNED SMALL BUSINESSES**: (% of "a") $[**] and [**]% (Base Year 1)

FY 11 (Base)	Year 2	FY 12 (Option 1)	Year 3	FY 13 (Option 2)	Year 4	FY 15 (Option 3)	Year 5
[**]		[**]		[**]		[**]	

e. Total estimated dollar value and percent of planned subcontracting with **HUBZone SMALL BUSINESSES**: (% of "a") $[**] and [**]% (Base Year 1)

FY 11 (Base)	Year 2	FY 12 (Option 1)	Year 3	FY 13 (Option 2)	Year 4	FY 15 (Option 3)	Year 5
[**]		[**]		[**]		[**]	

f. Total estimated dollar value and percent of planned subcontracting with **SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESSES**: (% of "a") $[**] and [**]% (Base Year 1)

FY 11 (Base)	Year 2	FY 12 (Option 1)	Year 3	FY 13 (Option 2)	Year 4	FY 15 (Option 3)	Year 5
[**]		[**]		[**]		[**]	

g. Total estimated dollar value and percent of planned subcontracting with "**OTHER THAN SMALL BUSINESSES**". *(As defined by the Small Business Administration as "any entity t that is not classified as a small business. This includes large businesses, state and local governments, non-profit organizations, public utilities, educational institutions and foreign-owned firms.)* (% of "a") $[**] and [**]% (Base Year 1)

FY 11 (Base)	Year 2	FY 12 (Option 1)	Year 3	FY 13 (Option 2)	Year 4	FY 15 (Option 3)	Year 5
[**]		[**]		[**]		[**]	

Note: Federal prime contract percentage goals may serve as objectives for subcontracting goal development:

- Total Small Business (SB) 19.00%
- 8(a) Program Participants 5.00%
- Small Disadvantaged Business (SDB) 5.00%
- Woman Owned Small Business (WOSB) 5.00%
- Historically Underutilized Business Zone (HUBZone) 3.00%
- Service Disabled Veteran Owned Small Business (SDVOSB) 3.00%

h. 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):

Products and/or Services		Other	Small Business	SDB	WOSB	Hubz	SDVOSB
1.	[**]	X	X		X		
2.	[**]	X					
3.	[**]	X					
4.	[**]	X					
5.	[**]		X				
6.	[**]	X					
7.	[**]		X				
8.	[**]		X				
9.	[**]	X					
10.	[**]	X					
11.	[**]	X					

12.	[**]	X	
13.	[**]	X	
14.	[**]	X	
15.	[**]		X
16.	[**]		X

i. Provide a description of the method used to develop the subcontracting goals for SB, SDB, WOSB, HUBZone 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, WOSB, HUBZone and SDVOSB concerns were determined, how the capabilities of these concerns were considered contract opportunities and how such data comports with the cost proposal. Identify any source lists or other resources used for the determination process. (Attach additional sheets, if necessary.)

Emergent Biodefense Operations Lansing Inc (EBOL) solicited proposals from those sources with the qualifications required to execute the contract. Those contractors that best met the business specifications, capability, performance expectations, cost competitiveness and other relevant criteria were considered for this effort.

Product/Service	Amount to be Subcontracted	Bus. Class
Consultants [**]		
[**]	[**]	WOSB
[**]	[**]	WOSB
[**]	[**]	SB
[**]	[**]	WOSB
[**]	[**]	Other
[**]	[**]	Other
[**]	[**]	SB
[**]	[**]	Other
[**]	[**]	SB
[**]	[**]	SB
[**]	[**]	SB
Subcontractors		
[**]	[**]	SB
[**]	[**]	Other
[**]	[**]	Other
[**]	[**]	SB
[**]	[**]	Other
[**]	[**]	Other
[**]	[**]	SB
[**]	[**]	SB
[**]	[**]	Other
[**]	[**]	Other
Professional Travel		
[**]	[**]	Other
Other Direct Costs		
[**]	[**]	Other
Materials and Supplies		
[**]	[**]	Other
[**]	[**]	Other
[**]	[**]	SB
[**]	[**]	SB

The proposed .contract leads to FDA approval of large-scale manufacture of BioThrax, the only FDA approved anthrax vaccine. Activities required to fulfill this contract include:

- [**]
  - [**]
  - [**]
  - [**]

EBOL plans to utilize small business concerns to the maximum extent practical and regularly surveys the healthcare community to identify small businesses with the skills and experience to undertake research, trials, and vaccine-related manufacturing. However, delivery under this-contract will require a niche skillset and due to the complexity and very specialized nature of the program there is a very small pool of qualified small businesses from which to make a selection.

As shown above, [**] subcontractors have been identified to fulfill the scope of this contract of which, [**] are small businesses.

The proposed subcontractors with the largest contributions to contract are [**]. After careful evaluation, these subcontractors were the only companies that could be identified to perform the activities required for the success of the project as outlined below:

[**]

We conducted an extensive search to identify qualified small businesses for each product/service to be subcontracted for this contract. The results of the search are as described below:

As it relates to the anthrax vaccine efficacy testing, [**] is the only company in the world who routinely performs anthrax vaccine efficacy testing that conforms to federal regulations and guidelines.

For clinical studies, [**] were identified as prospective subcontractors. After auditing the companies, it was determined that [**] did not have the capability to conduct the large clinical studies for this contract. Emergent is using [**] for clinical trials for other products at earlier stages of development, where the trials are not as large. However, for the proposed contract, [**] were selected to support the clinical trials.

Professional Travel

[**] – Emergent BioSolutions Inc. (EBSI) and its subsidiaries including Emergent Biodefense Operations Lansing Inc. (EBOL) use the same travel agency to ensure continuity of service and cost effectiveness. EBSI is a global corporation withoffices in the United States, Europe and Asia. The travel agency utilized must have the breadth to manage travel around the globe and across time zones while supplying the most economical travel. We regularly evaluate alternatives to [**] and consider small businesses as they are identified.

Other Direct Costs

[**] – Clinical Trial Insurance

[**]

Materials and Supplies

[**]

[**] .companies [**] providing materials and supplies are small businesses. EBOL will continue it's efforts to seek small businesses to replace it's large, business "suppliers that provide products equivalent to those currently being purchased to ensure adherence for federal and state quality assurance requirements for the development and manufacture of vaccines.

We-have identified small disadvantaged businesses to supply goods and services that fall within the category of indirect costs. We utilize these businesses whenever possible and therefore plan to include general and administrative costs from purchase of goods and services from small businesses to help meet our small business subcontracting goals. We fully support the government's interests in supporting small business concerns and will remain diligent in its efforts to meet the governments overall subcontracting goals and ensure that the maximum practical subcontracting opportunities are made available to respective small business concerns during contract performance.

j. Indirect costs [**] ____ been included in the dollar and percentage subcontracting goals above (check one).

k. If indirect costs have been included, explain the method used to determine the proportionare share of such costs to be allocated as subcontracts to SB, SDB, WOSB, HUBZone and SDVOSB concerns:

EBOL uses SB, SDB, WOSB, HUBZone and SDVOSB suppliers for office supplies, facility maintenance and other services that are included in its indirect costs. The proportionate share of these costs allocated to this contract will be determined using the following formula: [**].

3. Program Administrator:

NAME: [**]

TITLE: Director, US Government Contracts & #160;

ADDRESS: 300 Professional Drive, Suite 250

Gaithersburg, MD 20879

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? (If NO is checked, please who in the company performs those duties, or indicate why the duties are not performed in your company on a separate sheet of paper and submit with the proposed subcontracting plan.)

a.	Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contacts and subcontracts to SB, SDB, WOSB, HUBZone and SDVOSB concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing;	X	Yes	____	No
b.	Developing and maintaining bidder source lists of SB, SDB, WOSB, HUBZone and SDVOSB concerns from all possible sources;	X	Yes	____	No
c.	Ensuring periodic rotation of potential subcontractors on bidder's lists;	X	Yes	____	No
d.	Assuring that SB, SDB, WOSB, HUBZone and SDVOSB businesses are included on the bidders' list for every subcontract solicitation for products and services that they are capable of providing;	X	Yes	____	No
e.	Ensuring that Requests for Proposes (RFPs) are designed to permit the maximum practicable participating of SB, SDB, WOSB, HUBZone and SDVOSB concerns;	X	Yes	____	No
f.	Reviewing subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit small, 8(a), SDB, WOSB, HUBZone and SDVOSB small business participation;	X	Yes	____	No
g.	Accessing various sources for the identification of SB, SDB, WOSB, HUBZone and SDVOSB concerns to include the Central Contractor Registration (http://www.ccr.gov/), local small business and minority associations, local chambers of commerce and Federal agencies' Small Business Offices;	X	Yes	____	No
h.	Establishing and maintaining contract and subcontract award records;	X	Yes	____	No
i.	Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs,	X	Yes	____	No

	Procurement Conferences, etc.;				
j.	Ensuring the SB, SDB, WOSB, HUBZone and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company;	X	Yes	____	No
k.	Conducting or arranging for the conduct or training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended;	X	Yes	____	No
l.	Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals;	X	Yes	____	No
m.	Preparing and submitting timely, required subcontract reports;	X	Yes	____	No
n.	Conducting or arranging training for purchasing personnel regarding the intent and impact of 8(d) of the Small Business Act on purchasing procedures;	X	Yes	____	No
o.	Coordinating the company's activities during the conduct of compliance reviews by Federal agencies; and	X	Yes	____	No
p.	Other duties:				

4. Equitable Opportunity

Describe efforts the offeror will undertake to ensure that SB, SDB, WOSB, HUBZone 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. Contact minority and small business trade associations; 2) contact business development organizations and local chambers of commerce; 3) attend SB, SDB, WOSB, HUBZone and SDVOSB procurement conferences and trade fairs; 4) review sources from the Central Contractor Registration (http://www.ccr.gov/); 5) review sources from the Small Business Administration (SBA), Central Contractor Registration (CCR); 6) Consider using other sources such as the National Institutes of Health (NIH) e-Portals in Commerce, (e-PIC), (http://epic.od.nih.gov/). The NIH e-PIC is not a mandatory source; however, it may be used at the offeror's discretion; and 7) utilize newspaper and magazine ads to encourage new sources.

b. Internal efforts to guide and encourage purchasing personnel:

1. Conduct workshops, seminars and training programs;

2. Establish, maintain, and utilize SB, SDB, WOSB, HUBZone and SDVOSB source lists, guides, and other data for soliciting subcontractors; and

3. Monitor activities to evaluate compliance with the subcontracting plan.

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 $550,000 ($1,000,000 by construction), must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." Note: In accordance with FAR 52.212-5(e) and 52.244-6(c) the contractor is not required to include flow down clause FAR 52.219-9 if it is subcontracting commercial items.

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 illustrate compliance with the subcontracting plan; 3) submission of its Individual Subcontracting Report (ISR) and Summary Subcontract Report (SSR); and 4) subcontractors submission of ISRs and SSRs. **ISRs and SSRs shall be submitted via the Electronic Subcontracting Reporting System (eSRS) website https://esrs.symplicity.com/index?_tab=signin&cck=1**

Reporting Period	Report Due	Due Date
Oct 1 – Mar 31	ISR	4/30
Apr 1 – Sept 30	ISR	10/30
Oct 1 – Sept 30	SSR	10/30
Contract Completion	Year End SDB Report	30 days after completion

Please refer to FAR Part 19.7 for instruction concerning the submission of a Commercial Plan. SSR is due on 10/30 each year for the previous fiscal year ending 9/30.

a. Submit ISR (bi-annually) for the awarding Contracting Officer's review and acceptance via the eSRS website.

b. Currently, SSR (annually) must be submitted for the HHS eSRS Agency Coordinator review and acceptance via the eSRS website. (***Note***: Log onto the OSDBU website to view the HHS Agency Coordinator contact information (http://www.hhs.gov/osdbu/staff.html).

Note: The Request for Proposal (RFP) will indicate whether a subcontracting plan is required. Due to the nature and complexity of many HHS contracts, particularly the Centers for Medicare and Medicaid (CMS), the contracot may not be required to submit its subcontracting reports through the eSRS. The Contracting Officer will confirm reporting requirements prior to the issuance of an award. For more information, contact Teneshia Alston, Agency Coordinator – eSRS (Teneshia.Alston@HHS.GOV).

7. Recordkeeping

FAR 19.704(a)(11) requires a list of the types of records your company will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. 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 and SDVOSB source lists, guides and other data identifying such vendors;

b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone 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 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, record to support subcontract award data including the name, address, and business type and size of each subcontractor. (This is not required on a contract-by-contract basis for 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 procedure to ensure the timely payment of amounts due pursuant to the terms of your subcontracts with small business concerns, 8(a), SDB, women-owned small business, HubZone and service disabled veteran-owned small business concerns.

Your company has established and used such procedures: __X__ Yes No

9. Description of Good Faith Effort

Maximum practicable utilization of small, 8(a), small disadvantaged, women-owned, HubZone small and service disabled veteran owned concerns as subcontractors in Government contracts is a matter of nation all 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, SDB WOSB, HubZone and SDVOSB small business subcontracting goals, outline the steps your company plans to take. These steps will be negotiated with the contracting official prior to approval of the pl an.

[**]

SIGNATURE PAGE

Signatures Required:

This subcontracting plan was submitted by:

Signature: /s/ [**] ;

Typed Name: [**] & #160;

Title: Director, US Government Contracts &# 160;

Date: May 5, 2010 & #160;

This plan was reviewed by:

Signature: /s/ Ethan J. Mueller ;

Typed Name: Ethan J. Mueller

Title: Contracting Officer Date: 6/18/10 60;

This plan was reviewed by:

Signature: /s/ Nydia Sagna 0;

Typed Name: Nydia Sagna

Title: HHS Small Business Specialist (SBS) Date: 6/18/2010 60;

This plan was reviewed by:

Signature: *PCR reserve the right to review* 0;

Typed Name:

Title: Small Business Administration Procurement Center Representative

Date:

4.0 COST SUMMARY
CLIN 0001
CLIN 1
SUMMARY

		YEAR 1 (BASE YR)	YEAR 2 (OPTION YR)	YEAR 3 (OPTION YEAR)	YEAR 4 (OPTION YEAR)	YEAR 5 (OPTION YEAR)	TOTAL
TOTAL LABOR HOURS		[**]	[**]	[**]	[**]	[**]	[**]
DIRECT LABOR COST		[**]	[**]	[**]	[**]	[**]	[**]
FRINGE BENEFITS	[**]	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL DIRECT LABOR & FRINGE BENEFITS		[**]	[**]	[**]	[**]	[**]	[**]
DEVELOPMENT OVERHEAD	[**]	[**]	[**]	[**]	[**]	[**]	[**]
MATERIALS AND SUPPLIES		[**]	[**]	[**]	[**]	[**]	[**]
PROFESSIONAL TRAVEL		[**]	[**]	[**]	[**]	[**]	[**]
EQUIPMENT		[**]	[**]	[**]	[**]	[**]	[**]
CONSULTANTS		[**]	[**]	[**]	[**]	[**]	[**]
OTHER DIRECT COSTS		[**]	[**]	[**]	[**]	[**]	[**]
SUBCONTRACTS		[**]	[**]	[**]	[**]	[**]	[**]
TOTAL OTHER DIRECT COSTS		[**]	[**]	[**]	[**]	[**]	[**]
SUBTOTAL: OTHER DIRECT AND TOTAL LABOR		[**]	[**]	[**]	[**]	[**]	[**]
EXCLUSION FROM BASE FOR G&A		[**]	[**]	[**]	[**]	[**]	[**]
ADJUSTED BASE FOR G&A		[**]	[**]	[**]	[**]	[**]	[**]
G&A	[**]	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL PROPOSED COST EXCLUDING PROFIT		[**]	[**]	[**]	[**]	[**]	[**]
PROPOSED PROFIT	[**]	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL PROPOSED PRICE		[**]	[**]	[**]	[**]	[**]	[**]

CLIN 0002
CLIN 2
SUMMARY

		YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5	TOTAL
TOTAL LABOR HOURS		[**]	[**]	[**]	[**]	[**]	[**]
DIRECT LABOR COST		[**]	[**]	[**]	[**]	[**]	[**]
FRINGE BENEFITS	[**]	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL DIRECT LABOR & FRINGE BENEFITS		[**]	[**]	[**]	[**]	[**]	[**]
DEVELOPMENT OVERHEAD	[**]	[**]	[**]	[**]	[**]	[**]	[**]
MATERIALS AND SUPPLIES		[**]	[**]	[**]	[**]	[**]	[**]
PROFESSIONAL TRAVEL		[**]	[**]	[**]	[**]	[**]	[**]
EQUIPMENT		[**]	[**]	[**]	[**]	[**]	[**]
CONSULTANTS		[**]	[**]	[**]	[**]	[**]	[**]
OTHER DIRECT COSTS		[**]	[**]	[**]	[**]	[**]	[**]
SUBCONTRACTS		[**]	[**]	[**]	[**]	[**]	[**]
TOTAL OTHER DIRECT COSTS		[**]	[**]	[**]	[**]	[**]	[**]
SUBTOTAL: OTHER DIRECT AND TOTAL LABOR		[**]	[**]	[**]	[**]	[**]	[**]
EXCLUSION FROM BASE FOR G&A		[**]	[**]	[**]	[**]	[**]	[**]
ADJUSTED BASE FOR G&A		[**]	[**]	[**]	[**]	[**]	[**]
G&A	[**]	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL PROPOSED COST EXCLUDING PROFIT		[**]	[**]	[**]	[**]	[**]	[**]
PROPOSED PROFIT	[**]	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL PROPOSED PRICE		[**]	[**]	[**]	[**]	[**]	[**]

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

Exhibit 10.5

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES 1 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (*If applicable*)
00009	07/06/2010	N/A	

6. ISSUED BY	CODE	7. ADMINISTERED BY (*If other than Item 6*)	CODE
2540		2540	

Centers for Disease Control and Prevention (PGO)
Building & Facilities Contracts Branch
2920 Brandywine Road, MS-K71
Atlanta, GA 30341-5539

Centers for Disease Control and Prevention (PGO)
Building & Facilities Contracts Branch
2920 Brandywine Road, MS-K71
Atlanta, GA 30341-5539

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State, and ZIP Code*)	(✓)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT BIODEFENSE OPERATIONS LANSING INC. 3500 N MARTIN LUTHER KING JR BLVD # 1 LANSING, MI 48906-2933		9B. DATED (*See Item 11*)
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. 200-2009-30162
CODE 026489018 FACILITY CODE		10B. DATED (*See Item 13*) 09/30/2008

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers _____ is extended. _____ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning ____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment your desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
N/A

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(✓)	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
x	D. OTHER (*Specify type of modification and authority*) IAW FAR 45.106, Transferring Accountability and Mutual agreement of both parties.

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible.*)
The purpose of this modification is to:

a. Add Gary Gainous as Co-Project Officer to this contract. Jackie Thomas and Gary Gainous will have equal and shared responsibilities as Project Officers for this contract;

b. Add the Governments Furnished Property identified in Appendix A from Contract HHSO0100200700037C to this contract, 200-2009-30162. This transfer of property is of no additional cost to the USG;

c. Add Clause B.8 as shown on page 2

d. Update the Forecasted Delivery Schedule as shown on page 3 in J.7

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print*)	16A. NAME OF CONTRACTING OFFICER
FUAD EL-HIBRI, CEO	Vivian S. Hubbs

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Fuad El-Hibri (*Signature of person authorized to sign*)		By /s/ Vivian S. Hubbs (*Signature of Contracting Officer*)	July 16, 2010

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

B.8 **DSNS Quality Control Unit (QCU) Acceptance Procedure for BioThrax**

The DSNS QCU recommends that the temperature acceptance range for BioThrax, using the temperature monitoring device accuracy 0f ±0.22°C, would be [**] °C. This temperature is consistent with licensed label specifications (2°C to 8°C) and takes into account Emergent rounding practices (memo dated 8/12/09), and the accuracy of the temperature monitoring device (TempTale Bio).

At the time of delivery, all BioThrax lot(s) will be off-loaded from the trucks and placed into DSNS Quarantine pending receipt of the required lot distribution documentation from the contractor. As a clarification and guide for LOG consideration, the table below outlines temperature limits acceptable during shipment and the resulting actions under each scenario. This table is based on TempTale with an accuracy of ± 0.22°C. If any of the following changes occur, Emergent must notify QCU immediately:

- Type of temperature monitoring device (switched for another monitoring device)
- Accuracy of TempTale
- Other shipping practices
- Temperature monitoring practices

Temperature Range	Action
[**]°C	· BioThrax lot(s) will not be accepted · Emergent would be immediately notified · Return shipment would be Emergent's responsibility
[**]°C	Acceptable
[**]°C	· BioThrax lot(s) will be kept in DSNS quarantine · Acceptance would be pending quality disposition investigation, Emergent deviation process and remaining ambient exposure for the lot.
[**]°C	· BioThrax lot(s) will not be accepted · Emergent would be immediately notified · Return shipment would be Emergent's responsibility

Return of Unacceptable BioThrax®

In accordance with Page 14, Section F.2.a. of this contract which states “The delivery of this BioThrax® product shall be F.O.B. Destination to the SNS site(s)”, it will be Emergent’s responsibility to pay all cost related to the return of shipments from the SNS site(s).

Contract 200-2009-30162 Forecasted Targeted Delivery Schedule 2009-2011
Updated 07 / 2010

J.7

CLIN	Delivery #	Lot	Ship Date	Expiry Date	Remaining Expiry (Days)	Remaining Expiry (Months)	Expected Doses	ACTUAL Delivered Doses	Cum Doses	Date Accepted
[**]	[**]	[**]	[**]	[**]	[**]	[**]		[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]		[**]	[**]	[**]
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Contract 200-2009-30162 Forecasted Targeted Delivery Schedule 2009-2011
Updated 07 / 2010

J.7

CLIN	Delivery #	Lot	Ship Date	Expiry Date	Remaining Expiry (Days)	Remaining Expiry (Months)	Expected Doses	ACTUAL Delivered Doses	Cum Doses	Date Accepted
[**]	[**]	[**]	[**]	[**]	[**]	[**]		[**]	[**]	[**]
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[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]		[**]	
							[**]	**[**]**		
					Total Contract Doses		**[**]**			

Emergent BioDefense Operations Lansing, Inc.

U.S. Government Property

Asset	Tag #	Asset description	Cap.date	Acquisition Value

A total of 15 pages were omitted pursuant to a request for confidential treatment. [**]

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

Exhibit 10.6

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)	RATING N/A	PAGE 1	OF PAGES 41
2. CONTRACT (Proc. Inst. Ident.) NO. HHSO100201000059C	3. EFFECTIVE DATE See Block 20C.	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. OS45572		

5. ISSUED BY	CODE N/A	6. ADMINISTERED BY (If other than Item 6)	CODE N/A
HHS/OS/ASPR/BARDA 330 INDEPENDENCE AVE S.W., RM G640 WASHINGTON, D.C. 20201		See Block 5.	

7. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)	8. DELIVERY
Emergent Product Development Gaithersburg, Incorporated 300 Professional Drive, Suite 250 Gaithersburg, MD 20879 DUNS# 189488554 Cage Code: 057Y1	See Section F.2.
FACILITY CODE N/A	9. DISCOUNT FOR PROMPT PAYMENT N/A
	10. SUBMIT INVOICES ADDRESS SHOWN IN: ITEM See Section G.

11. SHIP TO/MARK FOR	CODE N/A	12. PAYMENT WILL BE MADE BY	CODE N/A
See Block 5.		See Block 5.	

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253(c)( )	Appropriate Year: 2010; Object Class: 25329 CAN# 1990087 $51,063,149.00

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
See Section B (CLIN 0001).					$51,063,149.00

15G. TOTAL AMOUNT OF CONTRACT $51,063,149.00

16. TABLE OF CONTENTS

(✓)	SEC.	DESCRIPTION	PAGE(S)	(✓)	SEC.	DESCRIPTION	PAGE(S)
		PART I – THE SCHEDULE				PART II – CONTRACT CLAUSES	
☒	A	SOLICITATION/CONTRACT FORM	1	☒	I	CONTRACT CLAUSES	34
☒	B	SUPPLIES OR SERVICES AND PRICE/COST	2			PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
☒	C	DESCRIPTION/SPECS./WORK STATEMENT	8	☒	J	LIST OF ATTACHMENTS	40
☒	D	PACKAGING AND MARKING	13			PART IV – REPRESENTATIONS AND INSTRUCTIONS	
☒	E	INSPECTION AND ACCEPTANCE	13	☒	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERERS	41
☒	F	DELIVERIES OR PERFORMANCE	14				
☒	G	CONTRACT ADMINISTRATION DATA	16	☐	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	N/A
☒	H	SPECIAL CONTRACT REQUIREMENTS	22	☐	M	EVALUATION FACTORS FOR AWARD	N/A

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required to sign this document and return 2 copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☐ AWARD *(Contractor is not required to sign this document.)* Your offer on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual documentation is necessary.

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
Daniel J. Abdun-Nabi, Vice President	Ethan J. Mueller

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
/s/ Daniel J. Abdun-Nabi (Signature of person authorized to sign)	9/10/10	BY /s/ Ethan J. Mueller (Signature of Contracting Officer)	9/17/10

PART I - THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of the contract is for the advanced development of Recombinant Protective Antigen (rPA) Anthrax Vaccine Revision 1.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The total estimated cost of the base period of performance contract is $[**]

b. The total fixed fee for the base period of performance contract is $[**]. The fixed fee shall be paid in accordance with and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The total amount of the contract, represented by the sum of the total estimated cost plus fixed fee is $51,063,149.00.

d. It is estimated that the amount currently allotted will cover performance of the contract through September 18, 2012.

CONTRACT LINE ITEM NUMBERS (CLINs)

BASE PERIOD

CLIN	PERIOD OF PERFORM.	SUPPLIES/SERVICES	TOTAL ESTIMATED COST	FIXED FEE	TOTAL ESTIMATED COST PLUS FIXED FEE
0001	9/19/2010-9/18/2012	[**]	[**]	[**]	$51,063,149.00

ARTICLE B.3. OPTION PRICES

a. Unless the Government exercises its option pursuant to the option clause referenced in ARTICLE 1.1., the contract consists only of the Base Period specified in the Statement of Work as defined in SECTIONS C and F, for the price set forth in ARTICLE B.2 of the contract.

b. Pursuant to H. 13. EXERCISE OF OPTIONS and **Option for Increased Quantity-Separately Priced Line Item (FAR Clause 52.217-7)** the Government may, by unilateral contract modification, require the Contractor to perform the Option(s) specified in the Statement of Work as defined in SECTIONS C and F of this contract. If the Government exercises this/these option(s), notice must be given before the expiration date of the contract. Specific information regarding the time frame for this notice is set forth in the OPTION CLAUSE Article in SECTION H of this contract. The estimated cost of the contract will be increased as set forth below:

CONTRACT OPTION PERIODS

Option Period 1 (CLIN 0002)

Option Period 2 (CLIN 0003)

Option Period 3 (CLIN 0004)

Option Non-Clinical Studies (CLIN 0005)

Option Non-Clinical Studies (CLIN 0006)

Option Non-Clinical Studies (CLIN 0007)

OPTION CLIN	PERIOD OF PERFORM.	SUPPLIES/SERVICES	TOTAL ESTIMATED COST	FIXED FEE	TOTAL ESTIMATED COST PLUS FIXED FEE
0002	9/19/2012-9/18/2013	[**]	[**]	[**]	$36,606,092.00
0003	9/19/2013-9/18/2014	[**]	[**]	[**]	$64,063,462.00
0004	9/19/2014-9/18/2015	[**]	[**]	[**]	$25,860,384.00
0005	9/19/2012-9/18/2013	[**]	[**]	[**]	$3,233,689.00
0006	9/19/2013-9/18/2014	[**]	[**]	[**]	$2,432,976.00
0007	9/19/2014-9/18/2015	[**]	[**]	[**]	$3,367,234.00

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable

Notwithstanding the clause, ALLOWABLE COST AND PAYMENT, incorporated in the contract, unless authorized in writing by the Contracting Officer via a Contracting Officer Authorization (COA) Letter, the costs of the following items or activities shall be unallowable as direct costs:

1. Acquisition, by purchase or lease, of any interest in real property;

2. Special rearrangement or alteration of facilities;

3. Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

4. Travel to attend general scientific meetings;

5. Foreign travel - See subparagraph b. below;

6. Consultant costs; Any cost reimbursement contracts for Consultant services and any firm fixed price (FFP) contract for Consultant services that exceed $100,000;

7. Subcontracts; Any cost reimbursement subcontracts and FFP subcontracts that exceed $100,000;

8. Research patient care costs - See Attachment 1;

9. Accountable Government property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and “sensitive items” (defined and listed in the Contractor’s Guide for Control of Government Property, see Article G.10), regardless of acquisition value.

10. Printing Costs (as defined in the Government Printing and Binding Regulations).

11. Light Refreshment and Meal Expenditures. Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Project Officer, with a copy to the Contracting Officer, at least six (6) weeks in advance of the event. The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provided; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshment and/or meal costs; and (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals. It is unlikely that BARDA will appr ove these requests since circumstances are very limited under which appropriated funds can be used for these costs.

b. Travel Costs

1. Domestic Travel

   a. Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed $45,000 during the base period (9/19/2010-9/18/2012) without the prior written approval of the Contracting Officer via a Contracting Officer Authorization (COA) Letter.

   b. Subject to the annual dollar limitation specified under B.A.b.l.a. above the Contractor shall invoice and be reimbursed for all travel costs in accordance with FAR Subpart 31.2 contracts with Commercial Organizations and FAR § 31.205-46 Travel Costs

2. Foreign Travel

   Requests for foreign travel must be submitted at least six weeks in advance and shall contain the following: (a) meeting(s) and place(s) to be visited, with costs and dates; (b) name(s) and title(s) of Contractor personnel to travel and their functions in the contract project; (c) contract purposes to be served by the travel; (d) how travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of AMCG contract funds; (e) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and (f) what additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

ARTICLE B.5. ADVANCE UNDERSTANDINGS

a. Man-in-Plant

With 7 days advance notice to the Contractor via in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor’s facility and shall be subject to the Contractor’s polices and procedures regarding security and facility access at all times while in the Contractor’s facility. The man-in-plant is restricted to observing, verifying, and surveying the Contractor’s performance under this contract.

b. Security Plan

The Contractor agrees to provide an updated Security Plan, if requested by the Contracting Officer, and within fifteen (15) working days after receipt of the request. The Contractor agrees to provide data generated from this contract that is related to security at the Contractor’s facility to the Contracting Officer upon request either in the form of an email attachment or via delivery to a secured Government eRoom.

c. Subcontracts and Consultants

Award of any FFP subcontract or FFP consulting agreement in excess of $100,000 or any cost reimbursement subcontract or consulting agreement shall not proceed without the prior written consent of the Contracting Officer via a Contracting Officer Authorization (COA) Letter upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract and consulting agreement shall be provided to the Contracting Officer.

d. Site Visits and Inspections

At the discretion of the U.S. Government and independent of activities conducted by the Contractor, within ten (10) business days notice to the Contractor via written notification from the Contracting Officer, the U.S. Government reserves the right to conduct site visits and inspections on an as needed basis, including collection of samples limited to [**] vials of Final Drug Product and samples of key intermediates held at the Contractor’s or Subcontractor’s site, provided that the Government’s collection of such samples should not frustrate the Contractor’s ability to perform under the contract.

e. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

a. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.

b. Fringe Benefits - Cite rate and amount
c. Overhead - Cite rate and amount
d. Materials & Supplies - Include detailed breakdown when total amount is over $1,000.
e. Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.
f. Consultant Fees - Identify individuals and amounts.
g. Subcontracts - Attach sub-Contractor invoice(s).
h. Equipment - Cite authorization and amount.
i. G&A - Cite rate and amount.
j. Total Cost
k. Fixed Fee
l. Total CPFF

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

f. Confidential Treatment of Sensitive Information

The Contractor shall guarantee strict confidentiality of any information/data of a sensitive nature that is generated by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of information/data that is sensitive in nature, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer. (See also HHSAR clause 352.224-70).

Notwithstanding the foregoing, such information/data shall not be deemed of a sensitive nature with respect to the Contractor for purposes of this contract if such information/data: (a) was already known to the Contractor; (b) was generally available or known, or was otherwise part of the public domain, at the time of its disclosure to the Contractor; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to the information/data by, the Contractor through no fault of the Contractor; (d) was disclosed to the Contractor, other than under an obligation of confidentiality or non-use, by a third party who had no obligation to the Government that controls such information/data not to disclose such information/data to others; or (e) was independently discovered or deve loped by the Contractor, as evidenced by its written records, without the use of information/data belonging to the Government.

Contractor may disclose information/data of a sensitive nature provided by the Government to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the Contractor shall first have given notice to the Government and give the Government a reasonable opportunity to quash such order and to obtain a protective order requiring that the information/data of a sensitive nature that is the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purpose s for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the information/data disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order; (b) otherwise required by law, in the opinion of legal counsel to the Contractor as expressed in an opinion letter in form and substance reasonably satisfactory to the Government, which shall be provided to the Government at least two (2) business days prior to the Contractor's disclosure of the information/data; or (c) made by the Contractor to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information/data.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work dated 16 August 2010 set forth in SECTION J-List of Attachments, attached hereto and made a part of the contract.

ARTICLE C.2. REPORTING REQUIREMENTS

Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this contract and in SECTION J-List of Attachments, attached hereto and made a part of the contract.

1. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;

SECTION I-An introduction covering the purpose and scope of the contract effort;

SECTION II-PROGRESS

SECTION II Part A: OVERALL PROGRESS-A description of overall progress;

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE-A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating, and managing subcontractor performance);

SECTION II Part C: TECHNICAL PROGRESS-For each activity, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project;

SECTION II Part D; PROPOSED WORK-A summary of work proposed for the next reporting period and preprints/reprints of papers and abstracts.

A Monthly Progress Report will not be required in the same month that the Quarterly or Annual Technical Progress Report is submitted.

2. Annual Progress Report

This report shall include a summation of the results of the entire contract work for the period covered. An Annual Technical Progress Report will not be required for the period when the Final Technical Progress Report is due. Monthly Reports shall not be submitted in the same month when an Annual Progress Report is due.

The first Annual Progress Report shall be due on or before the 15th Calendar day following the last day of the reporting period. Each Annual Progress Report shall include:

a) A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;

b) SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period;

c) SECTION II: PROGRESS

i) SECTION II Part A: OVERALL PROGRESS-A description of overall progress;

ii) SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE-A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating, and managing subcontractor performance; regulatory compliance audits);

iii) SECTION II Part C: TECHNICAL PROGRESS-A detailed description of the work performed structured to follow the activities and decision gates outlined in the approved Strategic Staged Product Development Plan. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved;

iv) SECTION II Part D; PROPOSED WORK-A summary of work proposed for the next year period.

a) Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and

b) A summary of any "Subject Inventions" as that term is defined under FAR Clause 52.227-11 (a) (see also Article C.3 herein).

3. Draft Final Technical Progress Report and Final Technical Progress Report

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Technical Progress Report will not be required for the period when the Final Technical Progress Report is due. The Draft Final Technical Progress Report shall be submitted ninety (90) calendar days before completion date of the contract and the Final Technical Progress Report shall be submitted on or before the completion date of the contract. The report shall conform to the following format:

(a) Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date;

(b) SECTION I: EXECUTIVE SUMMARY-Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

(c) SECTION II: RESULTS-A detailed description of the work performed, the results obtained, and the impact of the results on the scientific and/or public health community, including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance, and a summary of all inventions.

Draft Final Technical Progress Report: The Contractor is required to submit the Draft Final Technical Progress Report to the Contracting Officer's Technical Representative and Contracting Officer. This report is due 90 calendar days before the completion date of the contract. The Contracting Officer's Technical Representative and Contracting Officer will review the Draft Final Technical Progress Report and provide the Contractor with comments within 45 calendar days after receipt.

Final Technical Progress Report: The Contractor will deliver the final version of the Final Technical Progress Report on or before the completion date of the contract. The final version shall include or address the Contracting Officer's Technical Representative comments and Contracting Officer comments on the draft report.

4. Summary of Salient Results

The Contractor shall submit, with the Final Technical Progress Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

5. Other Technical Progress Reports

a. Draft Report for Clinical and Non-Clinical Studies and Final Report for Clinical and Non-Clinical Studies

- The non-clinical and clinical trial reports shall follow the format of International Conference on Harmonization document ICH E3 “Guidelines on Structure and Content of Clinical Study Reports” (http://www.pharmacontract.ch/support/su_ich_liste.htm).

- Draft Final Report for Clinical and Non-Clinical Studies will be submitted to the Contracting Officer’s Technical Representative and Contracting Officer (CO) for review and comment no later than 15 working days after completion of analysis of study data.

- The Contracting Officer shall provide written comments within 30 working days after the submission of the Draft Final Report for Clinical and Non-Clinical Studies.

- The comprehensive Final Report for Clinical and Non-Clinical Studies will be submitted to the Contracting Officer and the Contracting Officer’s Technical Representative within 30 calendar days after receiving comments on the Draft Final Report for Clinical and Non-Clinical Studies from the Contracting Officer. The final version shall include or address the Contracting Officer’s Technical Representative comments and Contracting Officer comments on the draft report.

b. Audit Reports

Within thirty (30) calendar days of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, or GCP guidelines, as it relates to performance under this contract where the results will adversely impact contract performance, the Contractor shall provide the Contracting Officer’s Technical Representative and the Contracting Officer with copies of the audit report and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

c. Clinical Trial Protocols

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf), the Contractor shall develop a protocol for each clinical trial and submit all protocols and protocol amendments for approval by the BARDA Contracting Officer’s Technical Representative. Important information regarding performing human subjects research is available at http://www3.niaid.nih.gov/healthscience/clinicalstudies/.

Any updates to technical reports are to be addressed in the Monthly, Quarterly and Annual Progress Reports. The Contractor shall advise the Contracting Officer’s Technical Representative or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

6. Other Reports/Deliverables

a. Copies of FDA Correspondence and Meeting Summaries

1. For any formal meeting with the FDA, the Contractor shall forward initial draft minutes and subsequently final meeting minutes within thirty (30) calendar days of receipt from the FDA to the BARDA Contracting Officer’s Technical Representative.

2. The Contractor shall forward the final draft minutes of any informal meeting with the FDA to BARDA.

3. The Contractor shall forward the dates and times of any meeting with the FDA to BARDA at least 30 days prior to the meeting and make arrangements for appropriate BARDA staff to attend FDA meetings.

4. The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA. The Contractor shall provide BARDA with five (5) business days in which to review and provide comments back to the Contractor.

b. Technology Transfer

Animal Models and other technology packages developed under the contract that include Complete protocols and critical reagents for animal models developed and/or improved with contract funding must be submitted at the request of the BARDA Contracting Officer’s Technical Representative. See FAR clause 52.227-11 (Patent Rights-Ownership by the Contractor).

c. Institutional Biosafety Approval

The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments at the request of the BARDA Contracting Officer’s Technical Representative.

d. Data

The Contractor shall provide raw data or specific analysis of data generated with contract funding at the request of the BARDA Contracting Officer’s Technical Representative. See FAR clause 52.227-14 (Rights in Data-General).

e. Meeting Minutes

The Contractor shall provide an electronic copy of conference call meeting minutes/summaries to the BARDA Contracting Officer’s Technical Representative and Contracting Officer within seven (7) calendar days after the conference call is held.

f. Audits/Site Visits

BARDA/AMCG Audits

The United States Government (USG) reserves the right to conduct an audit of the Contractor with five (5) business days notice. The USG reserves the right to accompany the Contractor on routine and for-cause site-visits/audits of subcontractors. At the discretion of the USG and independent of testing conducted by the Contractor, BARDA reserves the right to conduct site visits/audits.

g. Telephone conferences with the FDA

In addition to other requirements specified in this contract, the Contractor shall attempt to provide BARDA with a minimum of 48 hours advanced notice of any anticipated teleconference with the FDA and allow the BARDA COTR or the COTR's authorized representative to participate in the teleconference. If advanced notice is not possible or if for any reason BARDA is unable to participate in the teleconference, no later than 2 business days following the teleconference, the contractor shall provide the BARDA COTR with a written summation of all topics discussed in the teleconference.

ARTICLE C.3. SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 2207, MSC 7987, Bethesda, Maryland 20892-7987 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract. See also FAR clause 52.227-11 (Patent Rights-Ownership by the Contractor).

Reports and documentation submitted to the Contracting Officer shall be sent to the following address:

Contracting Officer

Ethan J. Mueller

Office of Acquisitions Management, Contracts, and Grants (AMCG)

330 Independence Avenue, S.W.

Room G640

Washington, D.C. 20201

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, "Interagency Edison," an electronic invention reporting system has been developed. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

ARTICLE C.4. TWICE MONTHLY CONFERENCE CALLS

A conference call between the Contracting Officer's Technical Representative and the principal investigator shall occur bi-monthly or as directed by the Contracting Officer's Technical Representative. During this call the principal investigator will discuss the activities during the reporting period, any problems that have arisen and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. The principal investigator may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Technic al Representative.

ARTICLE C.5. PROJECT MEETINGS

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Technical Representative. These meetings may include face-to-face meetings with BARDA/AMCG in Washington, D.C. and at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts and USG personnel as required by the Contracting Offi cer's Technical Representative in order to facilitate review of contract activities.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped 'in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

Report Deliverables

Unless otherwise specified by the Contracting Officer, delivery of reports to be furnished to the Government under this contract (including invoices), shall be addressed as follows:

Dr. Eric Espeland,

Contracting Officer's Technical Representative (COTR)

DHHS/OS/ASPR/BARDA

330 Independence Avenue, S.W.

Room 640G

Washington, D.C. 20201

E-mail: Eric.Espeland(@hhs. gov

Ethan J. Mueller, Contracting Officer

DHHS/OS/ASPR/AMCG

330 Independence Avenue, S.W.

Room 640G

Washington, D.C. 2020

E-mail: Ethan.Mueller@hhs.gov

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided under this contract.

b. For the purpose of this SECTION, the designated Contracting Officer's Technical Representative (COTR) is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:

Biomedical Advanced Research and Development Authority

Office of the Assistant Secretary for Preparedness and Response

U.S. Department of Health and Human Services

330 Independence Avenue, S.W., Room G644

Washington, D.C. 20201

d. The contract incorporates the following clause by reference with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause 52.246-8, Inspection of Research and Development-Cost Reimbursement (May 2001)

SECTION F - DELIVERIES OR PERFORMANCE

Deliveries and performance under these Contract Line Item Numbers (CLINs) and Option CLINs shall be as follows:

ARTICLE F.1. PERIOD OF PERFORMANCE

a. Under CLIN 0001, the base period of performance of this contract shall be from 9/19/2010- 9/18/2012.

b. If the Government exercises its options pursuant to the OPTION CLAUSE Article in Section H of the contract, the period of performance will be increased as listed below:

OPTION CLIN	PERIOD OF PERFORM.	SUPPLIES/SERVICES
0002	[**]	[**]
0003	[**]	[**]

0004	[**]	[**]
0005	[**]	[**]
0006	[**]	[**]
0007	[**]	[**]

ARTICLE F.2. REPORTING REQUIREMENTS AND DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work dated 16 August 2010 set forth in SECTION J-List of Attachments of this contract (the SOW) and upon delivery and acceptance, as required by the SOW, by the Contracting Officer, or the duly authorized representative, of the deliverables specified in the SOW as well as the following items in accordance with the stated delivery schedule specified below:

1. Other Contract Deliverables

Item	Deliverable	Quantity	Due Date
1.	Risk Management Plan	1 Electronic Copy Project Officer (PO) 1 Hard Copy – PO 1 Electronic Copy – Contracting Officer (CO) 1 Hard Copy – CO	Quarterly on the 15th day of the month due or as Determined by the Project Officer.

2. WBS Milestones/Deliverables and Technical Deliverables as contained in the Statement of Work dated 16 August 2010 set forth in SECTION J-List of Attachments.

The above items shall be addressed and delivered to:

Contracting Officer's address:	AMCG 330 Independence Avenue, S.W. Room G640 Washington, D.C. 20201 E-mail: Ethan.Mueller@hhs.gov
Contracting Officer's Technical Representative's address:	BARDA 330 Independence Avenue, S.W. Room G644 Washington, D.C. 20201 E-mail: Eric.Espeland@hhs.gov

The items specified above as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract and the Statement of Work dated 16 August 2010 set forth in SECTION J-List of Attachments will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified above and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract.

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

The contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http.7/www.acquisition.gov/coinp/far/index.html

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER

The following Contracting Officer will represent the Government for the purpose of this contract:

Ethan J. Mueller, Contracting Officer
DHHS/OS/ASPR/AMCG
330 Independence Avenue, S.W.
Room 640G Washington, D.C. 2020
E-mail: Ethan.Mueller@hhs.gov

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.

2) The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimburse to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.

3) 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 US Government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.

4) The Government may unilaterally change its COTR designation.

ARTICLE G.2. CONTRACTING OFFICER'S TECHNICAL REPRESENTATIVE (COTR)

The following COTR will represent the Government for the purpose of this contract:

1. Dr. Eric Espeland, COTR

   DHHS/OS/ASPR/BARDA

   330 Independence Avenue,

   S.W. Room 640G

   Washington, D.C. 20201

   E-mail: Eric.Espeland@hhs.gov

The COTR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) assisting the contracting Officer in interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

ARTICLE G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:

#	NAME	ORGANIZATION	TITLE
1	[**]	Emergent	Program Manager
2	[**]	Emergent	Program Management Lead
3	[**]	Emergent	Product Development Lead
4	[**]	Emergent	Manufacturing Operations Lead
5	[**]	Emergent	Regulatory Affairs Lead
6	[**]	Emergent	Non-Clinical Development Lead
7	[**]	Emergent	Clinical Development Lead

The key personnel specified in this contract are considered to be essential to work performance. At least 30 business days prior to diverting any of the specified individuals to other programs or contracts, including an instance when an individual must be replaced as a result of leaving the employ of the Contractor, the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of t he Contractor or Government.

ARTICLE G.4. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Financial Report of Individual Project/Contract (see Attachments 2 and 3) shall be submitted by the Contractor in accordance with the instructions for completing this form, which accompany the form, in an original and two copies, not later than the 30th business day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in that part of the instructions for completing this form, entitled " PREPARATION INSTRUCTIONS ," (see Attachment 4) all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated within the Attachment entitled, "Financial Report of Individual Project/Contract," located in SECTION J and made a part of this contract.

f. The Government may unilaterally revise the "Financial Report of Individual Project/Contract" to reflect the allotment of additional funds.

ARTICLE G.5. INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING

1) The Contractor shall submit an electronic copy of monthly contract invoices/financial reports to the address shown below:

   DHHS/OS/ASPR/AMCG

   Attn: Ethan J. Mueller, Contracting Officer

   330 Independence Ave., S.W.

   Room G640

   Washington, D.C. 20201

2) Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting made a part of the contract in Section J (See also Attachment 2) .

3) Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

4) The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Cost (FAR 52.232-20) clause in the contract.

5) All invoice submissions shall be in accordance with FAR Clause 52.232-25 (c) in Section I of this contract.

ARTICLE G.6. REIMBURSEMENT OF COST

1) The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with the clause entitled Allowable Cost and Payment in Section I, Contract Clauses, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

a) All direct materials and supplies that are used in the performing of the work provided for under the contract, including those purchased for subcontracts and purchase orders.

b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

d) Special expenditures which, upon request from the Contractor, the Contracting Officer approves as being an allowable cost under this contract, such as purchase or lease of office furniture or equipment, etc.

e) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:

(i) Air travel shall be by the most direct route using “air coach” or “air tourist” (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

(ii) Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.

(iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).

(iv) Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

ARTICLE G.7. INDIRECT COST RATES

The following rates will be utilized for billing purposes during the base period. Fringe benefits at [**]%, applied to a base sum of total direct labor, development overhead at [**]%, applied at a base sum of total direct labor plus fringe benefits and G&A at [**]% applied to a modified base that excludes subcontracts and equipment. The billing rates for each option period will be based on the incurred cost submission for the previous calendar year, subject to Government audit adjustments. Final rate proposals must be sent to the Contracting Officer, within 6 months subsequent to the fiscal year end. (see also FAR Clause 52.216-7 incorporated herein)

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

1. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted June 29, 2012.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

2. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

ARTICLE G.9. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

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

ARTICLE G.10. GOVERNMENT PROPERTY

1. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at:

http://www.hhs.gov/oamp/policies/contractors guideforcontrolofgov property.pdf.

Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

2. Notwithstanding the provisions outlined in the HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated in this contract in paragraph a. above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

3. Title will vest in the Government for equipment purchased as a direct cost.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4 (January 2006)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, a nd undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(c) If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Human Subject Assurances.

ARTICLE H.2. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-02 63 (formerly Optional Form 310).

ARTICLE H.3. RESEARCH INVOLVING HUMAN FETAL TISSUE

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-l and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-l(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

ARTICLE H.4. NEEDLE EXCHANGE

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.5. PRESS RELEASES

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.6. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5 (October 2009)

(a) Before undertaking performance of any contract involving animal-related activities where the species is regulated by USDA, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence

of the registration to the Contracting Officer.

(b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor agrees that the care, use and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (E-mail: ace@aphis.usda.gov; Web site: (http ://www.aphis.usda.gov/animal_welfare).

ARTICLE H.7. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:

http://grants 1.nih.gov/grants/olaw/references/phspol.htm .

ARTICLE H.8. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL:

http ://www.od.nih.gov/oma/manualchapters/intramural/3044-2/

ARTICLE H.9. PUBLICATION AND PUBLICITY

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer Technical Representative.

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, under Contract No. _____"

ARTICLE H.10. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General

Department of Health and Human Services

TIPS HOTLINE

P.O. Box 23489

Washington, D.C. 20026

ARTICLE H.11. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 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.

ARTICLE H.12. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of intere st is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions, which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this

contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, de bar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

ARTICLE H.13. EXERCISE OF OPTIONS

Unless the Government exercises its option pursuant to the Option Clause set forth in Section I, Article I.1, the contract will consist only of **CLIN 0001** of the Statement of Work, Deliverables and Requirements as defined in Sections C, F and J of the contract. Pursuant to FAR Clause **52.217-7 (Option for Increased Quantity- Separately Priced Line Item)** set forth in Section I of this contract, under Article I.1., the Government may, by unilateral contract modification, require the Contractor to perform **any of the additional CLINs listed in Section B, Article B.3.**, and as also defined in Sections C, F and J of this contract. If the Government exercises an option, notice must be given at least 60 days prior to the expiration date of the Period of Performance (PoP) applicable to the base period or the PoP applicable to any option period. The amount of the contract will then be increased as set forth in Section B, Article B.3.

ARTICLE H.14. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.203-70 ANTI-LOBBYING (Jan 2006)

The Contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United Stated Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person 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 any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions again st lobbying activities, see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, as set forth in HHSAR 352.203-70 "Anti-Lobbying" (January 2006), the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

ARTICLE H.15. PRIVACY ACT APPLICABILITY (Apr 2000)

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://www.gpoaccess.eov/cfr/index.html

2) The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

3) The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

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

ARTICLE H.16. 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.

ARTICLE H.17. DISSEMINATION OF INFORMATION (May 1998)

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer.

ARTICLE H.18. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will 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 directly related to and/or generated under 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.

ARTICLE H.19. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

Registration with the U. S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), http://www.nal.usda.gov/awic/legislat/awa.htm.

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) http://grants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS Policy http://grants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U. S. Public Health Service.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* http://www.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 CFR, Subchapter A) http://www.nal.usda.gov/awic/legislat/usdalegl.htm issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federated of Animal Sc ience Societies http://www.fass.org.

ARTICLE H.20. REQUIREMENTS FOR ADEQUATE ASSURANCE OF PROTECTION OF VERTEBRATE ANIMAL SUBJECTS

The PHS Policy on Humane Care and Use of Laboratory Animals requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS Policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. Also, the PHS policy defines "animal" as "any live, vertebrate animal used, or intended for use, in research, research training, experimentation, biological testing or for related purposes." This Policy implements and supple ments the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires that institutions use the Guide for the Care and Use of Laboratory Animals as a basis for developing and implementing an institutional animal care and use program. This Policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et. seq.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163. See http://grants.nih.gov/grants/olaw/olaw.htm.

No PHS supported work for research involving vertebrate animals will be conducted by an organization, unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the institution for further review in the case of apparent or potential violations of the PHS Policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with P HS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. Foreign applicant organizations are not required to submit IACUC approval, but should provide information that is satisfactory to the Government to provide assurances for the humane care of such animals.

ARTICLE H.21. APPROVAL OF REQUIRED ASSURANCE BY OLAW

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the Contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and inde pendent from those activities that do involve live vertebrate animals) may be conducted by the Contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants2.nih.gov/grants/olaw/references/phspol.htm

ARTICLE H.22. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individual s have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for Comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate indiv iduals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

ARTICLE H.23. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

ARTICLE H.24. ACKNOWLEDGMENT OF FEDERAL FUNDING

A. Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state (1) the percentage and dollar

amounts of the total program or project costs financed with Federal money, and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

B. Publication and Publicity

Publications: Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted for BARDA Project Officer review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201000059C."

C. Press Releases

(a) Pursuant to Section 508 of Public Law 105-78, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

(b) The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The Contractor shall ensure that the Project Officer has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

ARTICLE H.25. MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP)(21 CFR Parts 210-211) and regulations pertaining to biological products (21 CFR Part 600) and regulations pertaining to diagnostic products (21 CFR Part 860) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery 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 the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the USG Project Officer, or fails to provide a remediation plan that is acceptable to the Project Officer, then the contract may be terminated.

ARTICLE H.26. EXPORT CONTROL NOTIFICATION

Offerors are responsible for ensuring compliance with all export control laws and regulations that maybe applicable to the export of and foreign access to their proposed technologies. Offerors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CRF Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CRF Parts 730-774).

ARTICLE H.27. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest. For the purposes of this part relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children. 45 CFR Part 94 is available at the following Web site:

http ://ecfr.gpoaccess.gov/c gi/t/text/text-idx?c=ecfi"sid-9fl30b6d2d48bb73803ca91ce943be3a;rgn=div5;view=text;node^45%3A1.0.1.1.53;idno=45;cc=ecfr

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

ARTICLE H.28. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

1. The Small Business Subcontracting Plan, dated 10 August 2010 is attached hereto and made a part of this contract.

2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages- Subcontracting Plan."

b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

a. Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

April 30th

October 30th

Expiration Date of Contract

b. Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the Contract Specialist shall be included as a contact for notification purposes at the following e-mail address:

Ethan J. Mueller, Contracting Officer and Contract Specialist

DHHS/OS/ASPR/BARDA

ARTICLE H.29. HUMAN MATERIALS

It is understood that the acquisition and supply of all human specimen material (including fetal material) used under this contract will be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States and that no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.30. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individual s have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations,

and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate indiv iduals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http ://www.cdc.gov/od/sap/.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at these addresses: http://www.arnet.gov

General Clauses for Cost-Reimbursement Research and Development

(1) FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Jul 2004	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Sep 2007	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.203-13	Apr 2010	Contractor Code of Business Ethics and Conduct
52.203-14	Dec 2007	Display of Hotline Poster
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.204-7	Apr 2008	Central Contractor Registration
52.209-6	Sep 2006	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Mar 2009	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52:215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Oct 2004	Pension Adjustments and Asset Reversions
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment (Note: the following language is included in this clause – "(3) The designated payment office will make interim payments for contract financing on the 30th day after the designated billing office receives a proper payment request..."
52.216-8	Mar 1997	Fixed Fee
52.217-7	Mar 1989	Option for Increased Quantity- Separately Priced Line Item
52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jul 2010	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-3	Jun 2003	Convict Labor
52.222-19	Jul 2010	Child Labor - Cooperation with Authorities and Remedies
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Mar 2007	Equal Opportunity
52.222-35	Sep 2006	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Sep 2006	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-50	Feb 2009	Combating Trafficking in Persons
52.222-54	Jan 2009	Employment Eligibility Verification
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
52.224-1	April 1984	Privacy Act Notification
52.224-2	April 1984	Privacy Act
52.225-1	Feb 2009	Buy American Act - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Dec 2007	Patent Rights - Ownership by the Contractor
52.227-14	Dec 2007	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Oct 2008	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Oct 2008	Prompt Payment
52.232-33	Oct 2003	Payment by Electronic Funds Transfer—Central Contractor Registration
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (June 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim

52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.242-15	Apr 1989	Stop Work Order. Alt I (Aug 1984)
52.243-2 .	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	June 2007	Subcontracts
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.244-6	Jun 2010	Subcontracts for Commercial Items
52.245-1	Aug 2010	Government Property
52.245-9	Aug 2010	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	May 2004	Termination (Cost-Reimbursement)
52-249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

(2) DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2006	Definitions - with Alternate paragraph (h) (Jan 2001)
352.203-70	Jan 2006	Anti-Lobbying
352.216-70	Jan 2006	Additional Cost Principles
352.227-70	Jan 2006	Publications and Publicity
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.231-71	Jan. 2001	Pricing of adjustments.
352.233-71	Jan 2006	Litigation and Claims
352.234-3	Oct 2008	Full Earned Value Management System
352.242-70	Jan 2006	Key Personnel
352.242-73	Jan 2006	Withholding of Contract Payments
352.242-74	Apr 1984	Final Decisions on Audit Findings

ARTICLE I.2. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).
2. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program -- Disadvantaged Status and Reporting** (April 2008).
3. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause **352.223-70, Safety and Health** (January 2006).
2. HHSAR Clause **352.224-70, Privacy Act** (January 2006).
3. HHSAR Clause **352.201-70, Paperwork Reduction Act** (January 2006).

ARTICLE I.3. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1)CLAUSES:

a. FAR Clause 52.219-28, Post-Award Small Business Program Representation (April 2009).

(a) *Definitions*. As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is “not dominant in its field of operation” when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall represent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts—

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall represent its size status in accordance with the size standard in effect at the time of this representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/contractingopportiinities/officials/size/index.html.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the representation was completed:

The Contractor represents that it [ ] is, [X] is not a small business concern under NAICS Code assigned to contract number.

[Contractor to sign and date and insert authorized signer's name and title].

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work

Statement of Work, dated 16 August 2010.

2. Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for BARDA Cost- Reimbursement Type Contracts,
Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for BARDA Cost-Reimbursement Type Contracts, 5 pages.

3. Financial Report of Individual Project/Contract, 1 page

4. Instructions for Completing Financial Report of Individual Project/Contract, 3 pages

5. Inclusion Enrollment Report

Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01), 1 page.

6. Research Patient Care Costs Research Patient Care Costs, 1 page.

7. Report of Government Owned, Contractor Held Property

Report of Government Owned, Contractor Held Property, dated 12/2/09, 1 page. Located at: http://rcb.cancer.gov/rcb-internet/forms/Govt-Owned-Prop.pdf (Not Attached)

8. Small Business Subcontracting Plan

Small Business Subcontracting Plan, dated 10 August 2010.

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERERS

The following documents are incorporated by reference in this contract:

1) Annual Representations and Certifications completed at the Online Representations Applications (ORCA) website.

2) Representations & Certifications dated 11 May 2010.

3) Human Subjects Assurance Identification Number: 00011382

4) Animal Welfare Assurance Numbers: Battelle: A3034-01

Spring Valley Laboratories: A3731-01

ATTACHMENT 1 - Statement of Work, dated 16 August 2010.

SOW Task #	WBS	Activity	Base period Prior to 12 Month Development Stability Study Timepoint	Base Period Following 12 Month Development Stability Study Timepoint	Option Period 1	Option Period 2	Option Period 3
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
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[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

Figure 1. The currently-planned tasks and subtasks of the SOW by

the years in which they will occur

3.0 STATEMENT OF WORK BROAD AGENCY ANNOUNCEMENT (BAA) BARDA 09-34

Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures Statement of Work

rPA102 Anthrax Vaccine Development

Preamble

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work (SOW) submitted in response to Broad Agency Announcement (BAA) BARDA 09-34.

The Government reserves the right to modify the milestones, progress, schedule, budget, or product to add or delete products, process, or schedule as need may arise. Because of the nature of the (R&D) contract and complexities inherent in this and prior programs, at designated milestones the Government will evaluate whether work should be redirected or removed or whether schedule or budget adjustments should be made. In any event, the Government reserves the right to change product, process, schedule, or event to add or delete part or all of these elements as the need arise.

3.1 SCOPE

The scope of work for this contract includes anthrax vaccine development activities that fall into the following areas: process development and assay development, qualification and validation, manufacturing, non-clinical, clinical and regulatory activities that are PEP EUA and PEP and GUP BLA-enabling.

3.2 OBJECTIVE

The objective of this SOW is to conduct all necessary activities to advance the development of rPA102 anthrax vaccine towards licensure for both PEP and GUP.

3.3 TECHNICAL APPROACH

This section identifies representative tasks and sub-tasks for achieving the objective. We organize tasks and subtasks by year, Figure 1. 3.3.1 Development Approach 3.3.1.1 Non-Clinical Research and Development Representative

3.3.1 Development Approach

3.3.1.1 Non-Clinical Research and Development Representative

Representative activities include but are not limited to:

a) Evaluating the safety, comparability, immunogenicity, toxicity, efficacy, formulation, dose, route and schedule of rPA102 using both in vitro and animal models following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations 21 CFR Part §58), as and when appropriate.

Activities currently planned include:

[**]

3.3.1.2 Process Development, Formulation, and Manufacturing Development

Representative Activities include but are not limited to:

a) Process development activities to increase efficiency, yield, quality, and reduce the variability and risk factors in the manufacture of the drug sub-stance and drug product.

b) Developing analytical methods and assays appropriate for product characterization and product release, including tests for the identity, purity, potency, and stability of the bulk drug substance and final drag product. Emergent shall identify a stable source and availability of reagents and reference standards for these assays.

c) Developing Validation Protocols for analytical and assay methods to defining product manufacturing control, performance, potency and product stability indication.

d) Manufacture of non-GMP and of GMP lots of candidate product in amounts sufficient to carry out required/pro-posed non-clinical and clinical trials.

e) Identification of Critical Quality Attributes (CQA) and Critical Process Parameters.

f) Manufacturing scale-up plan to lead to consistency lot manufacturing of the candidate product.

g) Process flow for personnel, material and waste disposal.

h) Proposed packaging design and execution of fill-finish of final drag product.

i) Design of stability testing plan and conduct of stability studies on bulk and final product.

j) Develop a Risk Evaluation and Mitigation Strategy or similar risk mitigation strategy.

Activities currently planned include:

[**]

3.3.1.3 Clinical Evaluation Representative

Representative activities include but are not limited to:

Design and conduct of clinical trial(s) in accordance with applicable Federal regulations and GCP guidelines.

Activities currently planned include:

[**]

3.3.2 Management Approach:

3.3.2.1 Integrated Product Development Plan (IPDP) Representative

Within fourteen (14) days of the effective date of the BAA award, Emergent shall submit an updated IPDP based on the IPDP agreed upon by Emergent and BARDA in the final proposal revision. The IPDP shall be approved by the Project Officer and the Contracting Officer prior to initiation of any activities related to their implementation. During the course of contract performance, in response to a need to change the IPDP, Emergent shall submit a Deviation Report. This report shall request a change in the agreed-upon Plan and timelines. This report shall include:

a) Discussion of the justification/rationale for the proposed change.

b) Options for addressing the needed changes from the approved timelines, including a cost-benefit analysis of each option.

c) Recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget.

d) Emergent shall carry out activities within the contract SOW only as requested and approved by the Contracting Officer, and may not conduct work on the contract without prior approval from the Contracting Officer, including initiating work that deviates from the agreed-upon IPDP.

Activities include but are not limited to:

a) Representative activities and stages of product development that Emergent is proposing to perform under contract funding in a project plan that indicates the base period and option period activities and includes all of the functional areas of development listed below.

b) A detailed description of the experimental design, including the rationale for experimental approaches, and a description of alternative approaches to be employed if these methods do not achieve the defined goals.

c) Distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the IPDP. Figure 2 lists milestones and associated Go/No Go criteria.

d) The qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.

e) Milestones and timelines for the initiation, conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.

f) A listing of key personnel (including proposed consultants) who possess the necessary education, training, and experience to successfully perform the work identified in the technical proposal and their resumes.

g) A staffing plan that indicates personnel (in house and contracted) resources and the percentage of time to be dedicated to perform the work.

h) A clear and comprehensive regulatory master plan that focuses on the crucial pathway integrating all products, risk evaluation and mitigation at all development stages, non-clinical and clinical testing, manufacturing activities using the most current and available information, and documented and time-relevant FDA consultation.

i) Establishment and filing of regulatory submissions to the relevant FDA center.

Contract Yr	Mstn #	Milestones	Go Criteria	No-Go Criteria	Deliverable	SOW/WBS Number	Date
Base Period	01	[**]	[**]	[**]	[**]	[**]	[**]
	02	[**]	[**]	[**]	[**]	[**]	[**]
	03	[**]	[**]	[**]	[**]	[**]	[**]
	04	[**]	[**]	[**]	[**]	[**]	[**]
Option Year 1	05	[**]	[**]	[**]	[**]	[**]	[**]
	06	[**]	[**]	[**]	[**]	[**]	[**]
	07	[**]	[**]	[**]	[**]	[**]	[**]
Option Year 2	08	[**]	[**]	[**]	[**]	[**]	[**]
	09	[**]	[**]	[**]	[**]	[**]	[**]
	10	[**]	[**]	[**]	[**]	[**]	[**]
Option Year 3	11	[**]	[**]	[**]	[**]	[**]	[**]
	12	[**]	[**]	[**]	[**]	[**]	[**]
	13	[**]	[**]	[**]	[**]	[**]	[**]
	14	[**]	[**]	[**]	[**]	[**]	[**]
	15	[**]	[**]	[**]	[**]	[**]	[**]

j) A plan for additional studies to support future filing for FDA-approval/ clearance.

k) Summary of any prior communication with the FDA relevant to the product development; summary of audits and inspections.

l) Tentative schedule of regulatory milestones.

m) Potential Plan for consideration of an Emergency Use Authorization (EUA) of rPA102 anthrax vaccine.

n) A work breakdown structure (WBS) that is discernable and consistent. It may include data at the cost account level or at the work package level or at a lower level if there is significant complexity and risk associated with the task.

o) An approach for tracking milestones, costs, risks, subcontractor effort (if applicable), deliverables and proposed internal procedures for assuring timely responses to the Government's needs on any resulting contract.

p) An approach for performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both prime and sub-contractors on a real time bases.

3.3.2.2 Target Product Profile (TPP):

a) The intended use or indication of the proposed medical countermeasure.

b) The intended product profile (strength, quality, purity and identity) noting the performance specifications and features of the medical countermeasure that provide benefit.

c) A description of the medical counter-measure as it is currently configured.

d) A description of the manufacturing process including expected formulation (configuration) of the final product.

e) A description and developmental status of the assays for product release which provide characterization, strength, identity, and purity, as well as any needed assays for product activity and efficacy.

f) Discussions with appropriate FDA reviewers that is relevant to development activities for the proposed medical countermeasure, including plans for generating data to support an Investigational New Drug (IND) or Biologies License Application (BLA): summary of any prior, time-relevant communication with FDA relevant to the product development for the indication noted; summary of audits and inspections relative to the current development or proposed manufacturing (including at key sub-contractors) of the intended product.

3.3.2.3 Contractor Provided Facilities, Infrastructure, and other Resources

Emergent shall provide the following information to BARD A:

a) Current facility design for the manufacturing facilities including quality control labs for testing and release, laboratory areas supporting formulation and assay development, and manufacturing process flow.

b) Major equipment and layout for the manufacturing facilities (preliminary piping/instrumentation drawing).

c) Any manufacturing capacity expansion plans to match the proposed manufacturing scale up.

d) Overview of the management of Quality Systems at facilities as appropriate.

e) List of capabilities for clinical activities conducted in house and at contract research organizations.

f) Identification of qualified animal facilities where GLP studies would be conducted and appropriate certifications for humane care and use of vertebrate animals.

g) Information supporting the handling, storing and shipping of potentially dangerous biological and chemical agents, including Select Agents, under biosafety levels required for working with the biological agents under study.

h) Validation master plan for key equipment, analytical methods and manufacturing process.

3.3.2.4 Security Plan

Activities include but are not limited to:

a) The establishment of a comprehensive security program that provides a security plan for the overall protection of personnel, information, data, and facilities.

b) Security administration, as an element of the security program that address threat and risk assessments and related policies and procedures for personnel security, physical security, information security, information technology.

c) Security management, as an element of the security program that describe each element of security: physical, operations, personnel, information, information technology, transportation; and related training, auditing, and reporting requirements.

3.3.2.5 EVMS Implantation

An EVM System shall be implemented within 120 days of contract award to meet the requirements of a Tier 2 EVM implementation as outlined in the BARDA Tier 2 EVM System Implementation Intent Guide.

For the purposes of this contract, Emergent shall use EVMS in the management of this contract to meet the Seven Principles of Earned Value Management as follows:

a) Plan all work scope for the program to completion.

b) Break down the program work scope into finite pieces that can be assigned to a responsible person or organization for control of technical, schedule, and cost objectives.

c) Integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured. Control Changes to the baseline.

d) Use actual cost incurred and recorded in accomplishing the work performed.

e) Objectively assess accomplishments at the work performance level.

f) Analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.

g) Use earned value information in the company's management processes specific to this contract.

EVMS shall be applied to all CLINs under the contract as part of the Integrated Master Project Plan, Emergent shall submit a written summary of the management procedures that it will establish, maintain and use to comply with EVMS requirements.

3.4 DELIVERABLES

CDRL#	Deliverable	Description	Due Date
01	Kickoff Meeting/Status Update Meetings	The contractor shall complete a Kickoff meeting after contract award and shall hold recurring Program Review Meetings.	Within a month of contract award, but after submission of a draft IPDP, for Kick Off meeting (Final IPDP revision to be submitted per Deliverable #9). Program Review Meetings shall occur at least annually during contract period of performance.
02	Weekly Teleconference	The Contractor shall participate in weekly teleconferences with BARDA to discuss the performance of the contract. The Contractor shall record, maintain and provide draft meeting minutes to the Project Officer for approval within three days after teleconference. The Project Officer will approve the draft version. The Contractor shall distribute the final approved version duly marked as final within 3 business days after receipt of BARDA approval.	Weekly or as negotiated by all parties
03	Monthly & Annual Technical Progress Report	The Monthly and Annual Technical Progress report shall address each of the below items and be cross-referenced to the WBS in the Gantt chart and IPDP. 1.An Executive Summary in MS PowerPoint format, highlighting the progress, issues, and relevant activities in manufacturing, non-clinical, clinical, and regulatory. The Executive Summary should be limited to a few slides and also highlight only critical issues for that reporting period and resolution approach 2.Progress in meeting contract milestones - broken out by subtasks within each milestone, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned progress and actual progress during the period covered, explaining occurrences of any differences between the two, and the corrective steps and actions are planned, if behind schedule. 3.The reports shall also include a three month rolling forecast of key planned activities, referencing the WBS/IPDP. 4.A tracking log of progress on regulatory submissions with the FDA submission number, description of submission, date of submission, status of submission, and next steps 5.Estimated and Actual Expenses a. This report shall also contain a narrative statement as to whether there is any discrepancy at this time between the % of work completed and the cumulative costs incurred to date. This section of the report shall also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. These shall be listed for each subcontractor. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.	Monthly Reports shall be submitted on the 15th day of each month for the previous calendar month with an Annual Report submitted on the 15th day of the final month of each contract year for the previous twelve calendar months. Monthly progress reports are not required for the periods when the Annual Report(s) and Final Report is due.
04	Technical Documents	The contractor shall provide complete technical documents for BARDA review and approval. All documents shall be duly marked as either 'Draft or 'Final'. These technical documents shall include, but shall not be limited to, the following: [**]	Draft documents shall be submitted to BARDA for review and comment. BARDA will provide feedback within 5 business days. Contractor shall submit all final technical documents within 5 calendar days of completion or as mutually agreed to during the program execution with the Project Officer.
05	Draft Final Contract Report	A draft Final Contract Report containing a summation of the work performed and the results obtained for the entire contract period of	Due 90 days prior to the completion date of the contract.

		performance. The draft report shall be duly marked as 'Draft'.	
06	Final Contract Report	The Final Contract Report incorporating the feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire contract period of performance. The final report shall be duly marked as 'Final'. The Contractor shall submit one (1) copy of a comprehensive final report to the Contracting Officer and two (2) copies (one electronically on a CD) to the Project Officer. This final report shall detail, document and summarize the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved under all milestones.	Due on/before the completion of the contract
07	Milestone Reports	The Contractor shall provide a Milestone Report with final versions of key project documentation, after the completion of each Milestone unless otherwise agreed upon by the Project Officer and the Contracting Officer. All documents related to Milestone deliverables shall be submitted to BARDA in draft form for review and comments prior to submittal in final form in the final Milestone Report. All documents shall be duly marked as either 'Draft' or 'Final'. Milestone reports and monthly reports may be combined if agreed by the Project Officer and the Contracting Officer	Draft Milestone report shall be submitted within 15 calendar days after completion of Milestone. BARDA will provide comments on the Draft Milestone Report within 5 business days after receipt. Final Milestone Report shall be submitted within 15 calendar days from receipt of BARDA comments
08	Standard Operating Procedures	The contractor shall make internal and subcontractor Standard Operating Procedures (SOPs) available for review electronically.	Upon request from the project officer/contracting officer
09	IPDP	The Contractor shall be required to update the IPDP and include within the IPDP a table matrix capturing all program activities that will generate data and the documents that will be generated from each activity. In response to a need to change the IPDP, the contractor shall provide a deviation report identifying the reason for the deviation and request for change in the agreed upon plan and timelines.	Within 10 business days after the contract kick off meeting and following any revisions to the IPDP that occur during the contract Period of Performance. A deviation report shall be submitted as soon as the Contractor has sufficient data to support the need for a change from the approved IPDP.
10	FDA Correspondence and Mtgs Summaries	The contractor shall forward initial contractor and CBER-issued draft minutes and final minutes of any meeting with the FDA to BARDA. All documents shall be duly marked as either 'Draft' or 'Final'.	Within 5 business days of each meeting for contractor's minutes and upon receipt of • minutes from CBER
11	FDA Meetings	The contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (Project Officer, Contracting Officer, and up to 2 subject matter experts).	As and when scheduled during the contract period of performance
12	FDA Submissions	The contractor shall provide BARDA the opportunity to review and comment upon all draft regulatory documents before submission to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either 'Draft or 'Final'.	BARDA shall provide comment within 10 business days after receipt. BARDA reserves the right to request more than 10 business days for review of any regulatory submission that is of significant length. The contractor shall inform BARDA of the anticipated submission length so BARDA can make a determination if more than 10 business days will be needed to complete its review of the document. Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of its submission to CBER.
13	FDA Audits	The Contractor shall notify the Project Officer and Contracting Officer within 24 hours of FDA's arrival to conduct site visits/audits by FDA related to performance under this contract or for this product. In the event of an FDA inspection which occurs as a result of this contract and for this product, or for any other FDA inspection that has the reasonable potential to adversely impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483, and the Establishment Inspection Report (EIR). The contractor shall provide the Project Officer and Contracting Officer copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution, and a copy of all fi nal responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.	Within 24 hours of receipt from FDA or Subcontractor.
14	Contractor Audit/Site Visits	The contractor shall inform the Project Officer and Contracting Officer in advance of upcoming audits/site visits of subcontractors as part of the bi-weekly communications, including goals and agenda. Upon completion of the audit/site visit the contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, details concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution	Within 5 business days of report completion.
15	Publications	Any manuscript or scientific meeting abstract containing data	Within 30 calendar days for manuscripts and

		generated under this contract must be submitted to BARDA for review prior to submission	15 calendar days for abstracts
16	Press Releases	The contractor agrees lo accurately and factually represent the work conducted under this contract in all press releases	The contractor shall ensure that the Contracting Officer has received and approved an advanced copy of any press release lo this contract not less than 4 business days prior to the issuance of the press release
17	Security Reporting	The contractor shall report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products	Within 24 hours after occurrence of activity or incident
18	Contract Performance report Format 1	A monthly Contract Performance Report Format including a time phased CAP with BCWS, BCWP, and ACWP at the work package level by element of cost, at a reporting level below three using the BARDA provided Work Breakdown Structure	Due 20 days after the end of the Emergent Accounting Calendar
19	Level 4 Variance Analysis Report	A Level 4 Variance Analysis Report for each WBS reporting level that exceeds the agreed upon variance reporting threshold	Due 20 days after the month-end of the Emergent accounting calendar
20	Program Integrated Master Schedule	A program Integrated Master Schedule with monthly status updates (e.g. % complete for program tasks)	Initial IMS due 30 days after award. Monthly status updates are due 10 days after the month-end of the Emergent accounting calendar
21	Performance Measurement Baseline	Provide all EVM documentation to BARDA, providing proof of a Performance Management Baseline	Due 120 days after contract award.
22	Non-Clinical Gap Analysis Report	A report of the gap analysis of the non-clinical program to date for rPA to consolidate and evaluate the full body of data	Due within 2 months of contract award
23	Non-Clinical Development Strategy	Using the gap analysis, the contractor will prepare a prospective non-clinical development strategy using the FDA's" Guidance for Industry Animal Models -Essential Elements to Address Efficacy Under the Animal Rule" as a template	Due within 3 months of contract award

3.5 STATEMENT OF WORK BROAD AGENCY ANNOUNCEMENT (BAA) BARDA 09-34

Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures Statement of Work

[**]

Preamble

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work (SOW) submitted in response to Broad Agency Announcement (BAA) BARDA 09-34.

The Government reserves the right to modify the milestones, progress, schedule, budget, or product to add or delete products, process, or schedule as need may arise. Because of the nature of the (R&D) contract and complexities inherent in this and prior programs, at designated milestones the Government will evaluate whether work should be redirected or removed or whether schedule or budget adjustments should be made. In any event, the Government reserves the right to change product, process, schedule, or event to add or delete part or all of these elements as the need arise.

3.6 SCOPE

The scope of work for this contract option includes [**].

3.7 OBJECTIVE

The objective of this SOW is to conduct all necessary activities to [**].

3.8 TECHNICAL APPROACH

This section identifies representative tasks and sub-tasks for achieving the objective. We organize tasks and subtasks by year, Figure 3.

3.8.1 Development Approach

3.8.1.1 Non-Clinical Research and Development Representative

Representative activities include but are not limited to:

a) Developing [**] following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations 21 CFR Part §58), as and when appropriate.

Activities currently planned include:

[**]

3.8.2 Management Approach:

3.8.2.1 Integrated Product Development Plan (IPDP) Representative

Within fourteen (14) days of the effective date of exercise of the option, Emergent shall submit an updated IPDP based on the IPDP agreed upon by Emergent and BARDA in the final proposal revision. The IPDP shall be approved by the Project Officer and the Contracting Officer prior to initiation of any

activities related to implementation of the option. During the course of contract performance, in response to a need to change the IPDP, Emergent shall submit a Deviation Report. This report shall request a change in the agreed-upon Plan and timelines. This report shall include:

a) Discussion of the justification/rationale for the proposed change.

b) Options for addressing the needed changes from the approved timelines, including a cost-benefit analysis of each option.

c) Recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget.

d) Emergent shall carry out activities within the contract SOW only as requested and approved by the Contracting Officer, and may not conduct work on the contract without prior approval from the Contracting Officer, including initiating work that deviates from the agreed-upon IPDP.

Activities include but are not limited to:

a) Representative activities and stages of product development that Emergent is proposing to perform under contract funding in a project plan that indicates the base period and option period activities and includes all of the functional areas of development listed below.

b) A detailed description of the experimental design, including the rationale for experimental approaches, and a description of alternative approaches to be employed if these methods do not achieve the defined goals.

c) Distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the IPDP. Figure 4 lists milestones and associated Go/No Go criteria.

d) The qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.

e) Milestones and timelines for the initiation, conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.

f) A listing of key personnel (including proposed consultants) who possess the necessary education, training, and experience to successfully perform the work identified in the technical proposal and their resumes.

g) A staffing plan that indicates personnel (in house and contracted) resources and the percentage of time to be dedicated to perform the work.

h) A clear and comprehensive regulatory master plan that focuses on the crucial pathway integrating all products, risk evaluation and mitigation at all development stages, non-clinical and clinical testing, manufacturing activities using the most current and available information, and documented and time-relevant FDA consultation.

i) Establishment and filing of regulatory submissions to the relevant FDA center.

j) A plan for additional studies to support future filing for FDA-approval/ clearance.

k) Summary of any prior communication with the FDA relevant to the product development; summary of audits and inspections.

l) Tentative schedule of regulatory milestones.

m) Potential Plan for consideration of an Emergency Use Authorization (EUA) of rPA102 anthrax vaccine.

n) A work breakdown structure (WBS) that is discernable and consistent. It may include data at the cost account level or at the work package level or at a lower level if there is significant complexity and risk associated with the task.

o) An approach for tracking milestones, costs, risks, subcontractor effort (if applicable), deliverables and proposed internal procedures for assuring timely responses to the Government’s needs on any resulting contract.

SOW Task #	WBS	Activity	Option Period 1	Option Period 2	Option Period 3
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]

Figure 3. The currently-planned tasks and sub-tasks of the SOW for the Optional NHP [**]***Model Development Studies by the years in which they will occur***

Contract Yr	Mstn #	Milestones	Go Criteria	No-Go Criteria	Deliverable	SOW/WBS Number	Date
	01	[**]	[**]	[**]	[**]	[**]	[**]
Option Year 1	02	[**]	[**]	[**]	[**]	[**]	[**]
Option Year 2	03	[**]	[**]	[**]	[**]	[**]	[**]
Option Year 3	04	[**]	[**]	[**]	[**]	[**]	[**]

Figure 4. The currently-planned milestones and associated Go No/Go criteria, deliverables and completion dates for the Optional NHP [**] ***Model Development Studies***

p) An approach for performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both prime and sub-contractors on a real time bases.

3.8.2.2 Target Product Profile (TPP):

a) The intended use or indication of the proposed medical countermeasure.

b) The intended product profile (strength, quality, purity and identity) noting the performance specifications and features of the medical countermeasure that provide benefit.

c) A description of the medical counter- measure as it is currently configured.

d) A description of the manufacturing process including expected formulation (configuration) of the final product.

e) A description and developmental status of the assays for product release which provide characterization, strength, identity, and purity, as well as any needed assays for product activity and efficacy.

f) Discussions with appropriate FDA reviewers that is relevant to development activities for the proposed medical countermeasure, including plans for generating data to support an Investigational New Drug (IND) or Biologies License Application (BLA): summary of any prior, time-relevant communication with FDA relevant to the product development for the indication noted; summary of audits and inspections relative to the current development or proposed manufacturing (including at key sub-contractors) of the intended product.

3.8.2.3 Contractor Provided Facilities, Infrastructure, and other Resources

Emergent shall provide the following information to BARDA:

a) Overview of the management of Quality Systems at facilities as appropriate.

b) Identification of qualified animal facilities where GLP studies would be conducted and appropriate certifications for humane care and use of vertebrate animals.

c) Information supporting the handling, storing and shipping of potentially dangerous biological and chemical agents, including Select Agents, under biosafety levels required for working with the biological agents under study.

3.8.2.4 Security Plan

Activities include but are not limited to:

a) The establishment of a comprehensive security program that provides a security plan for the overall protection of personnel, information, data, and facilities.

b) Security administration, as an element of the security program that address threat and risk assessments and related policies and procedures for personnel security, physical security, information security, information technology.

c) Security management, as an element of the security program that describe each element of security: physical, operations, personnel, information, information technology, transportation; and related training, auditing, and reporting requirements.

3.8.2.5 EVMS Implentation

An EVM System shall be implemented within 120 days of contract award to meet the requirements of a Tier 2 EVM implementation as outlined in the BARDA Tier 2 EVM System Implementation Intent Guide.

For the purposes of this contract, Emergent shall use EVMS in the management of this contract to meet the Seven Principles of Earned Value Management as follows:

a) Plan all work scope for the program to completion.

b) Break down the program work scope into finite pieces that can be assigned to a responsible person or organization for control of technical, schedule, and cost objectives.

c) Integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured. Control Changes to the baseline.

d) Use actual cost incurred and recorded in accomplishing the work performed.

e) Objectively assess accomplishments at the work performance level.

f) Analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.

g) Use earned value information in the company's management processes specific to this contract.

EVMS shall be applied to all CLINs under the contract as part of the Integrated Master Project Plan, Emergent shall submit a written summary of the management procedures that it will establish, maintain and use to comply with EVMS requirements.

3.9 DELIVERABLES

CDRL #	Deliverable	Description	Due Date
01	Kickoff Meeting/Status Update Meetings	The contractor shall complete a Kickoff meeting after contract award and shall hold recurring Program Review Meetings.	Within a month of contract award, but after submission of a draft IPDP revision to be submitted per Deliverable #9). Program Review Meetings shall occur at least annually during contract period of performance.
02	Weekly Teleconference	The Contractor shall participate in weekly teleconferences with BARDA to discuss the performance of the contract. The Contractor shall record, maintain and provide draft meeting minutes to the Project Officer for approval within three days after teleconference. The Project Officer will approve the draft version. The Contractor shall distribute the final approved version duly marked as final within 3 business days after receipt of BARDA approval.	Weekly or as negotiate by all parties.
03	Monthly & Annual Technical Progress Report	The monthly and Annual Technical Progress report shall address each of the below items and be cross-referenced to the WBS in the Gantt chart and IPDP. 1. An Executive Summary in MS PowerPoint format, highlighting the progress issues, and relevant activities in manufacturing, non-clinical, clinical, and regulatory. The Executive Summary should be limited to a few slides and also highlight only critical issues for that reporting period and resolution approach. 2. Progress in meeting contract milestones – broken out by subtasks within each milestone, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned progress and actual progress during the period covered, explaining occurrences of any differences between the two, and the corrective steps and actions are planned, if behind schedule. 3. The reports shall also include a three month rolling forecast of key planned activities, referencing the WBS/IPDP. 4. A tracking log of progress on regulatory submissions with the FDA submission number, description of submission, date of submission, status of submission, and next steps. 5. Estimated and Actual Expenses a. This report also contain a narrative statement as to whether there is any discrepancy at this time between the % of work completed and the cumulative costs incurred to date. This section of the report shall also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. These shall be listed for each subcontractor. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.	Monthly Reports shall be submitted on the 15th day of each month for the previous calendar month with an Annual Report submitted on the 15th day of the final month of each contract year for the previous twelve calendar months. Monthly progress reports are not required for the periods when the Annual Report(s) and Final Report is due.
04	Technical Documents	The contractor shall provide complete technical documents for BARDA review and approval. All documents shall be duly marked as either "Draft" or "Final." These technical documents shall include, but shall not be limited to, the following: [**]	Draft documents shall be submitted to BARDA for review and comment BARDA will provide feedback within 5 business days. Contractor shall submit all final technical documents within 5 calendar days of completion or as mutually agreed to during the program execution with the Project Officer.
05	Draft Final Contract Report	A draft Final Contract Report containing a summation of the work performed and the results obtained for the entire contract period of performance. The draft report shall be duly marked as "Draft".	Due 90 days prior to the completion date of the contract.
06	Final Contract Report	The Final contract Report incorporating the feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire contract period of performance. The final report shall be duly marked as "Final." The Contractor shall submit one (1) copy of a comprehensive final report to the Contracting Officer and two (2) copies (one electronically on a CD) to the Project Officer. This final report shall detail, document and summarize the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved under all milestones.	Due on/before the completion of the contract.
07	Milestone Reports	The Contractor shall provide a Milestone Report with final versions of key project documentation, after the completion of each Milestone unless otherwise agreed upon by the Project Officer and the Contracting Officer. All documents related to Milestone deliverables shall be submitted to BARDA in draft form for review and comments prior to submittal in final form in the final Milestone Report. All	Draft Milestone report shall be submitted within 15 calendar days after completion of Milestone. BARDA will provide comments on the Draft Milestone Report within 5 business days after receipt. Final

		documents shall be duly marked as either “Draft” or “Final.” Milestone reports and monthly reports may be combined if agreed by the Project Officer and the Contracting Officer.	Milestone Report shall be submitted within 15 calendar days from receipt of BARDA comments
08	Standard Operating Procedures	The contractor shall make internal and subcontractor Standard Operating Procedures (SOPs) available for review electronically	Upon request from the project officer/contracting officer
09	IPDP	The Contractor shall be required to update the IPDP and include within the IPDP a table matrix capturing all program activities that will generate data and the documents that will be generated from each activity. In response to a need to change the IPDP, the contractor shall provide a deviation report identifying the reason for the deviation and request for change in the agreed upon plan and timelines.	Within 10 business days after the contract kick off meeting and following any revisions to the IPDP that occur during the contract Period of Performance. A deviation report shall be submitted as soon as the Contractor has sufficient data to support the need for a change from the approved IPDP.
10	FDA Correspondence and Mtgs. Summaries	The contractor shall forward initial contractor and CBER-issued draft minutes and final minutes of any meeting with the FDA to BARDA. All documents shall be duly marked as either “Draft” or “Final.”	Within 5 business days of each meeting for contractor’s minutes and upon receipt of minutes from CBER.
11	FDA Meetings	The contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (Project Officer, Contracting Officer, and up to 2 subject matter experts).	As and when scheduled during the contract period of performance.
12	FDA Submissions	The contractor shall provide BARDA the opportunity to review and comment upon all draft regulatory documents before submission to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission . All documents shall be duly marked as either “Draft” or “Final.”	BARDA shall provide comment within 10 business days after receipt. BARDA reserves the right to request more than 10 business days for review of any regulatory submission that is of significant length. The contractor shall inform BARDA of the anticipated submission length so BARDA can make a determination if more than 10 business days will be needed to complete its review of the document. Final FDA submission shall be submitted to BARDA concurrently or no later than 1 calendar day of its submission to CBER.
13	FDA Audits	The Contractor shall notify the Project Officer and Contracting Officer within 24 hours of FDA’s arrival to conduct site visits/audits by FDA related to performance under this contract or for this product. In the event of an FDA inspection which occurs as a result of this contract and for this product, or for any other FDA inspection that has the reasonable potential to adversely impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483, and the Establishment Inspection Report (EIR). The contractor shall provide the Project Officer and Contracting Officer copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution , and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.	Within 24 hours of receipt from FDA or Subcontractor.
14	Contractor Audit/Site Visits	The contractor shall inform the Project Officer and Contracting Officer in advance of upcoming audits/site visits of subcontractors as part of the bi-weekly communications, including goals and agenda. Upon completion of the audit/site visit the contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, details concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution	Within 5 business days of report completion.
15	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to BARDA for review prior to submission.	Within 30 calendar days for manuscripts and 15 calendar days for abstracts.
16	Press Release	The contractor agrees to accurately and factually represent the work conducted under this contract in all press releases	The contractor shall ensure that the Contracting Officer has received and approved an advanced copy of any press release to this contract not less than 4 business days prior to the issuance of the press release
17	Security Reporting	The contractor shall report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products	Within 24 hours after occurrence of activity or incident
18	Contract Performance report Format 1	A monthly Contract Performance Report Format including a time phased CAP with BCWS, BCWP, and ACWP at the work package level by element of cost, at a reporting level below three using the BARDA provided Work Breakdown Structure	Due 20 days after the end of the Emergent Accounting Calendar
19	Level 4 Variance Analysis Report	A Level 4 Variance Analysis Report for each WBS reporting level that exceeds the agreed upon variance reporting threshold	Due 20 days after the month-end of the Emergent accounting calendar
20	Program Integrated Master Schedule	A program Interated Master Schedule with monthly status updates (e.g. % complete for program tasks)	Initial IMS due 30 days after award. Monthly status updates are due 10

			days after the month-end of the Emergent accounting calendar
21	Performance Measurement Baseline	Provide all EVM documentation to BARDA, providing proof of a Performance Management Baseline	Due 120 days after contract award.
22	Non-Clinical Gap Analysis Report	A report of the gap analysis of the non-clinical program to date for rPA to consolidate and evaluate the full body of data.	Due within 2 months of contact award
23	Non-Clinical Development Strategy	Using the gap analysis, the contractor will prepare a prospective non-clinical development strategy using the FDA's "Guidance for Industry Animal Models – Essential Elements to Address Efficacy Under the Animal Rule" as a template	Due within 3 months of contract award

ATTACHMENT 2

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING INSTRUCTIONS FOR BARDA COST-REIMBURSEMENT TYPE CONTRACTS

Format: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All BARDA contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, which are not set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

Invoice/Financing Request Identification: Each payment request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request**: These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice**: The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice**: A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

(a) **Designated Billing Office Name and Address**: Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number**: Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of c ontact, VIN, and DUNS).

(c) **Invoice/Financing Request Number**: Insert the appropriate serial number of the payment request.

(d) **Date Invoice/Financing Request Prepared**: Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable)**: Insert the contract number and order number (if applicable).

(f) **Effective Date**: Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order**: Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee**: Insert the total fixed-fee (where applicable). For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(i) **Two-Way/Three-Way Match**: Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(j) **Office of Acquisitions**: Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Central Point of Distribution**: Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract

Schedule.

(l) **Billing Period**: Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period**: Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative**: Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs**: Insert the major cost elements For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor**: Include salaries and wages paid (or accrued) for direct performance of the contract.

For Level of Effort contracts only, the Contractor shall provide the following information on a separate sheet of paper attached to the payment request:

- hours or percentage of effort and cost by labor category (as specified in the Level of Effort Article in Section F of the contract) for the current billing period, and
- hours or percentage of effort and cost by labor category from contract inception through the current billing period. (NOTE: The Contracting Officer may require the Contractor to provide additional breakdown for direct labor, such as position title, employee name, and salary or hourly rate.)

(2) **Fringe Benefits**: List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property**: Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS Contractor's Guide for Control of Government Property). Show permanent research equipment separate from general purpose equipment.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. An asterisk (*) shall precede the item if the equipment is below the $1,000 approval level. Include reference to the following (as applicable):

- item number for the specific piece of equipment listed in the Property Schedule, and
- COA number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

(4) **Materials and Supplies**: Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) **Premium Pay**: List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee**: List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) **Travel**: Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs**: List subcontractor(s) by name and amount billed.

(9) **Other**: List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) **Cost of Money (COM)**: Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(q) **Indirect Costs**: Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) **Fixed-Fee**: Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) **Total Amounts Claimed**: Insert the total amounts claimed for the current and cumulative periods.

(t) **Adjustments**: Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(u) **Grand Totals**

(v) **Certification of Salary Rate Limitation**: If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

The Contracting Officer may require the Contractor to submit detailed support for costs claimed on one or more interim payment requests.

FINANCIAL REPORTING INSTRUCTIONS:

These instructions are keyed to the Columns on the sample invoice/financing request.

Column A - Expenditure Category: Enter the expenditure categories required by the contract.

Column B - Cumulative Percentage of Effort/Hrs. - Negotiated: Enter the percentage of effort or number of hours agreed to for each employee or labor category listed in Column A.

Column C - Cumulative Percentage of Effort/Hrs. - Actual: Enter the percentage of effort or number of hours worked by each employee or labor category listed in Column A.

Column D - Amount Billed - Current: Enter amounts billed during the current period.

Column E - Amount Billed - Cumulative: Enter the cumulative amounts to date.

Column F - Cost at Completion: Enter data only when the Contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column G - Contract Amount: Enter the costs agreed to for all expenditure categories listed in Column A.

Column H - Variance (Over or Under): Show the difference between the estimated costs at completion (Column F) and negotiated costs (Column G) when entries have been made in Column F. This column need not be filled in when Column F is blank. When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column F by Column G, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications: Any modification in the amount negotiated for an item since the preceding report should be listed in the appropriate cost category.

Expenditures Not Negotiated: An expenditure for an item for which no amount was negotiated (e.g., at the discretion of the Contractor in performance of its contract) should be listed in the appropriate cost category and all columns filled in, except for G. Column H will of course show a 100 percent variance and will be explained along with those identified under H above.

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a)Designated Billing Office Name and Address:
DHHS/OS/ASPR/BARDA
Attn: Contracting Officer
330 Independence Ave., S.W.
Room G644
Washington, D.C. 20201

(b)Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:

ABC CORPORATION
100 Main Street
Anywhere, USA Zip Code

(c)Invoice/Financing Request No.:
(d)Date Invoice Prepared:
(e)Contract No. and Order No. (if applicable):
(f)Effective Date:
(g)Total Estimated Cost of Contract/Order:
(h)Total Fixed-Fee (if applicable):
(i)Two-Way Match:
Three-Way Match:
(j)Office of Acquisitions:
(k)Central Point of Distribution:

Name, Title, Phone Number, and E-mail Address of person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent.

VIN:
DUNS or DUNS+4:

(l) This invoice/financing request represents reimbursable costs for the period from _____ to

	Cumulative Percentage of Effort/Hrs.		Amount Billed				
Expenditure Category* A	Negotiated B	Actual C	(m) Current D	(n) Cumulative E	Cost at Completion F	Contract Amount G	Variance H
(o) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(p) Cost of Money							
(q) Indirect Costs							
(r) Fixed Fee							
(s) Total Amount Claimed							
(t) Adjustments							
(u) Grand Totals							

I certify that all payments are for appropriate purposes and in accordance with the contract.

(Name of Official) (Title)
* Attach details as specified in the contract

ATTACHMENT 3

FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT Note: Complete this Form in Accordance with Accompanying Instructions.	Project Task:	Contract No.:	Date of Report:	0990-0134 0990-0131
	Reporting Period:	Contractor Name and Address:		

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost-Current Period	Cumulative Cost to Date (D + E)	Estimated Cost to Complete	Estimated Cost at Completion (F + G)	Negotiated Contract Amount	Variance (Over or Under) (I -H)
	Negotiated	Actual							
A	B	C	D	E	F	G	H	1	J

ATTACHMENT 4

INSTRUCTIONS FOR COMPLETING "FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. This Quarterly Financial Report is designed to: (1) provide a management tool for use by be BARDA in monitoring the application of financial and personnel resources to the BARDA contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the Contracting Officer's Technical Representative.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate quarterly report, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing the Quarterly Report. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Key Personnel**. Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel-Other**. List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits**. Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property**. Include nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."

(5) **Supplies**. Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care**. Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care**. Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel**. Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.

(9) **Consultant Fee**. Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.

(10) **Premium Pay**. Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts**. List each subcontract by name and amount billed.

(12) **Other Costs**. Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs**. Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expense**. Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) **Fee**. Cite the fee earned, if any.

(16) **Total Costs to the Government**.

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on the Quarterly Report.

Column A-Expenditure Category. Enter the expenditure categories required by the contract.

Column B-Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C-Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E-lncurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F-Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G—Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I--Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

Attachment 5

INCLUSION ENROLLMENT REPORT

This report format should NOT be used for data collection from study participants

Study Title:				
Total Enrollment:		**Protocol Number:**		
Contract Number:				
PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			
	Females	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				

PART B. HISPANIC ENROLLMENT REPORT:	**Number of Hispanics or Latinos Enrolled to Date (Cumulative)**			
Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				

*These totals must agree
**These totals must agree

ATTACHMENT 6

Research Patient Care Costs

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Research patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine research patient care costs. Research patient care rates or amounts shall be established by the Secretary of HHS or his/her duly authorized representative.

(c) Prior to submitting an invoice for research patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for research patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

ATTACHMENT 8

Small Business Subcontracting Plan, dated 10 August 2010

DHHS SUBCONTRACTING PLAN REVIEW FORM

SB No:	MULTIPLE AWARD	Yes	No ü (if yes, identify subcontracting plans)
MOB No. (if applicable)	1. Solicitation/Contract No.	2. Title of Acquisition	

3. Contractor's Name	4. Period of Performance (base & options)	5. Total Contract Amount (including options)
Emergent Product Development Gaithersburg	9/30/10 through 9/30/15	$186,626,986 Total MOD Amt (if applicable $[**] Base Year (if there are options) $51,063,150

6. Option #1 (if applicable)	Option #2 (if applicable)	Option #3 (if applicable)	Option #4 (if applicable)
$[**]	$[**]	$[**]	$

7. Contracting Officer/Specialist Name, Bldg., Room, Phone, Fax, & Email:	8. Date Received by SBS for Review:
Ethan J. Mueller, 409 3rd Street, SW, Washington, D.C. 20204, Phone: 202-205-4657, e-mail: Ethan.Mueller@HHS.Gov.	

1. SUBCONTRACTIGN PLAN TYPE: (check one) Individual:ü Master:
Commercial

SUBCONTRACTING PLAN REQUIREMENTS	CO		SBS		SBA/PCR	
2. Subcontracting Goal Data	A	U	A	U	A	U
a. Total Subcontracting Dollars [(b+g), except when subcontract baseline equals contract value) [**]	ü		ü			
b. Total Subcontracting Dollars & Percentage with Small Businesses (incl. SDB, WOSB, HUBZone, SDVOSB) – [Percentage of 2.a.] $[**] and [**]%	ü		ü			
c. Total Subcontracting Dollars & Percentage with Small Disadvantaged Businesses – [Percentage of 2.a.] $[**] and [**]%	ü		ü			
d. Total Subcontracting Dollars & Percentage with Woman-owned Small Businesses – [Percentage of 2.a.] $[**] and [**]%	ü		ü			
e. Total Subcontracting Dollars & Percentage with HUBZone Small Businesses – [Percentage of 2.o.] $[**] and [**]%	ü		ü			
f. Total Subcontracting Dollars & Percentage with Service-Disabled Veteran Small Businesses – [Percentage of 2.a.] $[**] and [**]%	ü		ü			
g. Total Subcontracting Dollars & Percentage with "Other" than Small Businesses – [Percentage of 2.a.] $[**] and [**]%	ü		ü			
h. Subcontracting Opportunities (description of all principal products/services to be subcontracted to all types of concerns)	ü		ü			
i, j, k. Methodology used to develop goals & identify potential sources (e.g. historical trends, information on technical and competitive bidding, formula for calculating goals, etc.)	ü		ü			

Subcontracting Plan Review Form (Rev. 09/07

SUBCONTRACTING PLAN REQUIREMENTS - CONTINUED	CO		SBS		SBA/PCR	
	A	U	A	U	A	U
3. Subcontracting Plan Administrator's Name and Duties	ü		ü			
4. Description of efforts to ensure the Small Businesses (incl. SDB, WOSB, HUBZone, SDVOSB) entities have equitable opportunity to compete for subcontracts	ü		ü			
5. Required flow-down clause to be included in prime contractor's subcontracts	ü		ü			
6. Reports and Records: a. Agreement to submit it required reports	ü		ü			
b. Agreement to cooperate in studies and surveys	ü		ü			

C.O. DETERMINATION – SBS AND SBA RECOMMENDATION:	CO		SBS		SBA/PCR	
	Y	N	Y	N	Y	N
1. The proposed plan meets the requirements of PAR 19.704 and, in accordance with 19.705-4, past performance has been considered when determining acceptability of this plan	ü		ü			
2. The proposed plan requires an additional pre-award review	ü		ü			
COMMENT: If any elements are determined to be unacceptable, summarize below:	ü		ü			

Based on the justification that Emergent has provided, I hereby determine as Contracting Officer, the proposed subcontracting goals to be acceptable.

/s/ Ethan Mueller	8/19/10	/s/ illegible	8/20/2010	PCR reserves the right to review	
CO Signature	Date	SBS Signature	Date	SBA/PCR Signature	Date

A=ACCEPTABLE U=UNACCEPTABLE Y=YES N=NO

NOTE:

Contracting Officers are responsible for distribution of award documents in accordance with FAR 19.705-6

Subcontracting Plan Review Form (Rev. 09/07)

Appendix 5

OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION SMALL BUSINESS SUBCONTRACTING PLAN

The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by the Federal Acquisition Regulations (FAR) Subpart 19.7. The U.S. Department of Health and Human Services (HHS), Office of Small and Disadvantaged Business Utilization (OSDBU) recommend offerers use the following format to submit proposed Individual Subcontracting Plans, including modifications. It is not intended to replace any existing Corporate/Commercial Plan that is more extensive, A subcontracting Plan is required if the estimated cost of the contract ***may exceed $550,000*** *(small businesses are excl uded). Questions should be forwarded to the Contracting Officer or Teneshia Alston, Senior Small Business Analyst (Teneshia.Alston@HHS.GOV).*

HHS Operating Division (OPDIV)s: BARDA &# 160;

SOLICITATION OR CONTRACT NUMBER: BAA-BARDA-09-34

DATE OF PLAN: August 10, 2010 ;

CONTRACTOR: Emergent Product Development Gaithersburg Inc.

ADDRESS: 300 Professional Drive, Suite 100 0;

STATE/ZIP CODE Gaithersburg, MD 20879

DUNN &. BRADSTREET NUMBER: &# 160;[**]

ITEM/SERVICE (Description): Advanced development of Recombinant Protective Antigen (rPA) anthrax vaccine

NEW /INITIAL CONTRACT

PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year):			9/30/10 - 9/30/15
Base Yr 1	$[**]	Performance Period/Quantity	9/30/10 - 9/30/11
Base Yr 2:	$[**]	Performance Period/Quantity	10/1/11 - 9/30/12
Option 1	$[**]	Performance Period/Quantity	10/1/12 - 9/30/13
Year 3			
Option 2:	$[**]	Performance Period/Quantity	10/1/13 - 9/30/14
Year 4			
Option 3:	$[**]	Performance Period/Quantity	10/1/14 - 9/30/15
Year 5			
CLIN 0005:	$[**]	Performance Period/Quantity	10/1/12 - 9/30/13
Year 3			
CLIN 0006:	$[**]	Performance Period/Quantity	10/1/13 - 9/30/14
Year 4			
CLIN 0007	$[**]	Performance Period/Quantity	10/1/14 - 9/30/15
Year 5			
$186,626,986		Total Contract Cost	

CONTRACT MODIFICATION (if applicable)

NEW PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year):

Original/Base	$	Performance Period/Quantity
Modification	$	Performance Period/Quantity
Task Order	$	Performance Period/Quantity
	$	Modified Total Contract Cost

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 requesting supplies or services required for performance of the contract or subcontract.

If assistance is needed to locate small business sources, contact the Small Business Specialist (SBS) supporting the OPDIV. SBS contact information is located on the OSDBU website (http://www.hhs.gov/osdbu/staff.html) or you may contact the OSDBU headquarters at (202) 690-7300.

HHS current subcontracting goal is **39.9%** for small business, including 8(a) Program Participants (hereafter referred to as SB), **5.00%** for Small Disadvantaged Business, including Alaska Native Corporations (ANC) and Indian Tribes (hereafter referred to as SDB), **5.00%** for women-owned business and economically disadvantaged women-owned business (hereafter referred to as WOSB), **3.00%** HubZone business (HUBZone) and **3.00%** service disabled veteran-owned small business (SDVOSB) concerns for **Fiscal Year (FY) 2008**. 0; For this procurement, HHS expects all proposed subcontracting plans to contain at a minimum the aforementioned percentages. These percentages shall be expressed as percentages of the total estimated subcontracting dollars. Zero goal statement removed.

1. Type of Plan (check one)

X ***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 (goals are negotiated with the initial agency on a company-wide basis rather than for individual contracts) this plan applies to the entire production of commercial service or items or a portion thereof. The contractor sells commercial products and services customarily used for non-government purposes. The plan is effective during the offeror's fiscal year (attach a copy). ***The Summary Subcontracting Report (SSR) must include a breakout of subcontracting prorated for HHS and other Federal agencies.***

2. GOALS

Below indicate the dollar and percentage goals for Small Business, Small Disadvantaged (SDB) including Alaska Native Corporations and Indian Tribes, Woman-owned and Economically Disadvantaged Women-Owned (WOSB), Historically Underutilized Business Zone (HUBZone), Service-Disabled Veteran-owned (SDVOSB) small businesses and "Other than small business" (Other) as subcontractors. Indicate the base year and each option year, as specified in FAR 19.704 or project annual subcontracting base and goals under commercial plans. If any contract has more four options, please attach additional sheets which illustrate dollar amounts and percentages.

a. **Total estimated dollar value of ALL planned subcontracting**, i.e., with ALL types of concerns under this contract is $[**] (Base Year 1).

FY 11 Year 2 (Base)	FY 12 Year 3 (Option 1)	FY 13 Year 4 (Option 2)	FY 14 Year 5 (Option 3)
[**]	[**]	[**]	[**]

b. **Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES** (including SDB, WOSB, HUBz and SDVOSB): (% of "a") $[**] and [**]% (Base Year 1)

FY 11 Year 2 (Base)		FY 12 Year 3 (Option 1)		FY 13 Year 4 (Option 2)		FY 14 Year 5 (Option 3)	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

c. Total estimated dollar value and percent of planned subcontracting with **SMALL DISADVANTAGED BUSINESSES**: (% of "a") $ [**] and [**]% (Base Year 1).

FY 11 Year 2 (Base)		FY 12 Year 3 (Option 1)		FY 13 Year 4 (Option 2)		FY 14 Year 5 (Option 3)	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

d. Total estimated dollar value and percent of planned subcontracting with **WOMAN-OWNED SMALL BUSINESSES**: (% of "a") $[**] and [**]% (Base Year 1)

FY 11 Year 2 (Base)		FY 12 Year 3 (Option 1)		FY 13 Year 4 (Option 2)		FY14 Year 5 (Option 3)	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

e. Total estimated dollar and percent of planned subcontracting with **HUBZone** SMALL BUSINESSES: (% of "a") $[**] and [**]% (Base Year 1)

FY 11 Year 2 (Base)		FY 12 Year 3 (Option 1)		FY 13 Year 4 (Option 2)		FY 14 Year 5 (Option 3)	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

f. Total estimated dollar and percent of planned subcontracting with **SERVICE-DISABLED VETERARN-OWNED SMALL BUSINESSES**: (% of "a") $[**] (% of "a") and [**]% (Base Year 1)

FY 11 Year 2 (Base)		FY 12 Year 3 (Option 1)		FY 13 Year 4 (Option 2)		FY 14 Year 5 (Option 3)	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

g. Total estimated dollar and percent of planned subcontracting with "**OTHER THAN SMALL BUSINESSES**" *(As defined by the Small Business Administration as "any entity that is not classified as a small business. This includes large businesses, state and local governments, non-profit organizations, public utilities, educational institutions and foreign-owned firms.)* (% of "a") $[**] and [**] % (Base Year 1)

FY 11 Year 2 (Base)		FY 12 Year 3 (Option 1)		FY 13 Year 4 (Option 2)		FY 14 Year 5 (Option 3)	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

Note: Federal prime contract percentage goals may serve as objectives for subcontracting goal development:

- Total Small Business (SB) 19.00%
- 8(a) Program Participants 5.00%
- Small Disadvantaged Business (SDB) 5.00%
- Woman Owned Small Business (WOSB) 5.00%
- Historically Underutilized Business Zone (HUBZone) 3.00%
- Service Disabled Veteran Owned Small Business (SDVOSB) 3.00%

h. 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):

	Products and/or Services	Other	Small Business	SDB	WOSB	Hubz	SDVOSB
1	[**]	X	X		X		
2	[**]	X					
3	[**]	X					
4	[**]		X				
5	[**]	X					
6	[**]	X					
7	[**]		X				
8	[**]		X				
9	[**]		X				
10	[**]	X					
11	[**]		X				
12	[**]		X				
13	[**]	X					
14	[**]	X					
15	[**]	X					

i. Provide a description of the method used to develop the subcontracting goals for SB, SDB, WOSB, HUBZone 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, WOSB, HUBZone and SDVOSB concerns were determined, how the capabilities of these concerns were considered contract 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.)

Emergent Product Development Gaithersburg Inc. (Emergent) solicited proposals from those sources with the qualifications required to execute the contract. Those contractors that best met the business specifications, capability, performance expectations, cost competitiveness and other relevant criteria were considered for this effort.

The total dollar amount to be subcontracted for each of the areas in h. above, and the associated business classifications related to the overall subcontracting dollar amount are as follows:

Product/Service	Amount to be Subcontracted	Bus. Class
Consultants		
[**]	[**]	SB
[**]	[**]	Other
[**]	[**]	Other
[**]	[**]	WOSB
[**]	[**]	SB
[**]	[**]	SB
[**]	[**]	SB
[**]	[**]	WOSB
[**]	[**]	SB
[**]	[**]	WOSB
[**]	[**]	Other
Subcontractors		
[**]	[**]	Other
[**]	[**]	Other
[**]	[**]	SB
[**]	[**]	Other
[**]	[**]	Other
[**]	[**]	SB
[**]	[**]	SB
[**]	[**]	SB
Professional Travel		
[**]	[**]	Other
Other Direct. Costs		
[**]	[**]	Other
Materials and Supplies		
[**]	[**]	Other
[**]	[**]	Other
[**]	[**]	Other
[**]	[**]	SB
[**]	[**]	SB

The proposed contract is to advance a new generation anthrax vaccine towards licensure by the Food and Drug Administration (FDA). Activities required to fulfill this contract include:

[**]

Emergent plans to utilize small business concerns to the maximum extent practical and regularly surveys the healthcare community to identify small businesses with the skills and experience to undertake research, trials, and vaccine-related manufacturing. However, delivery under this contract will require a niche skill set and due to the complexity and very specialized nature of the program, there is a very small pool of qualified small businesses from which to make a selection.

As shown above, [**] subcontractors have been identified to fulfill the scope of this contract of which, [**] are small businesses.

The proposed subcontractors with the largest contributions to contract are [**]. After careful evaluation, these subcontractors were the only companies that could be identified to perform the activities required for the success of the project as outlined below:

[**]

Emergent conducted an extensive search to identify qualified small businesses for each product/service to be subcontracted for this contract. The results of the search are as described below:

As it relates to large-scale process validation and manufacturing we identified [**] was selected over [**] because [**] did not have experience validating manufacturing processes and had not been inspected by the FDA. [**] had experience validating many manufacturing processes, had been inspected by the FDA and manufactured an FDA licensed product.

For clinical studies, [**] were identified as prospective subcontractors. The original plan was to use [**] for all of the clinical studies. However, after auditing the companies, it was determined that [**] did not have the capability to conduct the large clinical studies required for this contract. Emergent is using [**] for clinical trials for other products at earlier stages of development, where the trials are not as large. However, for the proposed contract, [**] were selected to support the clinical trials.

As it relates to the anthrax vaccine efficacy testing, [**] is the only company in the world who routinely performs anthrax vaccine efficacy testing that conforms to federal regulations and guidelines.

Professional Travel

[**] - Emergent BioSolutions Inc. (EBSI) and its subsidiaries including Emergent Product Development Gaithersburg Inc. use the same travel agency to ensure continuity of service and cost effectiveness. EBSI is a global corporation with offices in the United States, Europe, and Asia. The travel agency utilized must have the breadth to manage travel around the globe and across time zones while supplying the most economical travel, We regularly evaluate alternatives to [**] and consider small businesses as they are identified.

Other Direct Costs

[**] - Clinical Trial Insurance Carrier

Materials and Supplies

[**] companies [**] providing materials and Supplies are small businesses. Emergent will continue its efforts to seek small businesses to replace its large business suppliers that provide products equivalent to those currently being purchase to ensure adherence to federal and state quality assurance requirements for the development and manufacture of vaccines.

Emergent fully supports the government's interest in supporting small business concerns and will remain diligent in it efforts to meet the governments overall subcontracting goals and ensure that the maximum practical subcontracting opportunities are made available to respective small business concerns during contract performance.

j. Indirect costs [**] been included in the dollar and percentage subcontracting goals above (check one).

k. 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 and SDVOSB concerns:

Emergent uses SB, SDB, WOSB, HUBZone and SDVOSB suppliers for office supplies, facility maintenance and other services that are included in its indirect costs. The proportionate share of these costs allocated to this contract will be determined using the following formula: [**].

3. Program Administrator:

NAME:	[**]
TITLE:	Director, US Government Contracts
ADDRESS:	300 Professional Drive, Suite 250
	Gaithersburgr, MD 20879
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? (If NO is checked, please who in the company performs those duties, or indicate why the duties are not performed in your company on a separate sheet of paper and submit with the proposed subcontracting plan.)

a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone and SDVOSB concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing; X yes __ no

b. Developing and maintaining bidder source lists of SB, SDB, WOSB, HUBZone and SDVOSB concerns from all possible sources; X yes __ no

c. Ensuring periodic rotation of potential subcontractors on bidder's lists; X yes __ no

d. Assuring that SB, SDB, WOSB, HUBZONE and SDVOSB businesses are included on the bidders' list for every subcontract solicitation for products and services that they are capable of providing. X yes __ no

e. Ensuring that Requests for Proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone and SDVOSB concerns. X yes __ no

f. Reviewing subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit small, 8(a), SDB, WOSB, Hubz and SDVOSB small business participation. X yes __ no

g. Accessing various sources for the identification of SB, SDB, WOSB, HUBZone and SDVOSB concerns to include the Central Contractor Registration (http://www.ccr.gov/), local small business and minority associations, local chambers of commerce and Federal agencies' Small Business Offices; X yes __ no

h. Establishing and maintaining contract and subcontract award records; X yes __ no

i. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc; X yes __ no

j. Ensuring that SB, SDB, WOSB, HUBZone and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company; X yes __ no

k. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended; X yes __ no

l. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals; X yes __ no

m. Preparing and submitting timely, required subcontract reports; X yes __ no

n. Conducting or arranging training for purchasing personnel regarding the intent and impact of 8(d) of the Small Business Act on purchasing procedures; X yes __ no

o. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies; and X yes __ no

p. Other duties:

4. Equitable Opportunity

Describe efforts the offeror will undertake to ensure that SB, SDB, WOSB, HUBZone 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. Contact minority and small business trade associations; 2) contact business development organizations and local chambers of commerce; 3) attend SB, SDB, WOSB, HUBZone and SDVOSB procurement conferences and trade fairs; 4) review sources from the Central Contractor Registration (http://www.ccr.gov/); 5) review sources from the Small Business Administration (SBA), Central Contractor Registration (CCR); 6) Consider using other sources such as the National Institutes of Health (IMIH) e-Portals in Commerce, (e-PIC), (http://epic.od.nih.gov/). The NIH e-PIC is not a mandatory source; however, it may be used at the offerer's discretion; and 7) Utilize newspaper and magazine ads to encourage new sources.

b. Internal efforts to guide and encourage purchasing personnel:

1. Conduct workshops, seminars and training programs;

2. Establish, maintain, and utilize SB, SDB, WOSB, HUBZone and SDVOSB source lists, guides, and other data for soliciting subcontractors; and

3. Monitor activities to evaluate compliance with the subcontracting plan.

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 $550,000 ($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." Note: In accordance with FAR 52.212-5(e) and 52.244-6(c) the contractor is not required to include flow-down clause FAR 52.219.-9 if it is subcontracting commercial items.

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 illustrate compliance with the subcontracting plan; 3) submission of its Individual Subcontracting Report (ISR) and Summary Subcontract Report (SSR); and 4) subcontractors submission of ISRs and SSRs. **ISRs and SSRs shall be submitted via the Electronic Subcontracting Reporting System (eSRS) website https://esrs.symplicity.com/index?tab=signin&cck=1**

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	ISR	4/30
Apr 1 - Sept 30	ISR	10/30
Oct 1 - Sept 30	SSR	10/30
Contract Completion	Year End SDB Report	30 days after completion

Please refer to FAR Part 19.7 for instruction concerning the submission of a Commercial Plan: SSR is due on 10/30 each year for the previous fiscal year ending 9/30.

a. Submit ISR (bi-annually) for the awarding Contracting Officer's review and acceptance via the eSRS website.

b. Currently, SSR (annually) must be submitted for the HHS eSRS Agency Coordinator review and acceptance via the eSRS website. (***Note:*** Log onto the OSDBU website to view the HHS Agency Coordinator contact information (http://www.hhs.gov/osdbu/staff.html).

Note: ***The Request for Proposal (RFP) will indicate whether a subcontracting plan is required. Due to the nature and complexity of many HHS contracts, particularly the Centers for Medicare and Medicaid (CMS), the contractor may not be required to submit its subcontracting reports through the eSRS. The Contracting Officer will confirm reporting requirements prior to the issuance of an award. For more information, contact Teneshia Alston, Agency Coordinator-eSRS (Teneshia.Alston@HHS.GOV)***.

7. Record Keeping

FAR 19.704(a) (11) requires a list of the types of records your company will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. 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 and SDVOSB source lists, guides and other data identifying such vendors;

b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone 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 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 is not required on a contract-by-contract basis for 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, 8(a), SDB, women-owned small business, HubZone and service disabled veteran-owned small business concerns.

Your company has established and used such procedures: X yes __ no

9. Description of Good Faith Effort

Maximum practicable utilization of small, 8(a), small disadvantaged, woman-owned, HubZone small and service disabled veteran owned 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, SDB, WOSB, HubZone and SDVOSB small business subcontracting goals, outline the steps your company plans to take. These steps will be negotiated with the contracting official prior to approval of the plan.

[**]

SIGNATURE PAGE

Signatures Required:

This subcontracting plan was submitted by:

Signature:	/s/[**]
Typed Name:	[**]
Title:	Director, US Government Contracts
Date:	August 10, 2010

This plan was reviewed by:

Signature:	/s/Ethan J. Mueller	
Typed Name:	Ethan J. Mueller	
Title:	Contracting Officer	Date: 8/19/10

This plan was reviewed by:

Signature:	/s/Nydia Flynn	
Typed Name:	Nydia Flynn	
Title:	HHS Small Business Specialist (SBS)	Date: 8/20/2010

This plan was reviewed by:

Signature:	
Typed Name:	PCR RESERVES THE RIGHT TO REVIEW
Title:	Small Business Administration Procurement Center Representative
Date:	

5.0 COST SUMMARY

		BASE PERIOD YEAR 1	BASE PERIOD YEAR 2	OPTION YEAR 1	OPTION YEAR 2	OPTION YEAR 3	TOTAL
TOTAL LABOR HOURS		[**]	[**]	[**]	[**]	[**]	[**]
DIRECT LABOR COST		[**]	[**]	[**]	[**]	[**]	[**]
FRINGE BENEFITS	[**]	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL DIRECT LABOR & FRINGE BENEFITS		[**]	[**]	[**]	[**]	[**]	[**]
DEVELOPMENT OVERHEAD	[**]	[**]	[**]	[**]	[**]	[**]	[**]
MATERIALS AND SUPPLIES		[**]	[**]	[**]	[**]	[**]	[**]
PROFESSIONAL TRAVEL		[**]	[**]	[**]	[**]	[**]	[**]
EQUIPMENT		[**]	[**]	[**]	[**]	[**]	[**]
CONSULTANTS		[**]	[**]	[**]	[**]	[**]	[**]
OTHER DIRECT COSTS		[**]	[**]	[**]	[**]	[**]	[**]
SUCONTRACTS		[**]	[**]	[**]	[**]	[**]	[**]
TOTAL OTHER DIRECT COSTS		[**]	[**]	[**]	[**]	[**]	[**]
SUBTOTAL: OTHER DIRECT AND TOTAL LABOR		[**]	[**]	[**]	[**]	[**]	[**]
EXCLUSION FROM BASE FOR G&A		[**]	[**]	[**]	[**]	[**]	[**]
ADJUSTED BASE FOR G&A		[**]	[**]	[**]	[**]	[**]	[**]
G&A	[**]	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL PROPOSED COST EXCLUDING PROFIT		[**]	[**]	[**]	[**]	[**]	[**]
PROPOSED PROFIT	[**]	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL PROPOSED PRICE		[**]	[**]	[**]	[**]	[**]	[**]

Base Period - Year 1

TOTAL LABOR HOURS			CLIN 0001
DIRECT LABOR COST			[**]
FRINGE BENEFITS	[**]		[**]
			[**]
TOTAL DIRECT LABOR & FRINGE BENEFITS			[**]
DEVELOPMENT OVERHEAD	[**]		[**]
MATERIALS AND SUPPLIES SUBCONTRACTS			[**]
PROFESSIONAL TRAVEL			[**]
EQUIPMENT			[**]
CONSULTANTS			[**]
OTHER DIRECT COSTS			[**]
SUBCONTRACTS			[**]
TOTAL OTHER DIRECT COSTS			[**]
SUBTOTAL: OTHER DIRECT AND TOTAL LABOR			[**]
EXCLUSION FROM BASE FOR G&A			[**]
ADJUSTED BASE FOR G&A			[**]
G&A	[**]		[**]
TOTAL PROPOSED COST EXCLUDING PROFIT	[**]		[**]
PROPOSED PROFIT		[**]	
TOTAL PROPOSED PRICE		[**]	

Base Period - Year 2

TOTAL LABOR HOURS			CLIN 0001
DIRECT LABOR COST			[**]
FRINGE BENEFITS	[**]		[**]
			[**]
TOTAL DIRECT LABOR & FRINGE BENEFITS			[**]
DEVELOPMENT OVERHEAD	[**]		[**]
MATERIALS AND SUPPLIES SUBCONTRACTS			[**]
PROFESSIONAL TRAVEL			[**]
EQUIPMENT			[**]
CONSULTANTS			[**]
OTHER DIRECT COSTS			[**]
SUBCONTRACTS			[**]
TOTAL OTHER DIRECT COSTS			[**]
SUBTOTAL: OTHER DIRECT AND TOTAL LABOR			[**]
EXCLUSION FROM BASE FOR G&A			[**]

ADJUSTED BASE FOR G&A		[**]
G&A	[**]	[**]
TOTAL PROPOSED COST EXCLUDING PROFIT	[**]	[**]
PROPOSED PROFIT		[**]
TOTAL PROPOSED PRICE		[**]

OPTIONAL NON-CLINICAL STUDIES 5.0 COST SUMMARY

			CLIN 0005	CLIN 0006	CLIN 0007	
	BASE PERIOD	**BASE PERIOD 2**	**OPTION YR 1**	**OPTION YR 2**	**OPTION YR 3**	**TOTAL**
TOTAL LABOR HOURS	[**]	[**]	[**]	[**]	[**]	[**]
DIRECT LABOR COST	[**]	[**]	[**]	[**]	[**]	[**]
FRINGE BENEFITS[**]	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL DIRECT LABOR & FRINGE BENEFITS	[**]	[**]	[**]	[**]	[**]	[**]
DEVELOPMENT OVERHEAD[**]	[**]	[**]	[**]	[**]	[**]	[**]
MATERIALS AND SUPPLIES	[**]	[**]	[**]	[**]	[**]	[**]
PROFESSIONAL TRAVEL	[**]	[**]	[**]	[**]	[**]	[**]
EQUIPMENT	[**]	[**]	[**]	[**]	[**]	[**]
CONSULTANTS	[**]	[**]	[**]	[**]	[**]	[**]
OTHER DIRECT COSTS	[**]	[**]	[**]	[**]	[**]	[**]
SUCONTRACTS	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL OTHER DIRECT COSTS	[**]	[**]	[**]	[**]	[**]	[**]
SUBTOTAL: OTHER DIRECT AND TOTAL LABOR	[**]	[**]	[**]	[**]	[**]	[**]
EXCLUSION FROM BASE FOR G&A	[**]	[**]	[**]	[**]	[**]	[**]
ADJUSTED BASE FOR G&A	[**]	[**]	[**]	[**]	[**]	[**]
G&A[**]	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL PROPOSED COST EXCLUDING PROFIT	[**]	[**]	[**]	[**]	[**]	[**]
PROPOSED PROFIT[**]	[**]	[**]	[**]	[**]	[**]	[**]
TOTAL PROPOSED PRICE	[**]	[**]	[**]	[**]	[**]	[**]

Exhibit 10.7

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE N/A — Page 1 of 1

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (*If applicable*)
0007	See Block 16C		N/A

6. ISSUED BY	CODE	7. ADMINISTERED BY (IF OTHER THAN ITEM 6)	CODE
N/A		See Block 6	N/A

U.S. DEPT. OF HEALTH & HUMAN SERVICES
OS/ASPR/BARDA
330 INDEPENDENCE AVE SW, ROOM G640
WASHINGTON, D.C. 20201

8. NAME AND ADDRESS OF CONTRACTOR (*No., Street, County, State, and ZIP Code*)

EMERGENT BIODEFENSE OPERATIONS LANSING INC 330303
EMERGENT BIODEFENSE OPERATIONS LANS
3500 N MARTIN LUTHER KING JR BLVD # MI
LANSING 489062933

Tax ID Number: 38-3412788
DUNS Number: 026489018

☐ 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

☒ 10A. MODIFICATION OF CONTRACT/ORDER NO.
HHSO100200700037C

CODE N/A — FACILITY CODE N/A

10B. DATED (*SEE ITEM 13*) 9/25/2007

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:

(a) By completing Items 8 and 15, and returning ____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If Required*)
n/a

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify Authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103 (b).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

☒ D. OTHER (*Specify type of modification and authority*)
FAR 1.602-1 Authority and Mutual Agreement of the Parties

E. IMPORTANT: Contractor ☐ is NOT ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The purpose of this modification is to 1) extend the period of performance of this Contract, as noted in section F.1. of the Contract, at no additional cost from September 24, 2010 to December 31, 2010; 2) extend the delivery dates for CLIN's 0008, 0009, 0010, 0011, and 0012, as noted in section B.4 of the Contract, to December 31, 2010, and 3) extend the dates for contract deliverables for associated Milestones, as noted in section F.3. of the Contract, to December 31, 2010.

All other items and conditions remain unchanged by reason of this modification.

Period of Performance: 09/25/2007 to 12/31/2010

15A. NAME AND TITLE OF SIGNER	16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)
Daniel J. Abdun-Nabi,	Darrick A. Early, Contracting Officer

EXHIBIT 10.8

Amendment No. 5 to
Product Supply Agreement

This Amendment No. 5 ("***Amendment***"), effective as of August 31, 2010 (the "***Effective Date***"), is entered into by and between **Talecris Biotherapeutics, Inc.** ("***Talecris***"), with a business address of 79 T.W. Alexander Drive, 4101 Research Commons, P.O. Box 110526, Research Triangle Park, North Carolina 27709, and **Emergent Product Development Gaithersburg Inc.** ("***Emergent***"), with a business address of 300 Professional Drive, Gaithersburg, Maryland 20879. For the purposes of this Amendment, Emergent and Talecris shall each be deemed a "***Party***" and together the "***Parties***".

WHEREAS, the Parties entered into that certain Product Supply Agreement, dated June 12, 2006 (as subsequently amended and extended by the Parties, the "***Original Agreement***"); and

WHEREAS, the Parties desire to extend the Pre-Commercial Term of the Original Agreement, and to revise certain other terms and conditions;

NOW THEREFORE, for good and valuable consideration, including the promises set forth herein, the Parties agree as follows:

1) Recitals; Capitalized Terms; Controlling Effect. The foregoing recitals are deemed to be true and accurate in all respects and are hereby incorporated into this Amendment by reference. Capitalized terms used herein shall have the same meanings ascribed to them in the Original Agreement unless otherwise expressly defined herein. In the event of any conflict between the terms of the Original Agreement and the terms of this Amendment, the terms of this Amendment shall govern and control. The Original Agreement and this Amendment are collectively referred to hereinafter as the "**Agreement**".

2) Amendments to Original Agreement.

   a) Extension of Pre-Commercial Term: The Pre-Commercial Term is hereby extended until July 31, 2011. Accordingly, all instances of "August 31, 2010" are hereby replaced with "July 31, 2011."

   b) Negotiation: In the event Emergent requests Talecris to produce Pre-Commercial Product or Commercial Product, and notwithstanding the terms of the Agreement, the Parties shall negotiate in good faith regarding all aspects of such production; including without limitation, timing, price, quantity, and all necessary support.

   c) Talecris Reservation: Notwithstanding anything contained in the Agreement (including Sections 2(a) and 2(b) of this Amendment), in the event Emergent requests Talecris to produce Pre-Commercial Product or Commercial Product, Talecris reserves the absolute and exclusive right to delay or refuse such request without penalty or adverse consequences to Talecris.

3) Incorporation of Prior Agreements. The Agreement contains the entire understanding of the Parties hereto with respect to the subject matter hereof, and no prior or other written or oral agreement or undertaking pertaining to any such matter shall be effective for any purpose.

4) Governing Law. This Amendment, and any and all matters arising directly or indirectly herefrom shall be governed by and construed and enforced in accordance with the laws of the United States and the internal laws of the state of New York, without regard to conflict of law principles.

5) Interpretation; Full Force and Effect; Counterparts. The Amendment shall be construed reasonably to carry out its intent without presumption against or in favor of either Party. The Original Agreement shall remain in full force and effect in accordance with its original terms and provisions, except as expressly modified by the terms of this Amendment. This Amendment may be executed by the Parties hereto in one or more counterparts, all of which shall be valid and binding on the party or parties executing them and all counterparts shall constitute one and the same document for all purposes. Each Party represents and warrants that this Amendment has been duly authorized, executed and delivered by or on behalf of such Party.

IN WITNESS WHEREOF, Emergent and Talecris have entered into this Amendment as of the Effective Date.

Emergent Product Development Gaithersburg Inc.
By: /s/Kyle Keese
Name: Kyle W. Keese
Title: SVP Mfg Operations
Date: 2 Nov 10

Talecris Biotherapeutics, Inc.
By: /s/Craig Farquharson
Name: Craig Farquharson
Title: Sr. Director Global Supply Chain
Date: 11/03/2010

Exhibit 31.1

CERTIFICATION

I, Fuad El-Hibri certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Emergent BioSolutions Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to he designed tinder our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information, and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date:November 4, 2010

/s/Fuad El-Hibri
Fuad El-Hibri
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 he designed tinder our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information, and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date:November 4, 2010

/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 and nine months ended September 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Fuad El-Hibri, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

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

Date: November 4, 2010

/s/ Fuad El-Hibri
Fuad El-Hibri
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 and nine months ended September 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, R. Don Elsey, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

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

Date: November 4, 2010

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