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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2007

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. [X] Yes o No

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

o Large Accelerated Filer o Accelerated Filer x Non-Accelerated Filer

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

As of October 26, 2007, the registrant had 29,750,237 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 obtain new contracts with the U.S. government for sales of BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, and our performance under those contracts, including the timing of deliveries;
- our plans for future sales of BioThrax;
- our plans to pursue label expansions and improvements for BioThrax;
- our plans to expand our manufacturing facilities and capabilities;
- the rate and degree of market acceptance and clinical utility of our products;
- our ongoing and planned development programs, preclinical studies and clinical trials;
- our ability to identify and acquire or in-license products and product candidates that satisfy our selection criteria;
- the potential benefits of our existing collaboration agreements and our ability to enter into selective additional collaboration arrangements;
- 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; 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 and filed as exhibits hereto, completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume 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, 2007	December 31, 2006
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,266	$ 76,418
Accounts receivable	42,013	43,331
Inventories	25,623	24,721
Income taxes receivable	12,986	869
Deferred tax assets	-	295
Prepaid expenses and other current assets	2,475	1,703
Total current assets	107,363	147,337
Property, plant and equipment, net	103,479	78,174
Deferred tax assets, net of current	9,305	11,477
Restricted cash	5,192	192
Other assets	1,412	1,075
Total assets	$ 226,751	$ 238,255
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 19,383	$ 27,366
Accrued expenses and other current liabilities	4,055	3,253
Accrued compensation	7,616	7,190
Indebtedness under lines of credit	-	8,930
Long-term indebtedness, current portion	3,485	2,473
Income taxes payable	-	13,703
Deferred tax liability	243	-
Deferred revenue, current portion	729	1,432
Total current liabilities	35,511	64,347
Long-term indebtedness, net of current portion	43,488	31,368
Deferred revenue, net of current portion	2,685	2,997
Other liabilities	1,574	1,071
Total liabilities	83,258	99,783
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred Stock $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2007 and December 31, 2006	-	-
Common Stock, $0.001 par value; 100,000,000 shares authorized, 29,750,237 and 27,596,249 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively	30	28
Additional paid-in capital	101,992	90,920
Accumulated other comprehensive loss	(1,117)	(473)
Retained earnings	42,588	47,997
Total stockholders' equity	143,493	138,472
Total liabilities and stockholders' equity	$ 226,751	$ 238,255

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,	
	2007	2006	2007	2006
	(Unaudited)		(Unaudited)	
Revenues:				
Product sales	$ 41,786	$ 40,855	$ 89,750	$ 61,263
Contracts and grants	1,858	1,319	3,528	4,580
Total revenues	43,644	42,174	93,278	65,843
Operating expense:				
Cost of product sales	11,407	7,275	22,765	11,645
Research and development	12,777	13,544	41,689	29,240
Purchased in-process research and development	-	477	-	477
Selling, general and administrative	15,038	11,157	38,889	30,352
Income (loss) from operations	4,422	9,721	(10,065)	(5,871)
Other income (expense):				
Interest income	472	79	1,945	405
Interest expense	(7)	(546)	(54)	(778)
Other income (expense), net	(14)	167	164	291
Total other income (expense)	451	(300)	2,055	(82)
Income (loss) before provision for (benefit from) income taxes	4,873	9,421	(8,010)	(5,953)
Provision for (benefit from) income taxes	2,028	5,067	(3,205)	(2,617)
Net income (loss)	$ 2,845	$ 4,354	$ (4,805)	$ (3,336)
Earnings (loss) per share - basic	$ 0.10	$ 0.19	$ (0.17)	$ (0.15)
Earnings (loss) per share - diluted	$ 0.10	$ 0.18	$ (0.17)	$ (0.15)
Weighted-average number of shares - basic	29,739,797	22,389,620	28,741,380	22,370,191
Weighted-average number of shares - diluted	29,900,571	23,704,751	28,741,380	22,370,191

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,	
	2007	**2006**
	(Unaudited)	
Cash flows from operating activities:		
Net loss	$ (4,805)	$ (3,336)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation expense	1,895	442
Depreciation and amortization	3,597	3,265
Deferred income taxes	9,418	933
Excess tax benefits from stock-based compensation	(6,708)	-
Loss on disposal of property and equipment	-	82
Purchased in-process research and development	-	477
Changes in operating assets and liabilities:		
Accounts receivable	1,318	(744)
Inventories	(901)	(11,627)
Income taxes	(25,820)	(4,913)
Prepaid expenses and other assets	(1,109)	(3,653)
Accounts payable	(688)	(475)
Accrued expenses and other liabilities	697	1,442
Accrued compensation	426	(1,279)
Deferred revenue	(1,015)	4,639
Net cash used in operating activities	(23,695)	(14,747)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(36,197)	(25,712)
Acquisitions, net of cash received	-	(218)
Restricted cash deposits	(5,000)	(190)
Net cash used in investing activities	(41,197)	(26,120)
Cash flows from financing activities:		
Proceeds from borrowings on long term indebtedness and lines of credit	15,333	35,853
Issuance of common stock subject to exercise of stock options	2,474	43
Redemption of Class B common stock	-	(221)
Principal payments on long term indebtedness, notes payable to employees, and lines of credit	(11,131)	(11,290)
Excess tax benefits from stock-based compensation	6,708	-
Net cash provided by financing activities	13,384	24,385
Effect of exchange rate changes on cash and cash equivalents	(644)	94
Net decrease in cash and cash equivalents	(52,152)	(16,388)
Cash and cash equivalents at beginning of period	76,418	36,294
Cash and cash equivalents at end of period	24,266	19,906
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 2,217	$ 665
Cash paid during the period for income taxes	$ 14,329	$ 1,470
Supplemental information on non-cash investing and financing activities:		
Purchases of property, plant and equipment unpaid at period end	$ 7,295	$ 6,621

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

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 subsidiaries. All significant inter-company accounts and transactions have been eliminated in consolidation.

The unaudited consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2006, as filed with the Securities and Exchange Commission.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of September 30, 2007, results of operations for the three and nine month periods ended September 30, 2007 and 2006, and cash flows for the nine month periods ended September 30, 2007 and 2006. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Significant customers and accounts receivable

The Company's primary customers are the U.S. Department of Defense (the "DoD") and the U.S. Department of Health and Human Services ("HHS"). For the three months ended September 30, 2007 and 2006, sales of BioThrax to the DoD and HHS comprised 96% and 97% of total revenues, respectively. For the nine months ended September 30, 2007 and 2006, sales of BioThrax to the DoD and HHS comprised 96% and 92% of total revenues, respectively. As of September 30, 2007, 100% of the Company's accounts receivable balance was comprised of amounts due from these customers. Accounts receivable are stated at invoice amounts and generally consist of amounts due from the DoD and HHS as well as amounts due under reimbursement contracts with other government entities and non-government and philanthropic organizations.

Capitalized interest

The Company capitalizes interest expense in accordance with Statement of Financial Accounting Standards ("SFAS") No. 34, *Capitalization of Interest Cost*, based on the cost of major ongoing capital projects which have not yet been placed in service. For the three months ended September 30, 2007 and 2006, the Company capitalized $890 and $42 of interest, respectively. For the nine months ended September 30, 2007 and 2006, the Company capitalized $2,226 and $149 of interest, respectively.

Earnings per share

Basic net income (loss) per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income (loss) by the weighted average number of shares outstanding for the period. Diluted net income per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock during the period. For the nine months ended September 30, 2007 and 2006, diluted net loss per share is equal to basic net loss per share, as the inclusion of outstanding stock options would be anti-dilutive.

Accounting for stock-based compensation

Effective January 1, 2006, the Company adopted the fair value provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* ("SFAS No. 123(R)"), using the modified prospective method. Under the fair value recognition provisions of SFAS No. 123(R), the Company recognizes stock-based compensation net of an estimated forfeiture rate. Under the modified prospective method, compensation cost recognized in 2007 and 2006 includes: (1) compensation cost for all share-based payments granted prior to but not yet vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and (2) compensation cost for all share-based payments granted and vested subsequent to December 31, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R).

The Company accounts for equity instruments issued to non-employees in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS No. 123"), and Emerging Issues Task Force ("EITF") Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services,* ("EITF No. 96-18").

Based on options granted to employees as of September 30, 2007, total compensation expense not yet recognized related to unvested options is approximately $3,075, after tax. The Company expects to recognize that expense over a weighted average period of 3.0 years.

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 weighted-average 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		Nine Months ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
Expected dividend yield	0%	0%	0%	0%
Expected volatility	50%	50%	50%	50%
Risk-free interest rate	4.01%-4.95%	4.69%	4.01%-5.09%	4.69%-5.21%
Expected average life of options	3.0 years	2.7 years	3.0 years	2.9 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 — Volatility is 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 expected volatility used by similar companies at a similar stage of development to estimate expected volatility. The volatility used by these similar companies ranged from 33% to 79%, with an average estimated volatility of 53%;
- Risk-free interest rate — This is the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date the option was granted; and
- Expected average life of options — This is the period of time that the options granted are expected to remain outstanding. This estimate is based primarily on the employee position profile of option holders and the trading lock out periods that result from employee access to stock price sensitive information.

Prior to the adoption of SFAS No. 123(R), the Company presented all tax benefits of deductions resulting from the exercise of stock options as operating cash flows in the statement of cash flows. SFAS No. 123(R) requires the cash flows resulting from the tax benefits of deductions in excess of the compensation cost recognized for those options (excess tax benefits) to be classified as financing cash flows.

Comprehensive income (loss)

SFAS No. 130, *Reporting Comprehensive Income* ("SFAS No. 130"), requires the presentation of the comprehensive income (loss) and its components as part of the financial statements. Comprehensive income (loss) is comprised of net income (loss) and other changes in equity that are excluded from net income (loss). The Company includes gains and losses on inter-company transactions with foreign subsidiaries that are considered to be long-term investments and translation gains and losses incurred when converting its subsidiaries' financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income (loss). Comprehensive income for the three months ended September 30, 2007 and 2006 was $2,683 and $4,485, respectively. Comprehensive loss for the nine months ended September 30, 2007 and 2006 was $5,449 and $3,242, respectively.

Reclassifications

Certain prior period balances have been reclassified to conform to current period presentation.

Recent accounting pronouncements

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, *Fair Value Measurements* ("SFAS No. 157"). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. The provisions of SFAS No. 157 are effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company is currently evaluating the impact of the adoption of this statement on its financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115* ("SFAS No. 159"). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The provisions of SFAS No. 159 are effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of adoption of this statement on its financial statements.

In June 2007, the FASB issued EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ("EITF No. 07-3"). EITF No. 07-3 states that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. The provisions of EITF No. 07-3 are effective for fiscal years beginning after December 15, 2007. The Company is currently evaluating the impact of adoption of this statement on its financial statements.

2. Acquisitions

ViVacs GmbH

On July 14, 2006, the Company completed the acquisition of ViVacs GmbH, a German limited liability company (ViVacs), to expand the Company's commercial vaccine portfolio, pursuant to the terms and conditions of the Share Purchase and Assignment Agreement dated July 14, 2006 by and between the Company and ViVacs. The Company paid $150 in cash on the closing date of the agreement and agreed to pay $50 on each of the first and second anniversaries of the closing date. The acquisition agreement also provided for a potential variable earn-out purchase price of up to $220, based on future payments from third party licensees of the technology. As of September 30, 2007, the Company has not received any such payments from third party licensees. Because ViVacs was a development stage company and had not commenced its planned principal operations, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded.

Total purchase consideration consisted of:

Cash (including future guaranteed cash payments of $100)	$	250
Direct acquisition costs		180
Total purchase consideration	$	430

The assets acquired were accounted for in accordance with the provisions of SFAS No. 141, *Business Combinations* (SFAS No. 141). All of the tangible and intangible assets acquired and liabilities assumed of ViVacs were recorded at their estimated fair market values on the acquisition date.

The purchase price was allocated as follows:

Current assets	$ 153
Property and equipment	97
Current liabilities	(297)
Net liabilities acquired	(47)
In-process research and development	477
Total purchase consideration	$ 430

In connection with the transaction, the Company recorded a charge of $477 for acquired research projects associated with product candidates in development for which, at the acquisition date, technological feasibility had not been established and, for accounting purposes, no alternative future use existed.

3. Inventories

Inventories consist of the following:

	September 30, 2007	December 31, 2006
Raw materials and supplies	$ 2,372	$ 2,133
Work-in-process	17,420	22,239
Finished goods	5,831	349
Total inventories	$ 25,623	$ 24,721

4. Property, plant and equipment

Property, plant and equipment consist of the following:

	September 30, 2007	December 31, 2006
Land and improvements	$ 4,922	$ 4,922
Buildings and leasehold improvements	25,924	25,325
Furniture and equipment	18,587	15,401
Software	4,703	4,499
Construction-in-progress	66,269	41,563
	120,405	91,710
Less: Accumulated depreciation and amortization	(16,926)	(13,536)
Total property, plant and equipment, net	$ 103,479	$ 78,174

5. Stockholders' equity

Preferred stock

The Company is authorized to issue up to 15,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock"). Any Preferred Stock issued may have dividend rates, voting rights, conversion privileges, redemption characteristics, and sinking fund requirements as approved by the Company's Board of Directors. As of September 30, 2007, no Preferred Stock has been issued.

Common stock

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

On September 20, 2006, the Company's Board of Directors recommended to the stockholders of the Company an amendment of the Company's amended and restated certificate of incorporation, which the stockholders approved on October 27, 2006, that, among other things, reclassified the Company's previously outstanding class A common stock, $0.01 par value per share, as Common Stock, increased the number of authorized shares of Common Stock to 100,000,000 shares and adjusted the par value of the Preferred Stock from $0.01 par value per share to $0.001 par value per share. The amendment became effective on October 27, 2006.

On September 20, 2006, the Company's Board of Directors also authorized the pricing committee of the Board of Directors to effect a stock split of the Common Stock, in the form of a dividend of shares of Common Stock, and the Company's previously outstanding class B common stock, $0.01 par value per share ("Class B Common Stock"), in the form of a dividend of shares of Class B Common Stock. The pricing committee subsequently declared a 2.8771-for-one stock split of Common Stock and Class B Common Stock effective as of October 27, 2006.

Each share of Class B Common Stock automatically converted into one share of Common Stock immediately prior to the closing of the Company's initial public offering on November 20, 2006. The par values, the number of authorized shares and all share and per share amounts in the consolidated financial statements have been retroactively adjusted to give effect to the filing of the certificate of amendment of the Company's amended and restated certificate of incorporation, the stock split and the conversion of the Class B Common Stock into Common Stock.

Stock options

As of September 30, 2007, the Company has two stock-based employee compensation plans, the Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan") and the Emergent BioSolutions Employee Stock Option Plan (the "2004 Plan") (together, the "Emergent Plans"), under which the Company has granted options to purchase shares of Common Stock. The Emergent Plans have both incentive and non-qualified stock option features.

The 2006 Plan initially authorized the issuance of up to 1,089,461 shares of Common Stock. In addition, the 2006 Plan contains an "evergreen provision" that allows for increases in the number of shares authorized for issuance under the 2006 Plan in the first and third quarter of each year from 2007 through 2009. Each semi-annual increase in the number of shares will be equal to the lowest of: (1) a specified number of shares stipulated in the 2006 Plan; (2) a specified percentage of the aggregate number of shares outstanding; and (3) an amount determined by the Company's Board of Directors. The maximum specified number of shares per semi-annual increases range from 428,700 to 937,900. The maximum specified percentage of outstanding shares for each semi-annual increase ranges from 1.5% to 3.0%. Accordingly, an aggregate of 1,949,362 shares of Common Stock are authorized for issuance under the 2006 Plan as of September 30, 2007. The Company has granted options to purchase a total of 1,315,161 shares of Common Stock under the 2006 Plan as of September 30, 2007. The maximum number of options that may be granted per year under the 2006 Plan to a single participant is 287,700. The exercise price of each incentive option must be not less than 100% of the fair market value of the shares on the date of grant. Options granted under the 2006 Plan have a vesting period of no more than 5 years and a contractual life of no more than 10 years. Following the closing of the Company's initial public offering, the Company no longer grants options pursuant to the 2004 Plan.

The following is a summary of stock option activity:

	2004 Plan		2006 Plan		
	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2006	2,936,389	$ 2.53	1,030,500	$ 10.13	
Granted	-	-	466,561	10.22	
Exercised	(2,153,988)	1.15	-	-	
Forfeited	(57,923)	5.77	(181,900)	10.48	
Cancelled	(5,214)	1.49	-	-	
Outstanding at September 30, 2007	719,264	$ 6.41	1,315,161	$ 10.11	$ 2,469,682
Exercisable at September 30, 2007	401,828	$ 5.39	-	$ -	$ 1,593,956

The weighted average remaining contractual term of options outstanding as of September 30, 2007 and December 31, 2006 was 5.7 and 3.2 years, respectively. The weighted average remaining contractual term of options exercisable as of September 30, 2007 and December 31, 2006 was 4.5 and 1.1 years, respectively.

The weighted average grant date fair value of options granted during the three and nine months ended September 30, 2007 was $3.41 and $3.90, respectively. The total intrinsic value of options exercised during the three and nine months ended September 30, 2007 was $110 and $20,468, respectively. The total fair value of shares vested during the three and nine months ended September 30, 2007 was $96 and $479, respectively.

Stock-based compensation expense was recorded in the following financial statement line items:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Cost of sales	$ 19	$ -	$ 53	$ -
Research and development	97	21	272	63
General and administrative	619	132	1,570	379
Total share-based compensation expense	$ 735	$ 153	$ 1,895	$ 442

A summary of the activity of the Company's non-vested stock options at September 30, 2007 is presented below:

	2004 Plan		2006 Plan	
	Number of Shares	Weighted-Average Price	Number of Shares	Weighted-Average Price
Non-vested at December 31, 2006	537,532	$ 7.45	1,030,500	$ 10.13
Granted	-	-	466,561	10.22
Exercised	-	-	-	-
Vested	(167,829)	7.68	-	-
Forfeited	(52,267)	5.15	(181,900)	10.48
Non-vested at September 30, 2007	317,436	$ 7.70	1,315,161	$ 10.11

During the three and nine months ended September 30, 2007, the Company received a tax benefit from stock options exercised of approximately $0 and $6,700, respectively.

6. Income taxes

Significant components of the provision for income taxes attributable to operations consist of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Current				
Federal	$ 1,931	$ 3,299	$ (6,025)	$ (3,650)
State	214	-	317	100
Total current	2,145	3,299	(5,708)	(3,550)
Deferred				
Federal	(114)	1,665	2,229	833
State	(3)	103	274	100
Total deferred	(117)	1,768	2,503	933
Total provision for (benefit from) income taxes	$ 2,028	$ 5,067	$ (3,205)	$ (2,617)

The estimated effective annual tax rate for the nine months ended September 30, 2007 and 2006 was 40% and 44%, respectively. The estimated effective tax rate differs from statutory rates due primarily to the impact of foreign and state net operating losses and permanent differences, including incentive stock options.

In September 2006, the FASB issued FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109, Accounting for Income Taxes* ("FIN 48"). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 requires that the Company recognize in its financial statements the impact of a tax position if that position is more likely than not to be sustained on audit based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure.

The Company adopted the provisions of FIN 48 on January 1, 2007. As a result of the implementation of FIN 48, the Company recognized, as a cumulative effect of change in accounting principle, a $607 increase in tax-related liabilities for unrecognized tax benefits and a $607 reduction to beginning retained earnings. The Company recognizes interest in interest expense and recognizes potential penalties related to unrecognized tax benefits in selling, general and administrative expense. The Company accrued approximately $62 for the payment of interest and penalties as of September 30, 2007.

As of January 1, 2007, the Company recorded approximately $607 for unrecognized tax benefits, including accrued interest and penalties, related to prior years. During the three months ended September 30, 2007, the Company recorded a decrease in unrecognized tax benefits, including accrued interest and penalties, of $493. Of this $493, $426 represents a reduction in unrecognized tax benefits as a result of a lapse of the applicable statue of limitations during the quarter ended September 30, 2007, and $7 represents a reduction related to the 2005 federal income tax audit. During the three and nine months ended September 30, 2007, unrecognized tax benefits, including accrued interest and penalties, increased by $219 and $256, respectively. During the nine months ended September 30, 2007, the Company accrued $39 of interest expense related to unrecognized tax benefits of prior years. Substantially all of these reserves would impact the effective tax rate if released into income. Of the total unrecognized tax benefits recorded at September 30, 2007, $139 is classified as a current liability and $231 is classified as a non-current liability on the balance sheet. As of September 30, 2007, $37 of unrecognized tax benefits will reverse within the next twelve months.

The Company's federal and state income tax returns for the tax years 2004, 2005 and 2006 remain open to examination. The Company's tax returns in the United Kingdom remain open to examination for the tax years 2001, 2002, 2003, 2004, 2005 and 2006, and tax returns in Germany remain open indefinitely. A federal income tax audit of the Company's tax return for the 2004 tax year was completed in March 2007. As a result of this audit, the Company paid an assessment of $722, including $96 of interest. The Company is the subject of an ongoing federal income tax audit for the tax year ended December 31, 2005. The financial statement impact of the audit has been estimated at approximately $469, including $49 of interest. This amount has been accrued as of September 30, 2007.

7. Litigation

From time to time, the Company is involved in product liability litigation and other lawsuits that arise in the ordinary course of its business. The Company does not believe that any pending proceedings will have a material, adverse effect on the results of its operations. With respect to claims filed against the Company arising out of the use of BioThrax by the U.S. government, the Company relies on a combination of contractual indemnification provisions, the government contractor defense, statutory protections and product liability insurance to limit its potential liability.

8. Segment information

The Company operates in two business segments: biodefense and commercial. In the biodefense business, the Company develops, manufactures and commercializes immunobiotics, consisting of vaccines and therapeutics, for use against biological agents that are potential weapons of bioterrorism and biowarfare. Revenues in this segment relate to the Company's FDA-approved product, BioThrax. In the commercial business, the Company develops immunobiotics for use against infectious diseases that have resulted in significant unmet or underserved public health needs. Revenues in this segment consist predominantly of milestone payments and development and grant revenues received under collaboration and grant arrangements. The "All Other" segment relates to the general operating costs of the business and includes costs of the centralized services departments that are not allocated to the other segments. The assets in this segment consist primarily of cash and fixed assets.

	Reportable Segments			
	Biodefense	Commercial	All Other	Total
Nine Months Ended September 30, 2007				
External revenue	$ 90,643	$ 2,635	$ -	$ 93,278
Inter-segment revenue (expense)	-	-	-	-
Research and development	20,716	19,411	1,562	41,689
Interest income	-	-	1,945	1,945
Interest expense	-	-	(54)	(54)
Depreciation and amortization	2,599	685	313	3,597
Net income (loss)	26,120	(24,124)	(6,801)	(4,805)
Assets	156,695	19,738	50,318	226,751
Expenditures for long-lived assets	34,081	617	1,499	36,197
Nine Months Ended September 30, 2006				
External revenue	$ 61,260	$ 4,583	$ -	$ 65,843
Inter-segment revenue	-	-	-	-
Research and development	13,980	14,674	586	29,240
Interest income	-	-	405	405
Interest expense	-	-	(778)	(778)
Depreciation and amortization	2,530	559	176	3,265
Net income (loss)	15,920	(14,586)	(4,670)	(3,336)
Assets	74,655	14,761	41,415	130,831
Expenditures for long-lived assets	14,657	1,665	9,390	25,712

The accounting policies of the segments are the same as those described in Note 1 — Summary of significant accounting policies. There are no inter-segment transactions.

9. Related party transactions

The Company has engaged Wilmer Cutler Pickering Hale and Dorr LLP ("WilmerHale") to provide certain legal services to the Company. The Company's Senior Vice President Legal Affairs and General Counsel is married to a partner at WilmerHale, who has not participated in providing legal services to the Company. The Company has incurred fees for legal services rendered by WilmerHale of approximately $760 in 2007. Of this amount, approximately $318 was in accounts payable at September 30, 2007.

For the nine months ended September 30, 2007 and 2006, the Company paid approximately $178 and $383, respectively, for consulting, lease and transportation agreements with various persons or entities affiliated with the Chief Executive Officer or members of the Board of Directors. Of these amounts, $15 and $0 was in accounts payable at September 30, 2007 and 2006, respectively. The Company currently has an agreement with a director to perform corporate strategic issues consultation and direct project support to the marketing and communications group, and an agreement with a company owned by the Chief Executive Officer to provide transportation and logistical support.

10. Indebtedness

On June 8, 2007, the Company entered into a loan agreement with Fifth Third Bank, whereby Fifth Third Bank agreed to extend to the Company a revolving line of credit up to $15,000. Collateral for this loan consists of accounts receivable under supply contracts with the DoD and HHS. The Company can borrow under this line of credit through May 2008, at which time the agreement expires. No borrowings under this revolving line of credit were outstanding as of September 30, 2007.

On June 29, 2007, the Company entered into a loan agreement with HSBC Realty Credit Corporation (USA) ("HSBC"), under which HSBC provided the Company with a term loan of $30,000. This loan replaced a prior loan arrangement with HSBC under which HSBC agreed to loan the Company $15,000, consisting of a $10,000 term loan and a $5,000 revolving line of credit. Under the new loan agreement, the Company is required to maintain a minimum balance of $5,000 in a deposit account pledged to HSBC and to make monthly payments in the amount of $250 in principal plus accrued interest beginning in August 2007, with a residual principal payment due upon maturity in September 2012. Interest on the loan accrues at an annual rate of LIBOR plus 2.75%. Payment of the loan is secured by substantially all of the assets of Emergent BioDefense Operations, other than accounts receivable under BioThrax supply contracts with the DoD and HHS that are pledged as collateral to secure the $15,000 revolving line of credit with Fifth Third Bank.

11. HHS Contract

On September 25, 2007 the Company entered into an agreement with HHS to supply 18.75 million doses of BioThrax for placement into the Strategic National Stockpile (“SNS”). The term of the agreement is from September 25, 2007 through September 24, 2010. The first 5.5 million doses to be delivered under this contract are being sold to HHS at a discounted price, as specified in the contract, due to the limited remaining shelf life for those specific doses. This discounted price will not apply to the remaining 13.25 million doses that will be sold to HHS under the contract. The firm fixed price for the 18.75 million doses, including the discount, is $400,000 in the aggregate. If the Company receives FDA approval of an application to extend the shelf life of BioThrax from three years to four years, HHS has agreed to increase the price per dose for the remaining 13.25 million doses under the agreement. In that event, HHS would make a lump sum payment reflecting a price per dose increase for certain of these doses delivered prior to approval and an increase in the price per dose to be paid for doses delivered following the date of such approval. The aggregate value of such price increase is $34,000. If the Company does not receive FDA approval of four-year expiry dating during the term of the agreement there will be no adjustment in the price per dose, or lump sum payment, under the agreement. Under the agreement, the Company has also 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 approximately $2,200. HHS will be invoiced for each delivery upon acceptance of BioThrax doses delivered into the SNS. The agreement also provides for HHS to pay up to $11,500 in milestone payments in connection with the Company advancing a program to obtain a post-exposure prophylaxis indication for BioThrax. These funds are payable upon achievement of specific program milestones.

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 and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Special Note Regarding Forward-Looking Statements" and the "Risk Factors" section 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

We are a biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics, consisting of vaccines and therapeutics that assist the body's immune system to prevent or treat disease. We operate in two business segments: biodefense and commercial. Our biodefense business focuses on immunobiotics for use against biological agents that are potential weapons of bioterrorism and biowarfare. Our marketed product, BioThrax® (Anthrax Vaccine Adsorbed), or BioThrax, is the only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. Our commercial business focuses on immunobiotics for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. We expect to continue to seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties.

Our biodefense business has generated net income for each of the last three fiscal years. However, in our commercial business, we have not received approval to market any of our product candidates and, to date, have not received any product sales revenues.

Our only sources of revenue in our commercial business are development grant funding and an upfront license fee and additional payments for development work under a collaboration agreement with Sanofi Pasteur. As a result, our commercial business has incurred a net loss for each of the last three fiscal years.

Biodefense

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenues from BioThrax sales to the U.S. Department of Defense, or the DoD, and the U.S. Department of Health and Human Services, or HHS. Our total revenues from BioThrax sales were $127.3 million in 2005, $148.0 million in 2006 and $89.8 million for the nine months ended September 30, 2007. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers and pursuing label expansions and improvements for BioThrax.

In addition to BioThrax, our biodefense product portfolio includes multiple biodefense product candidates. We are developing an anthrax immune globulin candidate, in part with funding from the National Institute of Allergy and Infectious Diseases, or the NIAID, and the BioMedical Advanced Research and Development Authority, or BARDA. We have entered into collaboration agreements with the U.K. Health Protection Agency, or HPA, for the development of a recombinant botulinum vaccine candidate and a botulinum immune globulin candidate. We are actively pursuing additional government sponsored development grants and working with various government agencies to encourage them to conduct studies relating to BioThrax and our other biodefense product candidates.

Commercial

Our commercial product portfolio includes a typhoid vaccine candidate and a hepatitis B therapeutic vaccine candidate, both of which are in Phase II clinical development, a group B streptococcus vaccine candidate in Phase I clinical development and a chlamydia vaccine candidate and a meningitis B vaccine candidate, both of which are in preclinical development.

We plan to encourage government entities and non-government and philanthropic organizations to provide development funding for, or to conduct clinical studies of, one or more of our commercial product candidates. For example, the Wellcome Trust provided funding for the Phase I and Phase II clinical trials of our typhoid vaccine candidate. In addition, the NIAID is conducting and funding the Phase I clinical trial of our group B streptococcus vaccine candidate.

Manufacturing Infrastructure

We operate vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan. To augment our existing manufacturing capabilities, we are constructing a new 50,000 square foot manufacturing facility on our Lansing campus. We expect the facility to cost approximately $75 million when complete, including approximately $55 million for the building and associated capital equipment, with the balance related to validation and qualification activities required for regulatory approval and initiation of manufacturing. We have incurred costs of approximately $58 million for these purposes through September 2007.

We substantially completed construction of this facility in 2006, and are conducting installation, validation and qualification activities required for regulatory approval. This new facility is a large scale manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures. We also own two buildings in Frederick, Maryland that are available to support our future manufacturing requirements. We have incurred costs of approximately $3 million through September 2007 related to initial engineering design and preliminary utility build out of these facilities. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that would be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project. We may elect to lease all or a substantial portion of, or sell, one of these facilities to third parties.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, fair value of stock-based compensation and income taxes. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We recognize revenues from product sales in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition,* or SAB 104. SAB 104 requires recognition of revenues from product sales that require no continuing performance on our part if four basic criteria have been met:

- there is persuasive evidence of an arrangement;
- delivery has occurred or title has passed to our customer based on contract terms;
- the fee is fixed and determinable and no further obligation exists; and
- collectibility is reasonably assured.

We have generated BioThrax sales revenues under U.S. government contracts with the DoD and HHS. Under previous DoD contracts, we invoiced the DoD for progress payments upon reaching contractually specified stages in the manufacture of BioThrax. We recorded as deferred revenue the full amount of each progress payment invoice that we submitted to the DoD.

Title to the product passed to the DoD upon submission of the first invoice. The earnings process was considered complete upon FDA release of the product for sale and distribution. Following FDA release of the product, we segregated the product for later shipment and recognized as period revenue all deferred revenue related to the released product in accordance with the "bill and hold" sale requirements under SAB 104. At that time, we also invoiced the DoD for the final progress payment and recognized the amount of that invoice as period revenue. Under previous contracts with HHS, we invoiced HHS and recognized the related revenues upon delivery of the product to the government carrier, at which time title to the product passed to HHS. Under our current contract with HHS, we invoice HHS and recognize the related revenues upon acceptance by the government at the delivery site, at which time title to the product passes to HHS.

Under the collaboration agreement that we entered into with Sanofi Pasteur in May 2006 for our meningitis B vaccine candidate, we received an upfront license fee and are entitled to additional payments for development work under the collaboration and upon achieving contractually defined development and commercialization milestones. We evaluated the various components of the collaboration in accordance with Emerging Issues Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables,* or EITF No. 00-21, which addresses whether, for revenue recognition purposes, there is one or several units of accounting in an arrangement. We concluded that under EITF No. 00- 21, the upfront license fee, the development work and the milestone payments under our agreement with Sanofi Pasteur should be accounted for as a single unit of accounting.

We recognize amounts received under this agreement over the estimated development period as we perform services. We recorded the amount of the upfront license fee as deferred revenue. We are recognizing this revenue over the estimated development period under the contract, currently estimated at seven years, as adjusted from time to time for any delays or acceleration in the development of the product candidate.

Under the collaboration agreement, we are entitled to payments up to specified levels for development work we perform on behalf of Sanofi Pasteur. We invoice Sanofi Pasteur in advance of each quarter for the estimated work to occur in the upcoming quarter. We record the invoice amount as deferred revenue and as services are completed, recognize the amount of the related deferred revenue as period revenues. Under the collaboration agreement, we also will be entitled to royalty payments on any future net sales of this product candidate.

From time to time, we are awarded reimbursement contracts for services and development grant contracts with government entities and non-government and philanthropic organizations. Under these contracts, we typically are reimbursed for our costs in connection with specific development activities and may also be entitled to additional fees. We record the reimbursement of our costs and any associated fees as contract and grant revenues and the associated costs as research and development expense. We issue invoices under these contracts after we incur the reimbursable costs. We recognize revenue upon invoicing the sponsoring organization.

Inventories

Inventories are stated at the lower of cost or market, with cost being determined using a standard cost method, which approximates average cost. Average cost consists primarily of material, labor and manufacturing overhead expenses and includes the services and products of third party suppliers.

We analyze our inventory levels quarterly and write down in the applicable period inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand. We also write off in the applicable period the costs related to expired inventory. We capitalize the costs associated with the manufacture of BioThrax as inventory from the initiation of the manufacturing process through the completion of manufacturing, labeling and packaging.

Income Taxes

We account for income taxes in accordance with Statement of Financial Accounting Standards, or SFAS No. 109, *Accounting for Income Taxes,* or SFAS No. 109. Under the asset and liability method of SFAS No. 109, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the tax rates and laws that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A net deferred tax asset or liability is reported in the balance sheet. Our deferred tax assets include the unamortized portion of in-process research and development expenses, the anticipated future benefit of the net operating losses that we have incurred and other timing differences between the financial reporting basis of assets and liabilities.

We have historically incurred net operating losses for income tax purposes in some states and in some foreign jurisdictions, primarily the United Kingdom. The amount of the deferred tax assets on our balance sheet reflects our expectations regarding our ability to use our net operating losses to offset future taxable income. The applicable tax rules in particular jurisdictions limit our ability to use net operating losses as a result of ownership changes. In particular, we believe that these rules will significantly limit our ability to use net operating losses generated by Microscience Limited, or Microscience, and Antex Biologics, Inc., or Antex, prior to our acquisition of Microscience in June 2005 and our acquisition of substantially all of the assets of Antex in May 2003.

We review our deferred tax assets on a quarterly basis to assess our ability to realize the benefit from these deferred tax assets. If we determine that it is more likely than not that the amount of our expected future taxable income will not be sufficient to allow us to fully utilize our deferred tax assets, we increase our valuation allowance against deferred tax assets by recording a provision for income taxes on our income statement, which reduces net income, or increases net loss, for that period and reduces our deferred tax assets on our balance sheet. If we determine that the amount of our expected future taxable income will allow us to utilize net operating losses in excess of our net deferred tax assets, we reduce our valuation allowance by recording a benefit from income taxes on our income statement, which increases net income, or reduces net loss, for that period and increases our deferred tax assets on our balance sheet.

We account for uncertainty in income taxes in accordance with Financial Accounting Standards Board, or FASB, Interpretation 48, *Accounting for Uncertainty in Income Taxes — An Interpretation of FASB Statement No. 109, Accounting for Income Taxes,* or FIN 48. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Under FIN 48, the Company recognizes in its financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure.

Stock-based Compensation

We adopted SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS No. 123(R), on January 1, 2006 using the modified prospective method. SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their estimated grant date fair values.

We value our share-based payment transactions using the Black-Scholes valuation model. Under the modified prospective method, we recognize compensation cost in our financial statements for all awards granted after January 1, 2006 and for all awards outstanding as of January 1, 2006 for which the requisite service had not been rendered as of the date of adoption. We measure the amount of compensation cost based on the fair value of the underlying equity award on the date of grant. We recognize compensation cost over the period that an employee provides service in exchange for the award.

The effect of adopting SFAS No. 123(R) on net income (loss) and net income (loss) per share is not necessarily representative of the effects in future years due to, among other things, the vesting period of the stock options and the fair value of additional stock option grants in future years.

Purchased In-process Research and Development

We account for purchased in-process research and development in accordance with Statement of Financial Accounting Standards, or SFAS, No. 2, *Accounting for Research and Development Costs* along with Financial Accounting Standards Board, or FASB, Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method*.

Under these standards, we are required to determine whether the technology relating to a particular research and development project we acquire has an alternative future use. If we determine that the technology has no alternative future use, we expense the value of the research and development project not directly attributed to tangible assets. Otherwise, we capitalize the value of the research and development project not attributable to tangible assets as an intangible asset and conduct an impairment analysis at least annually. In connection with our acquisition of ViVacs, we allocated the value of the purchase consideration to current assets, current liabilities, fixed assets and development programs. Because we determined that the development programs at ViVacs had no future alternative use, we charged the value attributable to the development programs as in-process research and development. The ViVacs acquisition was a cash transaction; therefore no fair value determination was necessary.

Financial Operations Overview

Revenues

Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we have supplied approximately 10 million doses of BioThrax through September 2007 for immunization of military personnel. Our most recent contract with the DoD, as amended in October 2006, provided for the supply of a minimum of approximately 1.5 million doses of BioThrax to the DoD through September 2007. As a result of a further amendment of the DoD contract in June 2007, we completed delivery of all doses to the DoD under this contract prior to June 30, 2007.

On May 7, 2007, the DoD issued a sole source request for proposal, or RFP, for the manufacture, storage and delivery of BioThrax. On July 3, 2007, we submitted a response to this RFP. In October 2007, a White House Presidential Directive was issued that outlines the U.S. government's objective to enhance coordination and cooperation among federal agencies with respect to countermeasure procurement and stockpile management. Also in October 2007, the General Accounting Office of the federal government, or GAO, issued a report that was critical of HHS for lacking an effective strategy to minimize waste in the SNS, citing concerns of large amounts of BioThrax that will become unusable each year due to shelf-life expiration.

It is not clear at this time what effect the Presidential Directive and the GAO report will have on a potential agreement with the DoD. We believe that the operational requirements set forth by the DoD in the May 2007 RFP have not changed and that the DoD has a continued commitment to procure BioThrax, either directly or indirectly, for its active immunization program. However, at this time we anticipate that the procurement process related to doses procured by or for the DoD will take longer than previously expected, and may not be concluded before the end of 2007. As the negotiating process is complex and involves a number of factors, it is possible that we may not be able to reach an agreement with DoD.

Between May 2005 and February 2007, we supplied 10.0 million doses of BioThrax to HHS for inclusion in the strategic national stockpile, or SNS, under a base contract for 5.0 million doses for a fixed price of $123 million and a modification for an additional 5.0 million doses for a fixed price of $120 million. We completed delivery of all doses to HHS under this contract in February 2007.

On September 25, 2007, we entered into an agreement with HHS to supply 18.75 million doses of BioThrax to HHS for placement into the SNS. The term of the agreement is from September 25, 2007 through September 24, 2010. The first 5.5 million doses to be delivered under this contract are being sold to HHS at a discounted price, as specified in the contract, due to the limited remaining shelf life for those specific doses. This discounted price will not apply to the remaining 13.25 million doses that will be sold to HHS under the contract. The firm fixed price for the 18.75 million doses, including the discount, is $400 million in the aggregate. If we receive FDA approval of our pending application to extend the shelf life of BioThrax from three years to four years, HHS has agreed to increase the price per dose under the agreement for the remaining 13.25 million doses. In that event, HHS would make a lump sum payment to us reflecting a price per dose increase for certain of these doses delivered prior to approval and an increase in the price per dose to be paid for doses delivered following the date of such approval. The aggregate value of such price adjustment is $34 million. If we do not receive FDA approval of four-year expiry dating during the term of the agreement there will be no adjustment in the price per dose under the agreement. We delivered 2.4 million doses of BioThrax to HHS under this contract in September 2007. Under the current HHS contract, we have also 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 approximately $2.2 million. HHS will be invoiced for each delivery upon acceptance of BioThrax doses delivered into the SNS. The agreement also provides for HHS to pay up to $11.5 million in milestone payments in connection with us advancing a program to obtain a post-exposure prophylaxis indication for BioThrax. These funds are payable upon achievement of specific program milestones. In October 2007, we achieved the initial milestone and invoiced HHS for $8.8 million.

In May 2006, we entered into a collaboration agreement with Sanofi Pasteur relating to the development and commercialization of our meningitis B vaccine candidate under which we granted Sanofi Pasteur an exclusive, worldwide license under our proprietary technology to develop and commercialize our meningitis B vaccine candidate and received a $3.8 million upfront license fee. This agreement also provides for a series of milestone payments upon the achievement of specified development and commercialization objectives, payments for development work under the collaboration and royalties on net sales of this product. We deferred the upfront license fee, milestone payments and development reimbursement payments under this agreement, and record revenue in accordance with our revenue recognition policies. We are currently in negotiations with Sanofi Pasteur to amend this agreement.

In September 2007, we received a development contract from NIAID and BARDA, valued at up to $9.5 million, in support of non-clinical and clinical studies of our anthrax immune globulin product candidate. Under terms of the development award, the funds will be used to conduct various studies on this candidate, including non-clinical studies in support of efficacy; and a Phase I/II clinical study to evaluate pharmacokinetics and safety. To date, we have not yet invoiced under this contract.

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 attributable 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 for the specific earlier period in which the doses sold 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;
- costs of contract manufacturing services;
- 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 cost of facilities and the legal costs of pursuing patent protection of our intellectual property.

The successful development of our product candidates is highly uncertain. 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 cannot reasonably estimate or know the nature, timing and projected costs of the efforts that will be necessary to complete the remainder of the development for our product candidates, or the period, if any, in which material net cash inflows may commence from any of our product candidates. This is due to the numerous risks and uncertainties associated with developing biological products, including the uncertainty of:

- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- our ability to obtain adequate supplies of our product candidates required for later stage clinical trials, including from third party manufacturers;
- the potential benefits of our product candidates over other products;
- our ability to market, commercialize and achieve market acceptance for any of our product candidates that we are developing or may develop in the future;
- future clinical trial results;
- the terms and timing of regulatory approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. We expect to continue to incur significant development spending for all of our biodefense product candidates as our product development activities continue and we prepare for regulatory submissions and other regulatory activities. We expect our development expenses in our commercial business to increase in connection with our ongoing activities, particularly as we conduct additional and later stage clinical trials for our product candidates.

We expect that the magnitude of our research and development spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, the size, structure and duration of any follow-on clinical program that we may initiate, costs associated with manufacturing our product candidates on a large scale basis for later stage clinical trials, our ability to use data generated by government agencies, such as the ongoing studies by the Centers for Disease Control and Prevention, or the CDC, with BioThrax, and our ability to rely upon and utilize clinical and non-clinical data, such as the data generated by the CDC from use of the pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan.

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 DoD and HHS 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 principally of interest income and interest expense. We earn interest on our cash, cash equivalents and short-term investments, and we incur interest expense on our indebtedness. We capitalize interest expense in accordance with SFAS No. 34, *Capitalization of Interest Cost*, based on the cost of major ongoing projects which have not yet been placed in service, such as our new manufacturing facility. Our total interest cost will increase in future periods as compared to prior periods as a result of the term loan that we entered into in June 2007, as well as any borrowings under our revolving line of credit. In addition, some of our existing debt arrangements provide for increasing amortization of principal payments in future periods.

Results of Operations

Quarter Ended September 30, 2007 Compared to Quarter Ended September 30, 2006

Revenues

Product sales revenues in our biodefense segment increased by $931,000, or 2%, to $41.8 million for the three months ended September 30, 2007 from $40.9 million for the three months ended September 30, 2006. This increase in product sales revenues was primarily due to a 43% increase in the number of doses of BioThrax delivered, offset by a 29% decrease in the average sales price per dose attributable to a discounted price provided to HHS due to the limited remaining shelf life for those specific doses delivered. This discount will apply to some portion of the doses remaining to be sold and delivered to HHS during 2007. We do not expect this discount to apply to any other doses to be sold and delivered to HHS under the contract.

Product sales revenues for the three months ended September 30, 2007 consisted of BioThrax sales to the HHS of $41.8 million. Product sales revenues for the three months ended September 30, 2006 consisted of BioThrax sales to HHS of $17.5 million and sales to the DoD of $23.4 million.

Contracts and grant revenues increased by $539,000, or 41%, to $1.9 million for the three months ended September 30, 2007 from $1.3 million for the three months ended September 30, 2006. Contracts and grant revenues for the three months ended September 30, 2007 consisted of $545,000 from the Sanofi Pasteur collaboration related to recognition of deferred revenue associated with the upfront payment received in 2006 as well as development service revenue, grant revenue from NIH of $893,000 and grant revenue from the Wellcome Trust of $423,000. Contracts and grants revenues for the three months ended September 30, 2006 consisted of $1.3 million from the Sanofi Pasteur collaboration related to the recognition of deferred revenue associated with the upfront payment received in 2006 and development service revenue.

Cost of Product Sales

Cost of product sales increased by $4.1 million, or 57%, to $11.4 million for the three months ended September 30, 2007 from $7.3 million for the three months ended September 30, 2006. This increase was primarily attributable to a 43% increase in the number of doses delivered, coupled with increased costs associated with our annual production shut-down, the related impact on production yield and the write-off of waste during the period.

Research and Development Expense

Research and development expenses decreased by $768,000, or 6%, to $12.8 million for the three months ended September 30, 2007 from $13.5 million for the three months ended September 30, 2006. This decrease reflects decreased expenses of $2.4 million in the biodefense segment, partially offset by increased expenses of $1.5 million in the commercial segment and $186,000 for other research and development expense. The decrease in biodefense spending, detailed in the table below, was attributable to the timing of completion of various studies and commencement of subsequent studies and trials, as well as timing of plasma collection related to our anthrax immune globulin product candidate.

The spending for BioThrax enhancements is related to conducting animal efficacy studies to support applications for regulatory approval of these enhancements, which we expect to submit to the FDA in late 2008 or 2009. The spending for our immune globulin candidate development programs are related primarily to costs associated with the plasma collection and fractionation program for our anthrax immune globulin. The spending for the recombinant botulinum vaccine program resulted from advancing this program to the process development stage.

The spending for the next generation anthrax vaccine program resulted from feasibility studies and formulation development of product candidates. We continue to assess, and may alter, our future development plans for our products based on the interest of the U.S. government or other non-governmental organizations in providing funding for further development or procurement.

The increase in commercial spending, detailed in the table below, primarily reflects additional personnel and contract service costs. The spending in 2007 for our typhoid vaccine candidate resulted from the recently completed Phase II study in Vietnam. The spending in 2006 for typhoid resulted from ongoing work to prepare for the Phase II clinical trial in Vietnam, which we completed in the second quarter of 2006. The spending in 2007 for our hepatitis B therapeutic vaccine candidate resulted from conducting our Phase II clinical trial which commenced in the first quarter 2007. The spending in 2007 for our group B streptococcus vaccine candidate resulted from costs associated with preparation for Phase I clinical trials for two of the protein components of the vaccine candidate, which the NIAID is conducting and funding. Both our chlamydia vaccine and meningitis B vaccine candidates are in preclinical development.

The increase in other research and development expenses was primarily attributable to spending associated with product development programs that we acquired from ViVacs GmbH, or ViVacs, in July 2006. Our principal research and development expenses for the three months ended September 30, 2007 and 2006 are shown in the following table:

(in thousands)	Three Months Ended September 30, 2007	2006
	(unaudited)	
Biodefense:		
BioThrax enhancements	$ 995	$ 2,068
Immune globulin	2,183	3,832
Recombinant bivalent botulinum vaccine	514	567
Next generation anthrax vaccine	702	338
Total biodefense	4,394	6,805
Commercial:		
Typhoid vaccine	3,099	3,146
Hepatitis B therapeutic vaccine	1,520	914
Group B streptococcus vaccine	1,969	965
Chlamydia vaccine	910	670
Meningitis B vaccine	361	705
Total commercial	7,859	6,400
Other	524	339
Total	$ 12,777	$ 13,544

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $3.9 million, or 35%, to $15.0 million for the three months ended September 30, 2007 from $11.2 million for the three months ended September 30, 2006. The increase was primarily attributable to an increase in general and administrative expenses of approximately $2.2 million resulting from the addition of personnel related to our transition to a publicly traded company and increased legal and other professional services for our headquarters organization. Selling, general and administrative expenses related to our biodefense segment increased by $2.7 million, or 31%, to $11.5 million for the three months ended September 30, 2007 from $8.8 million for the three months ended September 30, 2006. Selling, general and administrative expenses related to our commercial segment increased by $1.2 million, or 51%, to $3.5 million for the three months ended September 30, 2007 from $2.3 million for the three months ended September 30, 2006.

Purchased In-process Research and Development

In July 2006, we recorded a non-cash charge for purchased in-process research and development of $477,000 associated with our acquisition of ViVacs. We paid total purchase consideration of $250,000 and assumed a net deficit of liabilities in excess of assets of $47,000. We valued the acquisition at $430,000 after the inclusion of acquisition costs. Of this amount, we identified $153,000 as current assets, $97,000 as fixed assets, $297,000 as current liabilities and $477,000 as the value attributable to development programs and technology. Because we determined that the development programs and technology had no future alternative use, we charged the value attributable to the development programs and technology as purchased in-process research and development. We are amortizing this charge for tax purposes over 15 years.

Total Other Income (Expense)

Total other income (expense) increased by $751,000 to $451,000 in net other income for the three months ended September 30, 2007 from $300,000 in net other expense for the three months ended September 30, 2006. This increase resulted primarily from an increase in interest income of $393,000 as a result of higher investment return on increased average cash balances, including the net proceeds of our initial public offering, a decrease in interest expense of $539,000 related primarily to the capitalization of interest based on the cost of major ongoing capital projects which have not yet been placed in service, and a decrease in other income (expense), net of $181,000.

Income Taxes

Provision for income taxes decreased by $3.0 million, or 60%, to $2.0 million for the three months ended September 30, 2007 from $5.1 million for the three months ended September 30, 2006. Our effective tax rate was 42% for the three months ended September 30, 2007 and 54% for the three months ended September 30, 2006. The effective estimated annual tax rate differs from statutory rates due primarily to the impact of foreign and state net operating losses and permanent differences, including incentive stock options. The benefit from income taxes also reflects research and development tax credits of $120,000 for the three months ended September 30, 2007 and $0 for the three months ended September 30, 2006.

Nine Months Ended September 30, 2007 Compared to Nine Months Ended September 30, 2006

Revenues

Product sales revenues in our biodefense segment increased by $28.5 million, or 46%, to $89.8 million for the nine months ended September 30, 2007 from $61.3 million for the nine months ended September 30, 2006. This increase in product sales revenues was primarily due to a 76% increase in the number of doses of BioThrax delivered, offset by a 17% decrease in the average sales price per dose attributable to a discounted price provided to HHS due to the limited remaining shelf life for those specific doses delivered. This discount will apply to some portion of the doses remaining to be sold and delivered to HHS during 2007. We do not expect this discount to apply to any other doses to be sold and delivered to HHS under the contract.

Product sales revenues for the nine months ended September 30, 2007 consisted of BioThrax sales to HHS of $63.5 million and sales to the DoD of $26.2 million. Product sales revenues for the nine months ended September 30, 2006 consisted of BioThrax sales to HHS of $35.4 million, sales to the DoD of $25.3 million and aggregate international and other sales of $630,000.

Contracts and grant revenues decreased by $1.1 million to $3.5 million for the nine months ended September 30, 2007 from $4.6 million for the nine months ended September 30, 2006. Contracts and grant revenues for the nine months ended September 30, 2007 consisted of $2.2 million from the Sanofi Pasteur collaboration, related to recognition of deferred revenue associated with the upfront payment received in 2006 as well as development service revenue, grant revenue from NIH of $893,000 and grant revenue from the Wellcome Trust of $423,000. Contracts and grant revenues for the nine months ended September 30, 2006 consisted of $3.2 million related to the recognition of deferred revenue associated with the upfront payment as well as development service revenues from the Sanofi Pasteur collaboration and $1.5 million in grant revenue from the Wellcome Trust.

Cost of Product Sales

Cost of product sales increased by $11.1 million, or 95%, to $22.8 million for the nine months ended September 30, 2007 from $11.6 million for the nine months ended September 30, 2006. This increase was primarily attributable to a 76% increase in the number of doses delivered, coupled with increased costs associated with our annual production shut-down, the related impact on production yield and the write-off of waste during the period.

Research and Development Expense

Research and development expenses increased by $12.4 million, or 43%, to $41.7 million for the nine months ended September 30, 2007 from $29.2 million for the nine months ended September 30, 2006. This increase reflects increased expenses of $6.7 million in the biodefense segment, $4.7 million in the commercial segment, and approximately $977,000 in other research and development expense.

The increase in biodefense spending, detailed in the table below, was attributable to increased efforts on our biodefense programs as we completed various studies and began subsequent studies and trials. This increase primarily reflects additional personnel and contract service costs. The spending for BioThrax enhancements is related to preparing for and conducting animal efficacy studies to support applications for marketing approval of these enhancements, which we expect to submit to the FDA in late 2008 or 2009. The spending for our immune globulin candidate development programs related primarily to costs associated with the plasma collection and fractionation program for our anthrax immune globulin. The spending for the recombinant botulinum vaccine program resulted from advancing this program to the process development stage and the manufacture of clinical trial material. The spending for the next generation anthrax vaccine program resulted from feasibility studies and formulation development of product candidates. We continue to assess, and may alter, our future development plans for our products based on the interest of the U.S. government or other non-governmental organizations in providing funding for further development or procurement.

The increase in commercial spending, detailed in the table below, primarily reflects additional personnel and contract service costs. The spending in 2007 for our typhoid vaccine candidate resulted from the ongoing Phase II study in Vietnam, which commenced in the first quarter 2007. The spending in 2006 for typhoid resulted from ongoing work for the Phase I clinical trial in Vietnam, which we completed in the second quarter of 2006.

The spending in 2007 for our hepatitis B therapeutic vaccine candidate resulted from preparing for and initiating our Phase II clinical trial, which commenced in the first quarter 2007. The spending in 2007 for our group B streptococcus vaccine candidate resulted from costs associated with preparation for Phase I clinical trials for two of the protein components of the vaccine candidate, which the NIAID is conducting and funding. Both our chlamydia vaccine and meningitis B vaccine candidates are in preclinical development.

The increase in other research and development expenses was primarily attributable to spending associated with preclinical programs that we acquired from ViVacs in July 2006. Our principal research and development expenses for the nine months ended September 30, 2007 and 2006 are shown in the following table:

(in thousands)	Nine Months Ended September 30, 2007	2006
Biodefense:	(unaudited)	
BioThrax enhancements	$ 4,196	$ 4,332
Immune globulin	11,744	7,691
Recombinant bivalent botulinum vaccine	2,928	1,268
Next generation anthrax vaccine	1,848	689
Total biodefense	20,716	13,980
Commercial:		
Typhoid vaccine	7,622	6,389
Hepatitis B therapeutic vaccine	3,988	2,120
Group B streptococcus vaccine	4,549	2,800
Chlamydia vaccine	2,304	1,317
Meningitis B vaccine	948	2,048
Total commercial	19,411	14,674
Other	1,562	586
Total	$ 41,689	$ 29,240

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $8.5 million, or 28%, to $38.9 million for the nine months ended September 30, 2007 from $30.4 million for the nine months ended September 30, 2006. The increase was primarily attributable to an increase in general and administrative expenses of approximately $7.0 million resulting from the addition of personnel related to our transition to a publicly traded company and increased legal and other professional services for our headquarters. Selling, general and administrative expenses related to our biodefense segment increased by $5.5 million, or 22%, to $30.1 million for the nine months ended September 30, 2007 from $24.6 million for the nine months ended September 30, 2006. Selling, general and administrative expenses related to our commercial segment increased by $3.1 million, or 54%, to $8.8 million for the nine months ended September 30, 2007 from $5.7 million for the nine months ended September 30, 2006.

Purchased In-process Research and Development

In July 2006, we recorded a non-cash charge for purchased in-process research and development of $477,000 associated with our acquisition of ViVacs. We paid total purchase consideration of $250,000 and assumed a net deficit of liabilities in excess of assets of $47,000.

We valued the acquisition at $430,000 after the inclusion of acquisition costs. Of this amount, we identified $153,000 as current assets, $97,000 as fixed assets, $297,000 as current liabilities and $477,000 as the value attributable to development programs and technology. Because we determined that the development programs and technology had no future alternative use, we charged the value attributable to the development programs and technology as purchased in-process research and development. We are amortizing this charge for tax purposes over 15 years.

Total Other Income (Expense)

Total other income (expense) increased by $2.1 million to $2.1million in net other income for the nine months ended September 30, 2007 from $82,000 in net other expense for the nine months ended September 30, 2006. This increase resulted primarily from an increase in interest income of $1.5 million as a result of higher investment return on increased average cash balances, including the net proceeds of our initial public offering, a decrease in interest expense of $724,000 related primarily to the capitalization of interest based on the cost of major ongoing capital projects which have not yet been placed in service, and a decrease in other income of $127,000.

Income Taxes

Benefit from income taxes increased by $588,000, or 22%, to $3.2 million for the nine months ended September 30, 2007 from $2.6 million for the nine months ended September 30, 2006. Our effective tax rate was 40% for the nine months ended September 30, 2007 and 44% for the nine months ended September 30, 2006. The effective estimated annual tax rate differs from statutory rates due primarily to the impact of foreign and state net operating losses and permanent differences, including incentive stock options. The benefit from income taxes also reflects research and development tax credits of $635,000 for the nine months ended September 30, 2007 and $0 for the nine months ended September 30, 2006.

Liquidity and Capital Resources

Sources of Liquidity

We require cash to meet our operating expenses and for capital expenditures, acquisitions and principal and interest payments on our debt. We have funded our cash requirements from inception through September 30, 2007 principally with a combination of revenues from BioThrax product sales, debt financings of the facility expansion in Lansing, revenues under our collaboration agreement with Sanofi Pasteur, 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 years in the three year period ended December 31, 2006.

As of September 30, 2007, we had cash and cash equivalents of $24.3 million. On November 20, 2006, we completed our initial public offering, in which we raised $54.2 million, net of issuance costs.

Cash Flows

The following table provides information regarding our cash flows as of September 30, 2007 and 2006:

(in thousands)	Nine Months Ended September 30, 2007	2006
Net cash provided by (used in):		
Operating activities(1)	$ (24,339)	$ (14,653)
Investing activities	(41,197)	(26,120)
Financing activities	13,384	24,385
Total net cash used	$ (52,152)	$ (16,388)

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

Net cash used in operating activities of $24.3 million for the nine months ended September 30, 2007 resulted principally from our net loss of $4.8 million, a decrease in income taxes payable of $13.7 million due to the timing of payment of our 2006 income tax liability and the impact of excess tax benefits related to stock option exercises of $6.7 million.

Net cash used in operating activities of $14.7 million for the nine months ended September 30, 2006 resulted principally from our net loss of $3.3 million, an increase in inventories of $11.6 million, reflecting the value of work in process for BioThrax lots being manufactured or awaiting delivery, and a non-cash benefit from income taxes of $4.9 million, reflecting our net loss before provision for income taxes for the period, offset by increase in deferred revenue of $4.6 million related to amounts billed under our contract with the DoD and deferral of a portion of the upfront license fee from Sanofi Pasteur.

Net cash used in investing activities for the nine months ended September 30, 2007 and 2006 resulted principally from the purchase of property, plant and equipment. Capital expenditures of $36.2 million and $25.7 million for the nine months ended September 30, 2007 and 2006, respectively, relate primarily to construction, installation, validation and qualification activities for our new building in Lansing and, in 2006, the purchase of our second facility in Frederick.

Net cash provided by financing activities of $13.4 million for the nine months ended September 30, 2007 resulted primarily from the additional proceeds from a term loan with HSBC of $15.3 million, $2.5 million in proceeds from the exercise of stock options and $6.7 million related to excess tax benefits from the exercise of stock options, partially offset by $11.1 million of principal payments on long-term indebtedness including the repayment of $8.9 million from our revolving line of credit with Fifth Third Bank.

Net cash provided by financing activities of $24.4 million for the nine months ended September 30, 2006 resulted primarily from proceeds from borrowings from HSBC related to the financing of the purchase of our Frederick facility in May 2006 and the financing of a portion of the costs related to the construction of our new building in Lansing.

Debt Financing

As of September 30, 2007, we had $47.0 million principal of debt outstanding, comprised primarily of the following:

- $2.5 million outstanding under a forgivable loan from the Department of Business and Economic Development of the State of Maryland used to finance eligible costs incurred to purchase the first facility in Frederick;
- $6.8 million outstanding under a mortgage loan from PNC Bank (formerly Mercantile Potomac Bank) used to finance the remaining portion of the purchase price for the first Frederick facility;
- $8.2 million outstanding under a mortgage loan from HSBC Realty Credit Corporation (USA) used to finance the purchase price for the second Frederick facility; and
- $29.5 million outstanding under a term loan from HSBC Realty Credit Corporation (USA) used to finance a portion of the costs of our facility expansion in Lansing, which has been refinanced as described below.

We also have a revolving line of credit for up to $15.0 million with Fifth Third Bank. We can borrow under this line of credit through May 2008.

On June 29, 2007, we entered into a loan agreement with HSBC Realty Credit Corporation (USA) under which HSBC provided us with a term loan of $30 million. This loan replaced our loan arrangement with HSBC under which HSBC had provided a $10 million term loan and a $5 million revolving line of credit. In the third quarter of 2007, we received and recorded $15.3 million in net proceeds related to the new loan agreement. Under the new loan agreement, we are required to make monthly payments in the amount of $250,000 in principal plus accrued interest beginning in August 2007, with a residual principal payment due upon maturity in September 2012. Interest on the loan accrues at an annual rate of LIBOR plus 2.75%. Payment of the loan is secured by substantially all of the assets of Emergent BioDefense Operations, other than accounts receivable under BioThrax supply contracts with the DoD and HHS that are pledged as collateral to secure a $15 million revolving line of credit with Fifth Third Bank. Additionally, under the loan agreement, we are required to either satisfy certain financial covenants or maintain a minimum balance of $5 million in a deposit account pledged to HSBC.

Tax Benefits

In connection with our facility expansion in Lansing, the State of Michigan and the City of Lansing have provided us a variety of tax credits and abatements. We estimate that the total value of these tax benefits may be up to $18.5 million over a period of up to 15 years, beginning in 2006. These tax benefits are based on our $75 million planned investment in our Lansing facility. In addition, we must maintain a specified number of employees in Lansing to continue to qualify for these tax benefits.

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 and other committed sources of funding. There are numerous risks and uncertainties associated with BioThrax product sales and with the development and commercialization of our product candidates.

We may seek to raise additional external debt financing to provide additional financial flexibility. Our committed external sources of funds consist of the remaining borrowing availability under our revolving line of credit with Fifth Third Bank, development funding under our collaboration agreement with Sanofi Pasteur, funding from the NIAID, including for studies related to our anthrax immune globulin candidate, funding from the Wellcome Trust for our Phase II clinical trial of our typhoid vaccine candidate, and milestone payments from HHS related to post-exposure prophylaxis indication for BioThrax. Our ability to borrow additional amounts under our loan agreements is subject to our satisfaction of specified conditions.

Our future capital requirements will depend on many factors, including:

- the level and timing of BioThrax product sales and cost of product sales;
- the timing of, and the costs involved in, constructing our new manufacturing facility in Lansing and the build out of our manufacturing facilities in Frederick;
- 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 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 businesses, products and technologies;
- our ability to obtain development funding from government entities and non-government and philanthropic organizations; and
- our ability to establish and maintain collaborations, such as our collaboration with Sanofi Pasteur.

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.

Additional equity or debt financing, grants, or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts. 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.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements,* or SFAS No. 157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. The provisions of SFAS No. 157 are effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We are currently evaluating the impact of the adoption of this statement on our financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115*, or SFAS No. 159. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The provisions of SFAS No. 159 are effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact of the adoption of this statement on our financial statements.

In June 2007, the FASB issued EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ("EITF No. 07-3"). EITF No. 07-3 states that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. The provisions of EITF No. 07-3 are effective for fiscal years beginning after December 15, 2007. We are currently evaluating the impact of adoption of this statement on its financial statements.

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. We currently do not hedge interest rate exposure or foreign currency exchange exposure. 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 expense associated with our debt.

ITEM 4. 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, 2007. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls or 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, 2007, 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.

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 three months ended September 30, 2007 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

BioThrax product liability litigation. On October 14, 2005, January 9, 2006 and January 17, 2006, we were named as a defendant in three federal lawsuits filed on behalf of three individuals who claimed damages resulting from personal injuries allegedly suffered because of vaccinations of BioThrax by the DoD. The plaintiffs in each of these three lawsuits claimed different injuries and sought varying amounts of damages. The plaintiff in the first case alleged that the vaccine caused erosive rheumatoid arthritis and requested damages in excess of $1 million. The plaintiff in the second case alleged that the vaccine caused Bell's palsy and other related conditions and requested damages in excess of $75,000. The plaintiff in the third case alleged that the vaccine caused a condition that originally was diagnosed as encephalitis related to a gastrointestinal infection and caused him to fall into a coma for many weeks and requested damages in excess of $10 million. The second lawsuit was dismissed with prejudice on September 5, 2007. In the remaining two lawsuits, we have moved to dismiss for lack of personal jurisdiction, or in the alternative, to transfer the lawsuits to federal court in Michigan. On October 27, 2006, one of these lawsuits was transferred to the U.S. District Court for the Western District of Michigan. On October 31, 2006, the other was dismissed for lack of personal jurisdiction. The plaintiff in that lawsuit appealed the dismissal to the U.S. Court of Appeals for the Ninth Circuit, and that appeal remains pending. These lawsuits are in the preliminary stages of litigation, and we believe that we are entitled to indemnification under our contract with the DoD for legal fees and any damages that may result from these claims.

In April 2006, the U.S. District Court for the Western District of Michigan entered summary judgment in our favor in four other consolidated lawsuits asserting similar claims brought by approximately 120 individuals. The District Court's ruling in the four cases was based on two grounds. First, the District Court found that we were entitled to protection under a Michigan state statute that provides immunity for drug manufacturers if the drug was approved by the FDA and its labeling is in compliance with FDA approval, unless the plaintiffs establish that the manufacturer intentionally withheld or misrepresented information to the FDA and the drug would not have been approved, or the FDA would have withdrawn approval, if the information had been accurately submitted. Second, the District Court found that we were entitled to the immunity afforded by the government contractor defense, which, under specified circumstances, extends the sovereign immunity of the United States to government contractors who manufacture a product for the government. Specifically, the government contractor defense applies when the government approves reasonably precise specifications, the product conforms to those specifications and the supplier warns the government about known dangers arising from the use of the product. The District Court found that we established each of those factors. We intend to rely on similar defenses with respect to the substantive claims asserted in our pending lawsuits. We also expect to rely on contractual indemnification provisions with the DoD and statutory protections to limit our potential liability resulting from the pending lawsuits.

Insurance coverage litigation. On December 26, 2006, we were named as a defendant in a lawsuit brought by Evanston Insurance Company in the U.S. District Court for the Western District of Michigan captioned *Evanston Insurance Company v. BioPort Corporation and Robert C. Myers.* Evanston issued a general liability policy to us in 2000, and we made a claim for coverage under that policy for defense and indemnity costs incurred as a result of the claims asserted in the BioThrax product liability litigation discussed above and the thimerosal litigation discussed below. In its complaint, Evanston asserts a number of purported bases for the court to void or reduce its obligation to defend or indemnify us, including a claim that we failed to disclose on our insurance application our alleged knowledge of "incidents, conditions, circumstances, effects or suspected defects which may result in claims." Evanston seeks rescission or reformation of the policy to exclude a duty to defend or indemnify us for the claims asserted in the BioThrax product liability litigation and the thimerosal litigation. Evanston also seeks a refund of the approximately $331,000 that it has reimbursed us for defense costs.

MilVax litigation. In 2003, six unidentified plaintiffs filed suit in the U.S. District Court for the District of Columbia against the U.S. government seeking to enjoin the Anthrax Vaccine Immunization Program administered under MilVax under which all military personnel were required to be vaccinated with BioThrax. In October 2004, the District Court enjoined the DoD from administering BioThrax to military personnel on a mandatory basis without their informed consent or a Presidential waiver. This ruling was based in part on the District Court's finding that the FDA, as part of its review of all biological products approved prior to 1972, had not properly issued a final order determining that BioThrax is safe and effective and not misbranded. In December 2005, the FDA issued a final order determining that BioThrax is safe and effective and not misbranded. In February 2006, the U.S. Court of Appeals for the District of Columbia, on appeal of the injunction by the government, ruled that the injunction had dissolved by its own terms as a result of the FDA's final order. The matter remains pending in the District Court, where subsequent proceedings have focused on whether the plaintiffs are entitled to recover attorneys' fees from the government.

In October 2006, the DoD announced that it was resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency DoD civilian personnel and contractors. In December 2006, the same counsel who represented the plaintiffs in the 2003 litigation filed a new lawsuit against the government in the same federal court, on behalf of unnamed service members and the DoD civilian employees or contractors and purportedly on behalf of a class of similarly situated individuals. The suit contends on various grounds that the FDA's 2005 final order should be set aside as substantively and procedurally flawed and that BioThrax is not properly approved for use in the DoD's vaccination program. The plaintiffs seek a declaration that BioThrax is improperly licensed and is not approved for use against inhalation anthrax, an order vacating the FDA's 2005 final order, and an injunction prohibiting the DoD from using BioThrax in a mandatory vaccination program. In February 2007, the government moved to dismiss the case. Although we are not a party to either of the Milvax lawsuits, if the District Court were to grant all or part of the requested relief, the amount of future purchases of BioThrax by DoD could be affected.

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 is 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 used in the manufacture of some vaccines, caused personal injuries, including brain damage, central nervous system damage and autism. No specific dollar amount of damages has been claimed. Emergent BioDefense Operations is currently a named defendant in 40 lawsuits pending in two jurisdictions: 3 in California and 37 in Illinois. The products at issue in these lawsuits are pediatric vaccines. Because we are not currently and have not historically been in the business of manufacturing or selling pediatric vaccines, we do not believe that we manufactured the pediatric vaccines at issue in the lawsuits.

Under a contractual obligation to the State of Michigan, we manufactured one batch of vaccine suitable for pediatric use. However, the contract required the State to use the vaccine solely for Michigan public health purposes. We no longer manufacture any products that contain thimerosal. We have submitted a request for coverage of the defense and indemnity costs incurred as a result of these thimerosal claims to our insurance carriers. The insurance carrier that issued our general liability policies during the relevant years is disputing coverage

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 our BioThrax anthrax vaccine, our only marketed product, under contracts with the U.S. Department of Defense and the U.S. Department of Health and Human Services. If the DoD and HHS 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 of BioThrax, our FDA-approved anthrax vaccine and only marketed product. In 2006 and for the nine months ended September 30, 2007, we derived substantially all of our revenue from our BioThrax contracts with the DoD and HHS. The DoD has issued a sole source RFP for the manufacture, storage and delivery of BioThrax. On July 3, 2007, we submitted a response to this RFP. In October 2007, a White House Presidential Directive was issued that outlines the U.S. government's objective to enhance coordination and cooperation among federal agencies with respect to countermeasure procurement and stockpile management. Also in October 2007, the GAO issued a report that was critical of HHS for lacking an effective strategy to minimize waste in the SNS, citing concerns of large amounts of BioThrax that will become unusable each year due to shelf-life expiration. We believe that the operational requirements set forth by the DoD in the May 2007 RFP have not changed and that the DoD has a continued commitment to procure BioThrax, either directly or indirectly, for its active immunization program. It is not clear what effect, if any, the Presidential Directive or GAO Report will have on the procurement process. We may not be awarded a follow-on contract by the DoD, or we may be awarded a contract on less favorable terms than our prior contracts with the DoD.

Our existing and prior contracts with the DoD and HHS 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 price per dose, the number of doses and the timing of deliveries for BioThrax sales to the U.S. government.

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

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

- the need to devote 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; and
- the expenses that we might incur and the delays that we might suffer if our competitors protest or challenge contract awards made to us pursuant to competitive bidding, and the risk that any such protest or challenge could 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 to award future contracts for the supply of anthrax vaccines and other biodefense product candidates that we are developing to our competitors instead of to us. 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, if any other company is successful in developing a next generation anthrax vaccine, U.S. government customers may purchase only the next generation vaccine and not BioThrax.

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 for BioThrax require ongoing funding decisions by the government. The failure to fund one or more of these contracts could cause our financial condition and operating results to suffer materially.

Our principal customer for BioThrax, our only marketed product, is the U.S. government. In addition, we anticipate that the U.S. government will 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 government programs is subject to Congressional appropriations, generally made on a fiscal year basis even though a program may continue for several years. For example, our prior DoD contracts for BioThrax were structured with one base year during which the DoD agreed to purchase a minimum number of doses of BioThrax with options for the DoD to purchase further quantities in future years. Any future contract that we enter into with the DoD may be structured in a similar manner.

Our government customers are subject to stringent budgetary constraints and political considerations. 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 additional regulations and obligations under our U.S. government contracts.

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

- procurement integrity;
- export control;
- government security regulations;
- 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.

On September 25, 2007 we entered into an agreement with HHS to supply 18.75 million doses of BioThrax to HHS for placement into the SNS for a firm fixed price of $400 million. If we receive FDA approval of an application to extend the shelf life of BioThrax from three years to four years, HHS has agreed to adjust the price per dose under the agreement, with an aggregate value of such price increase of approximately $34 million. The regulatory approval process is complex and uncertain, and there is no guarantee that we will receive approval of four-year expiry dating. If we do not receive FDA approval of four-year expiry dating during the term of the agreement, we will be unable to earn the $34 million.

The pricing under our fixed price government contracts is based on estimates of the time, resources and expenses required to deliver the specified doses of BioThrax. If our estimates are not accurate, we may not be able to earn an adequate return under these contracts.

Our existing and prior contracts for the supply of BioThrax with the DoD and HHS have been fixed price contracts. We expect that our future contracts with the U.S. government 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 absorb any costs in excess of the fixed price. Estimating costs that are related to performance in accordance with contract specifications is difficult. 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 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;
- 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 specified in a contract;
- decline to exercise an option to purchase the maximum amount specified in a contract;
- claim rights in 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 U.S. government 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 terminated company 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. In addition, if the U.S. government decides to withdraw military personnel from high threat areas, including Iraq, or otherwise determines that it will decrease the number of military personnel to be immunized with BioThrax, the DoD's demand for BioThrax may be reduced substantially. In addition, any follow-on contract with the DoD may not provide sufficient indemnification, and the DoD may require us to accept a greater risk of loss for the product manufacture, storage and delivery. 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.

Ongoing legal proceedings or any future similar lawsuits could limit future purchases of BioThrax by the U.S. government.

The results of ongoing or future legal proceedings could reduce demand for BioThrax by the U.S. government. For example, in 2003, a group of unnamed military personnel filed a lawsuit seeking to enjoin the DoD from administering BioThrax on a mandatory basis without informed consent of the recipient or a Presidential waiver, and, in 2004, a federal court issued the requested injunction. 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 military personnel and emergency DoD civilian personnel and contractors.

In December 2006, the same counsel who brought the prior lawsuit filed a new lawsuit contending that the FDA's 2005 final order should be set aside and that BioThrax is not properly approved for use in the DoD's vaccination program. In February 2007, the government moved to dismiss the case. Although we are not a party to the lawsuits challenging DoD's mandatory use of the vaccine, if a court were to again enjoin the DoD's use of BioThrax on a mandatory basis, the amount of future purchases of BioThrax 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. In addition, lawsuits brought directly against us by third parties, even if not successful, require us to spend time and money defending the related litigation.

Risks Related to Our Financial Position and Need for Additional Financing

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

We commenced operations in 1998, and the FDA approved the manufacture of BioThrax at our renovated facilities in Lansing in December 2001. Although we were 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 the timing of our fulfilling orders from the U.S. government. 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, 2007, we had $47.0 million principal amount of debt outstanding and remaining borrowing availability of $15.0 million under our revolving lines of credit. We may seek to raise substantial external debt financing to provide additional financial flexibility. Our leverage 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.

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. 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 are committed to substantial capital expenditures in connection with our facility expansion in Lansing and may undertake additional facility projects in the future.

As of September 30, 2007, we had $24.3 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;
- the timing of, and the costs involved in, constructing our new manufacturing facility in Lansing and the build out of our manufacturing facilities in Frederick;
- 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 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 businesses, products and technologies;
- our ability to obtain development funding from government entities and non-government and philanthropic organizations; and
- our ability to establish and maintain collaborations, such as our collaboration with Sanofi Pasteur.

Our committed external sources of funds consist of the remaining borrowing availability under our revolving line of credit with Fifth Third Bank, development funding under our collaboration agreement with Sanofi Pasteur, funding from the NIAID and BARDA, including for animal efficacy studies of our anthrax immune globulin candidate, and funding from the Wellcome Trust for our subsequent Phase II clinical trial of our typhoid vaccine candidate. 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, which we may not be able to obtain when needed or on attractive terms, which would force us to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

Our ability to borrow additional amounts under our loan agreements 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 have initiated a manufacturing facility expansion program. Delays in completing and receiving regulatory approvals for these manufacturing facility projects could limit our potential revenues and growth.

We are spending significant amounts for the installation, validation and qualification activities for our new 50,000 square foot manufacturing facility on our Lansing campus, which has been designed and constructed to enable us to manufacture BioThrax on a large scale for our existing and potential future customers. We expect this new facility to accommodate large scale commercial manufacturing of multiple vaccine products, subject to complying with appropriate change-over procedures.

We also own two buildings in Frederick that are available to address our future manufacturing requirements and have initiated initial engineering design and preliminary utility build out for these facilities. The completion of the Lansing facility and, if we proceed, the build out of the Frederick facilities, will involve substantial expenditures and likely require external sources of funds. Any delays in the installation, validation and qualification activities may adversely affect our ability to manufacture our commercial product candidates for clinical trials or commercial sale.

We anticipate that we will initiate large scale manufacturing of BioThrax at the new Lansing facility in 2008. Our plans assume that the FDA will not require us to complete a human bridging trial demonstrating that BioThrax manufactured at our new facility is bioequivalent to BioThrax manufactured at our existing facility. We currently expect to rely on non-clinical studies for these purposes. However, the FDA has not approved our plan to rely on non-clinical studies without conducting a human bridging trial and may not do so. If the FDA requires us to conduct a human bridging trial, the initiation of large scale manufacturing of BioThrax at our new Lansing facility will be delayed and we will incur additional unanticipated costs.

Constructing and preparing a facility for commercial vaccine manufacturing is a significant project. For example, constructing the new Lansing facility with increased manufacturing capacity requires that we scale-up both fermentation and downstream processing compared to levels at our existing production facility. These projects may result in unanticipated delays and cost more than expected due to a number of factors, including regulatory requirements. The FDA must approve our new manufacturing facilities before they can be used to commercially manufacture our products. For example, we are required to show that the product we manufacture in our new Lansing facility is comparable to BioThrax manufactured at our existing facility, which may require additional clinical studies. The costs and time required to comply with the FDA's current Good Manufacturing Practice, or cGMP, regulations, or similar regulatory requirements for sales of our products outside the United States, may be significant. If installation, validation and qualification activities of our new facility in Lansing are delayed, we may not be able to manufacture sufficient quantities of BioThrax to allow us to increase sales of BioThrax to the U.S. government and other customers, which would limit our opportunities for growth. Cost overruns associated with constructing either our Lansing or Frederick facilities could require us to raise additional funds from external sources. We may not be able to do so on favorable terms or at all.

BioThrax and our immunobiotic product candidates are complex to manufacture, especially on a large scale commercial basis, which could cause us to delay product launches or experience 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 obtaining materials, filling, labeling, packaging, storage and shipping and quality control and testing, some of which we experience from time to time, may result in lot failures, delay in the release of lots, product recalls or spoilage. We will not be able to sell any lots that fail to satisfy release testing specifications.

FDA approval is required for the release of each lot. 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 have no redundancy. In developing redundancy, we may face significant regulatory hurdles. In the event of a problem with this strain, if we have not developed redundancy, we would not be able to provide the FDA with required potency testing. .

In addition, BioThrax must be maintained at a prescribed temperature range during shipping, and variations from that temperature range could result in loss of product and could adversely affect profitability. Delays, lot failures, and shipping deviations or spoilage 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 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.

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.

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, under our most recent BioThrax supply contract with the DoD, the DoD was obligated to acquire a minimum number of doses of BioThrax and had the right to acquire up to a maximum number of doses. Any future contract with the DoD may contain a similar provision. If in connection with such a contract, the DoD elects to purchase the maximum number of doses of BioThrax under the contract, we may not have sufficient available production capacity at our existing manufacturing facility in Lansing to increase sales of BioThrax to customers other than the U.S. government. In addition, 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, we could incur significant unrecoverable costs from creating excess capacity.

For example, if we do not maintain and increase sales of BioThrax to the U.S. government and other customers, we may not be able to generate an adequate return on the significant amounts that we have spent on construction and are spending for installation, validation and qualification activities for our new manufacturing facility in Lansing. In addition, if we do not successfully develop and commercialize any of our product candidates, we may never require the production capacity that we expect to have available at our Frederick site.

If third parties do not manufacture our product candidates or products 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 on third parties to manufacture the supplies of our immunobiotic product candidates that we require for preclinical and clinical development, including our immune globulin product candidates, typhoid vaccine, hepatitis B therapeutic vaccine, and Group B streptococcus vaccine candidates. Any significant delay in obtaining adequate supplies of our product candidates could adversely affect our ability to develop or commercialize these product candidates. Although we recently commissioned a new pilot plant manufacturing facility on our Lansing campus and plan to construct a pilot plant in Maryland for production of preclinical and clinical supplies of our product candidates, we expect that we will continue to use third parties for these purposes.

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 for our immune globulin product candidates and contract fill and finish operations. If our contract manufacturers are unable to scale-up production to generate enough materials for commercial launch, 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.

Third party manufacturers under short-term supply agreements are not obligated to accept any purchase orders we may submit. If any third party terminates its agreement with us, based on its own business priorities, 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 may require review from the FDA and satisfaction of comparable foreign requirements. This review may be costly and time consuming. There are a limited number of manufacturers that operate under the FDA's cGMP requirements and that are both capable of manufacturing for us and willing to do so. Our only current long-term manufacturing agreements are our agreement with Talecris Biotherapeutics, Inc., for fractionation and purification of plasma for our anthrax immune globulin candidate, and our collaboration with HPA, under which HPA provides specialized manufacturing capabilities for our recombinant bivalent botulinum vaccine candidate and the bivalent botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin candidate.

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 United States. 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. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS and the DoD.

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

We also are subject to export control regulations governing the export of BioThrax and technology and materials used to develop and manufacture BioThrax and our product candidates. 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. 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.

The general liability policy currently has a $15,000 per occurrence deductible. 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 a $1 million annual aggregate limit and a $10,000 per claim deductible. The insurance that we currently hold may not be adequate to cover all liabilities relating to accidental contamination or injury as a result of pollution conditions or other extraordinary or unanticipated events.

If the company on whom 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, Hollister-Stier Laboratories LLC. Our contract with Hollister-Stier expires on December 31, 2010. We have not established internal redundancy for our filling functions and currently have no substitute provider that can handle our filling needs. If Hollister-Stier is unable to perform filling services for us, we would need to identify and engage 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 obtain FDA approval for filling BioThrax at its facilities. Identifying and engaging a new contract filling company or developing our own filling capabilities and obtaining FDA approval could involve significant cost and delay. As a result, we might not be able to deliver BioThrax orders on a timely basis and our revenues could decrease.

Risks Related to Product Development

Our business depends significantly on our success in completing development and commercializing product candidates that are still under development. If we are unable to commercialize these product candidates, or experience significant delays 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 immunobiotic product candidates. In addition to BioThrax product sales, our ability to generate near term revenue is particularly dependent on the success of our anthrax immune globulin candidate. The commercial success of our product candidates will depend on many factors, including:

- successful development, formulation and cGMP scale-up of biological manufacturing that meets FDA requirements;
- successful development of animal models by the U.S. government;
- successful completion of non-clinical development, including in approved animal models;
- successful completion of clinical trials;
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities;
- a determination by the Secretary of HHS that our biodefense product candidates should be purchased for the SNS 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, whether alone or in collaboration with others; and
- acceptance of the product by potential government customers, physicians, patients, healthcare payors and others in the medical community.

We expect to rely on FDA regulations known as the animal rule to obtain approval for our biodefense 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 immunobiotic product candidates in humans. If we are not successful in completing the development and commercialization of our immunobiotic product candidates, or if we are significantly delayed in doing so, our business will be materially harmed.

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

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

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;
- 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 candidates contain live attenuated viruses, our testing of these vaccine 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 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 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;
- not be able to obtain marketing approval; or
- obtain approval for indications that are not as broad as intended.

In addition, our development plan for BioThrax as a post-exposure prophylaxis for anthrax infection provides for a non-human primate efficacy study. However, the timing of our non-human primate efficacy study depends upon the successful development of a non-human primate model by the NIAID. If the NIAID does not successfully develop a non-human primate model, our development plans for BioThrax as a post-exposure prophylaxis for anthrax infection will be delayed, possibly significantly.

Our product development costs will also increase if we experience delays in testing or approvals. 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 product candidates may 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 the U.S. Postal Service, foreign governments, state and local governments, which we expect will be interested in BioThrax to protect first responders and emergency personnel, 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 new and undeveloped, and we may not be successful in generating meaningful sales of BioThrax to these potential customers. To date, we have made only minimal sales to these customers. In particular, we have supplied small amounts of BioThrax directly to several foreign governments. In 2006, our sales of BioThrax to customers other than the U.S. government represented less than one percent 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 and the terms of our U.S. government contracts may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, 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, 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 controls could limit our sales of BioThrax to foreign governments and other foreign customers. In addition, the DoD has contractual and statutory rights that could interfere with sales of BioThrax to customers other than the U.S. government. 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 are otherwise specified in our contract with the DoD.

If the DoD required delivery of these additional doses, it could affect our production schedule and deplete BioThrax supplies that would otherwise be available for commercial sales. In addition, the DoD could either sell BioThrax directly to foreign governments at a lower price than we may offer or donate BioThrax to foreign governments under the DoD's Foreign Military Sales program.

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 facility in Lansing to manufacture BioThrax for sale to U.S. government customers.

Our plan is to initiate large scale manufacturing of BioThrax at our new manufacturing facility in 2008. If installation, validation and qualification activates for our new facility in Lansing are delayed, we may not be able to manufacture sufficient quantities of BioThrax to allow us to increase sales of BioThrax to customers other that the U.S. government which would limit our opportunities for growth.

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 immunobiotic 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 U.S. government Accountability Office, or GAO, reiterated concerns regarding BioThrax in Congressional testimony in May 2006 that it had previously identified beginning in 1999. These concerns include the need for a 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.

In another report, issued in October 2007, the GAO questioned whether both HHS and DoD should purchase BioThrax directly from the Company and suggested that DoD acquire BioThrax from the SNS rather than from the manufacturer. DoD may decide that it will use BioThrax from the SNS rather than entering into separate procurement contracts with the Company. Such determination could result in a lower volume of overall BioThrax sales to the U.S. government.

The use of vaccines carries a risk of adverse health effects. The adverse reactions that have been associated with the administration of BioThrax are similar to those observed following the administration of other adult vaccines and include local reactions, such as redness, swelling and 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. The report of any such adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event. These serious adverse events, including diabetes, heart attacks, autoimmune diseases, including Guillian Barre syndrome, lupus and multiple sclerosis, lymphoma and death, have not been causally linked to the administration of BioThrax.

If any products that we develop do not achieve an adequate level of acceptance, we may not generate material revenues with respect to 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 will be 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 2004, members of the military and various activist groups who opposed mandatory inoculation with BioThrax petitioned the FDA and a federal court to revoke the license for BioThrax and to terminate the DoD program for the mandatory administration of BioThrax to military personnel. Although the DoD prevailed in the challenge to its mandatory vaccination program, the actions of these groups created negative publicity about BioThrax. Lawsuits or publicity campaigns could limit the demand for BioThrax and our biodefense product candidates and harm our future business.

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

To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We currently market and sell BioThrax directly to the DoD and HHS through a small, targeted marketing and sales 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 marketing and sales 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 immunobiotics 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 major 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 immunobiotics are a number of pharmaceutical companies that have vaccine programs, including GlaxoSmithKline, Sanofi-Aventis, Wyeth, Merck and Novartis, as well as smaller more focused companies engaged in immunobiotic development, such as Cangene, Human Genome Sciences, Acambis, Avant Immunotherapeutics, Dor BioPharma, Dynport Vaccine Corporation, Elusys, Bavarian Nordic, Pharmathene and Avecia.

Any immunobiotic product candidate that we successfully develop and commercialize is likely to compete with currently marketed products, such as vaccines and therapeutics, including antibiotics, 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, we face significant competition for the supply of this vaccine to the U.S. government. We also face significant competition for our biodefense immunobiotic product candidates.

HHS has awarded SNS supply contracts to Cangene for an anthrax immune globulin and Human Genome Sciences for a monoclonal antibody to anthrax as a post-exposure therapeutic for anthrax infection. HHS has advised us that it is supplying Cangene with BioThrax doses that we delivered to HHS for placement into the SNS in order that Cangene can immunize donors and obtain plasma for its anthrax immune globulin product candidate. Several companies have botulinum vaccines in early clinical or preclinical development, and HHS is procuring from Cangene a botulinum immune globulin derived from equine plasma for the SNS.

One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the United States and Europe. Numerous companies have vaccine candidates in development that would compete with any of our commercial immunobiotic product candidates for which we obtain marketing approval.

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 collaborative arrangements with large and established companies. These competitors 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 DoD and HHS 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 general immunity for manufacturers of biodefense countermeasures, including security countermeasures, when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is meant to provide general 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 this protection in cases of willful misconduct. Upon a declaration by the Secretary, 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. However, 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. Our September 2007 contract with HHS provides that BioThrax in the SNS will not be administered in humans until the Secretary of HHS issues a PREP Act declaration applicable to BioThrax. We do not know, however, whether the PREP Act would provide adequate coverage or survive anticipated legal challenges to its validity.

In August 2006, the Department of Homeland Security approved our application under the 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 United States 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 DoD and HHS provided that the U.S. government would indemnify us for any damages resulting from product liability claims, our current contract with HHS does not contain such indemnification, and we cannot be certain that we will be able to negotiate similar indemnification provisions in future contracts or that the U.S. government will honor its indemnification obligations. For example, although we have notified the DoD of 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, the DoD has not yet acted on our claim for indemnification pending resolution of our claims under our product liability insurance. Members of Congress have proposed and may in the future propose legislation that reduces or eliminates the statutory liability protections for manufacturers of biodefense countermeasures

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 currently are a defendant in two federal lawsuits filed on behalf of two individuals 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 plaintiff in these lawsuits claimed different injuries and sought varying amounts of damages.

The plaintiff in one of the actions has alleged that the vaccine caused erosive rheumatoid arthritis and has requested damages in excess of $1 million. The plaintiff in the other suit has alleged that the vaccine caused a condition that originally was diagnosed as encephalitis related to a gastrointestinal infection and caused him to fall into a coma for many weeks and has requested damages in excess of $10 million.

If we cannot successfully defend ourselves against claims that our product or product candidates caused injuries and if we are not entitled to indemnity by the U.S. government, we will incur substantial liabilities. Regardless of merit or eventual outcome, 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 $10 million annual aggregate limit with a deductible of $75,000 per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Product liability insurance is difficult to obtain and increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. For example, from 2002 through February 2006, we were unable to obtain product liability insurance for sales of BioThrax on commercially reasonable terms. We do not believe that the amount of insurance we have been able to obtain for BioThrax is sufficient to manage the risk associated with the potential large-scale deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on contractual indemnification provisions and statutory protections to limit 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 United States 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 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 United States, 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.

Federal legislation, enacted in December 2003, has altered the way in which physician-administered drugs and biologics covered by Medicare are reimbursed. Under the new reimbursement methodology, physicians are reimbursed based on a product's "average sales price." This new reimbursement methodology has generally led to lower reimbursement levels. The new federal legislation also has added an outpatient prescription drug benefit to Medicare, which went into effect in January 2006. These benefits will be provided primarily through private entities, which we expect will attempt to negotiate price concessions from pharmaceutical manufacturers.

Any products we may develop may also 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 Medicare 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.

Legislation has been introduced into Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the United States, which may include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. 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 the following executives to be key to our BioThrax operations and our efforts to develop and commercialize our product candidates: Fuad El-Hibri, chief executive officer and chairman of our Board of Directors; Daniel J. Abdun-Nabi, president, chief operating officer and secretary; R. Don Elsey, chief financial officer and treasurer; and Robert G. Kramer, executive vice president manufacturing operations. All 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 could be adversely affected by a negative audit by the U.S. government.

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 doing 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 do 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 Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

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. The 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 can do business and, in some instances, impose added costs on our business. Any changes in applicable laws and regulations could restrict our ability to maintain our existing contracts and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our revenues and results of operations.

We rely on property and equipment owned by the DoD in the manufacturing process for BioThrax.

We have the right to use certain property and equipment owned by the DoD, referred to as government furnished equipment, or GFE, at our Lansing, Michigan site in the manufacture of BioThrax. We pay the DoD a small usage fee for the GFE based on the number of doses of BioThrax that we produce for sale to customers other than the U.S. government. We have the option to purchase all or part of existing GFE from the DoD on terms to be negotiated with the DoD. If the DoD 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 DoD concerning the terms of the purchase of that part of the GFE necessary for our business, our business could be harmed. If the U.S. government were to terminate or fail to extend all BioThrax supply contracts with us, we potentially could be required to rent or purchase that part of the GFE necessary for the continued production of BioThrax in our current manufacturing facility.

Risks Related to Regulatory Approvals

If we 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 their 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, information about product manufacturing processes and inspection of facilities and supporting information to the FDA 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, our biodefense product candidates and our commercial product candidates are regulated by the FDA as biologics. To obtain approval from the FDA to market these product candidates, other than biodefense products purchased by HHS for the SNS, we will be required to submit to the FDA a biologics license application, or BLA. Ordinarily, the FDA requires a sponsor to support a BLA application 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. Because humans are rarely exposed to anthrax or botulinum toxins under natural conditions, and cannot be intentionally exposed, statistically significant effectiveness of our biodefense product candidates cannot be demonstrated in humans, but instead must be demonstrated, in part, by utilizing animal models before they can be approved for marketing.

We believe that, according to the FDA's current BLA requirements for biologics that cannot be ethically or feasibly tested in humans in Phase III efficacy trials, we may instead be able to obtain BLA approval based on clinical data from Phase II and Phase III trials in healthy subjects that demonstrate adequate safety and immune response and effectiveness data from studies in animals. Specifically, we intend to pursue FDA approval of BioThrax as a post-exposure prophylaxis, our immune globulin candidates, our recombinant bivalent botulinum vaccine candidate and a next generation anthrax vaccine under the FDA animal rule. Under the animal rule, if human efficacy trials are not ethical or feasible, the FDA can approve drugs or biologics used to treat or prevent serious or life threatening conditions caused by exposure to lethal or permanently disabling toxic chemical, biological, radiological or nuclear substances based on human clinical data demonstrating safety and immunogenicity and evidence of efficacy from appropriate non-clinical animal studies and any additional supporting data. Products approved under the animal rule are subject to additional regulation not normally required of other products. Additional regulation may include post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

We have applied to the FDA to reduce the number of required doses of BioThrax for pre-exposure prophylaxis from six to five, with an annual booster dose thereafter. Our application is based on an interim analysis of data from an ongoing clinical trial being conducted by the CDC to evaluate whether as few as three doses of BioThrax, administered over six months, with booster doses up to three years apart, will confer adequate immune response. In April 2006, the FDA issued a complete response letter to our application, requesting clarification and requiring additional analysis of the data that we submitted. The data is being further analyzed, and we plan to submit an amendment to our application when this analysis is completed. If the FDA does not find our response to be adequate, we might be required to conduct additional independent testing to continue to pursue the development of this reduced dosing regimen. Responding to the FDA's complete response letter will delay potential approval of our application. If we are unable ultimately to respond satisfactorily to the FDA, our application will not be approved.

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 each 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 immunobiotic 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, including through inspections of our facilities. 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 at reasonable times and in a reasonable manner.

After we acquired BioThrax and related vaccine manufacturing facilities in Lansing 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 and May 2006. Following each of these inspections, the FDA issued inspectional observations on Form FDA 483. We responded to the FDA regarding the inspectional observations relating to each inspection and, where necessary, implemented corrective action. In December 2005, the FDA stated in its final order on BioThrax that at that time we were in compliance with all regulatory requirements related to the manufacture of BioThrax and that the FDA would continue to evaluate the production of BioThrax to assure compliance with federal standards and regulations. We have filed with the FDA our responses to all inspectional observations relating to the May 2006 inspection. The FDA has acknowledged receipt of our responses and has advised us that it has concluded that the May 2006 inspection is closed. Pursuant to its standard procedures, we expect that the FDA will review and assess our corrective actions at its next inspection. If in connection with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, 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.

We may not be able to obtain orphan drug exclusivity for our products. If our competitors are able to obtain orphan drug exclusivity for their products that are the same as our products, we may not be able to have competing products approved by the applicable regulatory authorities for a significant period of time.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug or biologic for that time period for the same indication.

Orphan drug exclusivity in Europe lasts for ten years, but can be reduced to six years if a drug or biologic no longer meets the criteria for orphan drug designation or if the drug or biologic is sufficiently profitable so that market exclusivity is no longer justified. If a competitor 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. None of our products or product candidates have been designated as orphan drugs. 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 BioThrax as a post-exposure prophylaxis for anthrax infection may not actually lead to a faster development or regulatory review or approval process.

If a drug or biologic is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation. We have obtained a Fast Track designation from the FDA for BioThrax as a post-exposure prophylaxis for anthrax infection. However, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw our Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical development program. Our 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 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 file for regulatory approvals and may not receive necessary 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 for ourselves or entering into collaboration arrangements with leading pharmaceutical or biotechnology companies or non-governmental organizations, such as our collaboration agreement with Sanofi Pasteur for our meningitis B vaccine candidate. 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. The terms of any collaborations or other arrangements that we establish may not be favorable to us.

Any collaboration that we enter into may not be successful. 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. In particular, the successful development of our meningitis B vaccine candidate will initially depend on the success of our research collaboration with Sanofi Pasteur and whether Sanofi Pasteur selects one or more viable candidates pursuant to the collaboration for development of a product.

Thereafter, Sanofi Pasteur will have significant discretion in the development and commercialization of any such candidate. Sanofi Pasteur may choose not to pursue further development and commercialization of any candidate that it selects based on many factors outside our control. Sanofi Pasteur has the ability to suspend development of a candidate under the collaboration in various circumstances. 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 decide not to continue to work with us in the development of our product candidates.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. For example, Sanofi Pasteur has the right to terminate our meningitis B vaccine collaboration at any time after April 1, 2007 upon six months' prior written notice. Sanofi Pasteur can also terminate the collaboration upon a change of control or insolvency event involving us or upon our uncured material breach. Those terminations or expirations would adversely affect us financially and could harm our business reputation.

If third parties on whom we rely for 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 our business may suffer.

We do not have the ability to independently conduct the 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 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 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 and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. 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. For example, the CDC is currently conducting an independent clinical trial to evaluate the administration of BioThrax in a regimen of fewer doses. We participate in monthly meetings with the trial investigators and in the annual review meeting for this trial and provide input to the CDC for responses to FDA questions and requests for additional information.

We expect to rely on data from these development efforts in 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 interim trial report provided to us by the CDC from its ongoing clinical trial. We currently are awaiting the final data from the CDC trial. 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. In prior years, there has been some uncertainty whether Congress would choose to fund the CDC trial. Although the trial has been funded to date, Congress may not continue to fund the trial.

Risks Related to Our Intellectual Property

We may fail to protect our intellectual property rights, which would harm our business.

Our success, particularly with respect to our commercial business, will depend in large part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology and products. The patent situation in the field of immunobiotics 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 length of term 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 United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States 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 product candidate may consume part or all of the patent term. We are not able to accurately predict the remaining length of the applicable patent term following regulatory approval of any of our product candidates.

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. Under our collaboration agreement with Sanofi Pasteur for our meningitis B vaccine candidate, we have the right to prosecute and maintain our patent rights under the collaboration agreement.

Sanofi Pasteur is responsible for prosecuting and maintaining joint patent rights under the collaboration agreement, although we have the right to support the continued prosecution or maintenance of the joint patent rights if Sanofi Pasteur fails to do so. In addition, Sanofi Pasteur has the first right to pursue claims against third parties for infringement of the patent rights under the collaboration agreement and assume the defense of any infringement claims that may arise, although we have the right to pursue infringement claims against third parties and assume the defense of infringement claims if Sanofi Pasteur fails to do so.

Under our licenses with HPA relating to our recombinant bivalent botulinum vaccine candidate and the botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin candidate, HPA is responsible for prosecuting and maintaining patent rights, although we have the right to support the continued prosecution or maintenance of the patent rights if HPA fails to do so. In addition, we have the first right to pursue claims against third parties for infringement of the patent rights and assume the defense of any infringement claims that may arise.

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. We consider our licenses with HPA relating to our recombinant bivalent botulinum vaccine candidate and the botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin candidate to be material to our business. Under these license agreements, we obtained the exclusive, worldwide right to develop, manufacture and commercialize pharmaceutical products that consist of botulinum toxoid components or recombinant botulinum toxin components for the prevention or treatment of illness in humans caused by exposure to the botulinum toxin, subject to HPA's non-exclusive right to make, use or sell recombinant botulinum products to meet public health requirements in the United Kingdom.

We expect to enter into additional licenses in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

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

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for BioThrax, the label expansions and improvements that we are pursuing for BioThrax, our only intellectual property protection for BioThrax 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. Third parties may own or control these patents and intellectual property rights in the United States 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. 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, we monitored ongoing litigation between Bavarian Nordic and Acambis relating to the manufacture of the modified vaccinia Ankara virus, or MVA, as a smallpox vaccine for biodefense use by the U.S. government. This litigation was terminated by a settlement and consent order filed by the parties with the U.S. International Trade Commission, or ITC, in August 2007 and subsequently published in the U.S. Federal Registrar. According to the published terms of the consent order, Acambis agreed not to import or sell within the United States it MVA3000 vaccine product, and further agreed not to challenge the validity or enforceability or certain Bavarian Nordic patents. In addition, the consent order vacated the initial determination of the ITC that Bavarian Nordics' patents were invalid, but if valid would have been infringed by importation or sale of MVA3000 in the United States.

We have licensed from the Bavarian State Ministry of the Environment, Public Health and Consumer Protection 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 on these rights. Our ability to use our MVA platform technology could be negatively affected by patent infringement litigation or other legal actions brought by Bavarian Nordic or other parties challenging our rights to use MVA materials or technology.

For example, we have filed an opposition in the European Patent Office against Bavarian Nordic's patent covering certain aspects of the MVA technology. We may also become a party to trademark invalidation and interference proceedings in foreign trademark offices. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Risks Related to Our Acquisition Strategy

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

We have pursued an acquisition strategy since our inception to build our business of developing, manufacturing and commercializing immunobiotics. 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 and vaccine development and production know-how from the Michigan Biologic Products Institute. We acquired our pipeline of commercial vaccine candidates through our acquisition of ViVacs in 2006 and Microscience in 2005 and our acquisition of substantially all of the assets of Antex in 2003.

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 immunobiotics 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 product;
- 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 immunobiotic field to increase, which may mean 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, 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 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;
- disruption of our ongoing business;
- difficulty and expense in assimilating 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; and
- subsequent loss of key personnel.

If we are unable to successfully manage 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 substantial control 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 and voting arrangements among our significant stockholders. As of October 26, 2007, Mr. El-Hibri was the beneficial owner of over half of our outstanding common stock. Because Mr. El-Hibri has the ability to control the election of the members of our board, and because of his substantial control of our capital stock, Mr. El-Hibri will likely have the ability to delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

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

Provisions of our certificate of incorporation and by-laws may discourage, delay or prevent a merger, acquisition or other change 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;

- following November 20, 2008, 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.

Until November 20, 2008, the affirmative vote of holders of our capital stock representing a majority 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. Following November 20, 2008, 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. Until November 20, 2008, the affirmative vote of either at least 75% of the directors then in office or holders of our capital stock representing a majority of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws. Following November 20, 2008, 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.

If our stock price is volatile, 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 26, 2007, our common stock has traded as high as $7.67 per share and as low as $17.75 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. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. 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 United States 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. 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 are restricted from immediate resale but 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. Moreover, holders of an aggregate of approximately 21.4 million shares of our common stock outstanding as of October 26, 2007 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

On November 20, 2006, we completed an initial public offering of 5,000,000 shares of our common stock pursuant to a registration statement on Form S-1 (File No. 333-136622), which was declared effective by the SEC on November 14, 2006. We received net proceeds from the offering of approximately $54.2 million, after deducting underwriting discounts and commissions and other offering expenses.

Through September 30, 2007, we have used approximately $3.6 million of the net proceeds from the offering to fund development of our biodefense product candidates, comprised of approximately $1.1 million for label expansions and improvements for BioThrax, approximately $740,000 for a next generation anthrax vaccine candidate and approximately $1.7 million for our anthrax immune globulin candidate; approximately $4.7 million of the net proceeds to fund development of our commercial product candidates, comprised of approximately $2.3 million for our typhoid vaccine candidate and approximately $2.4 million for our hepatitis B therapeutic vaccine candidate; and approximately $15.8 million of the net proceeds to fund a portion of the construction, installation, validation and qualification activities costs for our new manufacturing facility in Lansing. We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10 percent or more of our common stock or to any affiliate of ours. We have invested the balance of the net proceeds from the offering in short-term, investment grade, interest-bearing instruments. There has been no material change in our planned use of the balance of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

ITEM 5. OTHER INFORMATION

Effective October 30, 2007, our Board of Directors approved amendments to Article IV, Sections 4.2, 4.3 and 4.6 of our Amended and Restated By-laws to permit the issuance and transfer of both certificated and uncertificated shares of capital stock, to comply with rules enacted by the New York Stock Exchange ("NYSE"). The NYSE rules require all securities listed on the NYSE to be eligible for a "direct registration system" operated by a clearing agency by January 2008. The direct registration system allows investors to have shares registered in their own names by book-entry. Book-entry allows shares to be owned, recorded and transferred electronically without issuance of physical stock certificates, which enables transactions without the risks and delays associated with transferring physical certificates. Prior to this amendment, the Amended and Restated By-laws were silent on the issuance of uncertificated shares.

The summary of changes to the Amended and Restated By-laws set forth above is qualified in its entirety by reference to the full text of the amendment, a copy of which is attached to this report as Exhibit 3.2 and incorporated herein by reference.

ITEM 6. EXHIBITS

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

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

Date: November 2, 2007

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

Date: November 2, 2007

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

EXHIBIT INDEX

Exhibit Number	Description
3.2	Amendment to Amended and Restated By-Laws
10.1	Contract No. HHSO100200700037C, dated September 25, 2007, between Emergent BioDefense Operations Lansing Inc. and Department of Health and Human Services
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

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS
OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER	PAGE 1 OF 28
ASPR 07041-30681	

2. CONTRACT NO.	3. AWARD/EFFECTIVE DATE	4. ORDER NUMBER	5. SOLICITATION NUMBER	6. SOLICITATION ISSUE DATE
HHSO100200700037C	09/25/2007	N/A	OPHEMC-V&B-07-02	5/3/07

7. FOR SOLICITATION INFORMATION CALL: ▶	a. NAME	b. TELEPHONE NUMBER (*No collect calls*)	8. OFFER DUE DATE/ LOCAL TIME
	N/A	N/A	6/8/07

9. ISSUED BY: CODE

DHHS/OS/ASPR/BARDA
330 Independence Ave,. S.W. Room G640
Washington, D.C. 20201

10. THIS ACQUISITION IS
☐ UNRESTRICTED OR ☐ SET ASIDE FOR
☐ SMALL BUSINESS ☐ EMERGING SMALL BUSINESS
☐ HUBZONE SMALL BUSINESS
NAICS:
SIZE STANDARD:
☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS ☐ 8(A)

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED	12. DISCOUNT TERMS:	13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	13b. RATING
☐ SEE SCHEDULE			14. METHOD OF SOLICITATION ☐ RFQ ☐ IFB ☒ RFP

15. DELIVER TO: CODE

SNS

16. ADMINISTERED BY: CODE

same as block 9

17a. CONTRACTOR/ OFFEROR: CODE / FACILITY CODE

Emergent BioDefense Operations Lansing Inc.
3500 N. Martin Luther King, Jr. Blvd.
Lansing, Michigan 48906

TELEPHONE NO. 517-327-7288 EBD is a Large Business

18a. PAYMENT WILL BE MADE BY: CODE

same as block 9

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	See Section B.4 (Prices) and Section C (SOW)				

25. ACCOUNTING AND APPROPRIATION DATA
Appropriation:757005/130714.001 CAN:199999E OCC:26201

26. TOTAL AWARD AMOUNT (For Govt. Use Only)
$447,650,001

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED (Clause & Provision)
☒ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☒ ARE ☐ ARE NOT ATTACHED (Clause & Provision)

☒ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 2 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED HEREIN.

☐ 29. AWARD OF CONTRACT: REF OFFER DATED ____ YOUR OFFER ON SOLICITATION (BLOCK 5) INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR		31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER	
/s/ Daniel J. Abdun-Nabi		/s/ Daniel J. Abdun-Nabi	
30b. NAME AND TITLE OF SIGNER (*Type or print*)	30c. DATE SIGNED	31b. NAME OF CONTRACTING OFFICER (*Type or print*)	31c. DATE SIGNED
Daniel J. Abdun-Nabi, Secretary	9/24/07	Brian K. Goodger	9/25/07

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 3/2005)
PRESCRIBED BY GSA – FAR (48 CFR) 53.212

TABLE OF CONTENTS

Section B – Supplies or Service and Price/Costs

B.1. Brief description of supplies or services

The Federal Response Plan of the Department of Homeland Security designates the Department of Health and Human Services (HHS) as the lead agency for public health and medical response to manmade or natural disasters. Within HHS, the Office of the Assistant Secretary for Preparedness and Response is responsible for the implementation of a comprehensive HHS strategy to protect from, and be prepared to respond to, acts of bioterrorism and other public health emergencies threatening the civilian population. The BioMedical Advanced Research & Development Authority (BARDA) has the primary responsibility within HHS to contract for large-scale manufacturing and delivery of licensed and licensable products to the Strategic National Stockpile (SNS) in preparation for response to a public health emergency.

Significant changes in both the nature, regularity, and degree of the threat posed by the use of infectious agents as weapons of biological warfare have generated increased concern for the safety of the general American populace. Following the deliberate exposure of citizens of the United States to *Bacillus anthracis (B. anthracis)* spores in 2001, there is an urgent need to stockpile appropriate and effective medical countermeasures to safeguard against this potential threat. The USG has established a requirement for the procurement of licensed Anthrax Vaccine Adsorbed (here after referred to as BioThrax®) to meet this urgent need.

B.2 Project Identification and Purpose

Provide 18.75 million doses of FDA licensed BioThrax® in multi-dose vials in appropriately packaged containers under controlled and secure conditions to the SNS.

B.3 Specific Technical Requirements

The Contractor shall provide the necessary qualified personnel, facilities, material, equipment (except Government property) and services to produce, test, bottle, package, and prepare for BioThrax ® delivery. The manufacture, formulation, filling, and testing of BioThrax® shall be done in accordance with the contractor's Standard Operating Procedures, and the contractor's Food and Drug Administration Biologics License, and all federal statutory requirements.

B.4 Prices:

CLIN #	Type	# of doses	Price per dose	Credit	Price
0001	[**]	[**]	$[**]	[**]	$[**]
0002A	[**]	[**]	$[**]	[**]	$[**]
0002B	[**]			[**]	$[**]
0003A	[**]	[**]	$[**]	[**]	$[**]
0003B	[**]			[**]	$[**]
0004A	[**]	[**]	$[**]	[**]	$[**]
0004B	[**]			[**]	$[**]

Total doses 18,750,000 Doses sub total 434,017,046

see section B.5, Advance understanding, paragraph (b) for a description of this credit.

CLIN #	Type	Requirement	Delivery Date	Price
0005	[**]	PEP Milestone #1	[**]	$ [**]
0006	[**]	PEP Milestone #2	[**]	$ [**]
0007	[**]	PEP Milestone #3	[**]	$ [**]
0008	[**]	PEP Milestone #4	[**]	$ [**]
0009	[**]	PEP Milestone #5	[**]	$ [**]
0010	[**]	PEP Milestone #6	[**]	$ [**]
0011	[**]	PEP Milestone #7	[**]	$[**]

PEP sub total $11,482,955

0012	[**]	[**] [**]	[**]	$ [**]
0013	[**]	[**]	[**]	$ [**]
0014	[**]	[**] [**]	[**]	$[**]

TOTAL $447,650,001

B.5 Advanced Understandings:

a. Commercial Item Contract Clauses

The clauses in the addenda in section I.3 (FAR addenda) shall take precedence over the applicable clauses listed in I.1. (FAR 52.212-4) (i.e., terminations for default and convenience, changes) as negotiated and agreed to by the parties.

b. Credit

The credit represents the per dose amount to be held back until FDA approves four-year dating for BioThrax®. If FDA does not approve four-year dating for BioThrax during the period of performance, the Contractor shall not be entitled to payment of the credit.

At such time as FDA approves four-year dating, the USG will pay the contractor the cumulative amount of the credit as of the date of approval, calculated as (1) the total number of doses delivered to the USG prior to such date multiplied by (2) the credit per dose applicable to each of those doses. The cumulative amount of the credit will be paid in a lump sum to contractor upon FDA approval of four-year expiry.

Subsequent to four year dating approval, all product will be invoiced as follows:

CLIN 0001	$[**] per dose
CLIN 0002	$[**] per dose
CLIN 0003	$[**] per dose
CLIN 0004	$[**] per dose

c. Ranges of doses manufactured and shipped

The delivery schedule are based upon projections in the contractor's anticipated production schedule, assumptions regarding lot release dates, and orders placed by the Department of Defense (DOD). Lot numbers, quantities, and dates are not guaranteed and may change as a result of lot failures, FDA lot release dates, DOD orders, and other factors. Should the projected number of doses not be delivered on any projected delivery date, the contractor shall adjust the delivery schedule to make up for deficiencies in prior deliveries, so long as the contractor delivers a total of 18,750,000 doses at a firm fixed price of $434,017,046 (presuming 4 year dating is approved by the FDA) or $400,047,864 (for [**] month dated product if 4 year dating is not approved by the FDA).

d. Shelf Life

The product shall have no less than [**] months shelf life and shall have following targeted average shelf life per CLIN:

CLIN 0001 –	[**] months
CLIN 0002A –	[**] months
CLIN 0003A –	[**] months*
CLIN 0004A –	[**] months*

* Assumes [**] obtained on or before [**]. The average remaining shelf life will be [**].

e. Use of product by the USG

With respect to any product released from the SNS for the purpose of being provided to other BioShield contractors the USG agrees that it will exhaust all inventory from product delivered under contract HHSO1002006000019C (covered under P.L. 85-804).

At such time as the product delivered under contract HHS01002006000019C has expired (expected [**]), the USG will refer all BioShield contractors to Emergent for the purchase of AVA at fair and reasonable price, but not greater than $[**] per dose.

Notwithstanding, the terms of this clause, if the contractor does not permit the sale of AVA to any BioShield contractor, the USG can provide the product to any BioShield contractor.

f. Subcontracts

The contractor shall submit all subcontracts with respect to PEP and extended expiry to the Contracting Officer.

g. Data Rights

Data provided by or obtained from the contractor shall be solely for the purposes of negotiation and award of this contract. All such data shall be proprietary and confidential and, except or unless required by federal law, shall not be distributed outside of the USG without the advance written consent of the contractor.

Section C. Statement of Work

C.1 Vaccine Production and cGMP Compliance:

a) The Contractor shall manufacture BioThrax? in accordance with current Good Manufacturing Practices (cGMP) guidelines. The Contractor shall manufacture 18.75 million doses of Final Drug Product (FDP) in 5 mL, ten dose vials in accordance with the delivery schedule.

b) BioThrax® shall be shipped within one week of the scheduled shipment date in accordance with the delivery schedule in C.2, unless otherwise approved by the Contracting Officer.

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

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

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

f) The Contractor shall provide BARDA 48 hours to review and comment (prior to the contractor summiting a document to the FDA), on submissions to FDA with regards to four-year dating, five- year dating, and PEP, with confidentiality restrictions and or redactions as applicable.

g) The Contractor will be subject to quarterly inspections by the Project Officer or the Project Officer designee(s).

h) The contractor shall use industry standards to pursue FDA approval for Post Exposure Prophylaxis (PEP) indication for BioThrax® during the period of performance of this contract. The prices in these CLINs (0005-0011) will be paid in accordance with the milestone schedule set forth in Section F.3 (b).

i) The contractor shall use best commercially reasonable efforts to obtain FDA approval for a 4 year expiration dating for BioThrax® during the period of performance of this contract.

j) The contractor shall use industry standards to pursue FDA approval for a 5-year expiration dating for BioThrax® during the period of performance of this contract.

k) The contractor shall obtain an acceptable Cost Accounting Standards (CAS) system within [**] months of contract award.

l) The product shall be delivered and shipped in accordance with cGMP (current Good Manufacturing Practices). The USG shall make payment for shipping to the SNS as set forth in CLIN 0014.

C.2 Delivery Schedule:

a) The contractor shall ship BioThraxâ to the SNS in accordance with Section B.5.c (Range of Doses), F.2 (Place and Method of Delivery), and within one week of the established delivery dates in Attachment #6 (Estimated Delivery Schedule) in Section J.

b) The USG shall make payments for shipping set forth in CLIN 0014

C.3 Audits/Site Visits:

a) Security: The USG shall perform a pre-award security audit and security audits as deemed necessary by the USG through the period of performance of the contract.

b) Quality: The USG shall perform a pre-award quality audit, and quality audits on a quarterly basis or as deemed necessary by the USG through the period of performance of the contract.

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

d) All audits shall be conducted between 8am and 6pm Monday through Friday.

C.4 Monthly Meetings:

The contractor shall participate in a monthly meeting (teleconference) to discuss performance under the contract. The meetings will be scheduled by the Project Officer or Contracting Officer.

C.5 Reporting Requirements:

See Section F.4

Section D – Packaging and Marking

D.1 Method of Delivery

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

D.2 Packaging

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

Section E – Inspection and Acceptance

FAR Source	Title and Date
FAR Clause 52.243-1	Changes – Fixed Price (Aug 1987)
FAR Clause 52.246-1	Contractor Inspection Requirements (Apr 1984)
FAR Clause 52.246-2	Inspection of Supplies – Fixed Price (Aug 1996)
FAR Clause 52.246-16	Responsibility of Supplies (Apr 1984)

E.1 Inspection and Acceptance (July 1999)

Inspection and acceptance of the articles, services, and documentation called for herein shall be accomplished by the Contracting Officer, or his duly authorized representative (who for the purposes of this contract shall be the Project Officer) at the destination of the articles, services or documentation.

Section F - Deliveries or Performance

FAR Source	Title and Date
FAR Clause 52.211-17	Delivery of Excess Quantities (Sept 1989)
FAR Clause 52.242-15	Stop Work Order (Aug 1989)
FAR Clause 52.242-15, Alt 1	Stop Work Order, Alternate 1 (Apr 1984)
FAR Clause 52.242-17	Government Delay of Work (Apr 1984)
FAR Clause, 52.247-34	FOB Destination (Nov 1991)

F.1 Period of Performance

The base period of performance of this contract is September 25, 2007 – September 24, 2010.

F. 2. Place and Method of Delivery

The delivery of this **BioThrax**®product shall be F.O.B. Destination to the SNS.

F.3 Contract Deliverables

a. The following deliverables are applicable to CLIN 0001-0004:

1) 18,750,000 doses of BioThrax® in accordance with the statement of work.

b. The following deliverables are applicable to CLIN 0005-0011:

The contractor shall submit a strategy for achieving a Post Exposure Prophylaxis Indication and once upon attaining an FDA approval for Post Exposure Prophylaxis (PEP) provide a copy of the approval notice to the Contracting Officer.

Milestone #1- Submission of Final Study Report (FSR) for Clinical Trial [**]
Milestone #2- Submission of FSR for [**] Studies 1&2 [**]
Milestone #3- Submission of FSR for [**] Study 1: [**]
Milestone #4- Submission of FSR for [**] Study 2: [**]
Milestone #5- Submission of FSR Clinical Trial: [**]
Milestone #6- Submission of BLA, [**]
Milestone #7- FDA Approval, [**]

c. The following deliverables are applicable to CLIN 0012:

1) The contractor shall submit a copy of the FDA approval documentation for 5 year expiry dating.

d. The following deliverables are applicable to CLIN 0013:

1) The contractor shall submit a letter to the Contracting Officer within [**] months of award confirming compliance and implementation of CAS.

e. The following deliverables are applicable to CLIN 0014:

1) invoice

F.4 Reporting Requirements

The Contractor shall submit to the Contracting Officer and to the Project Officer progress reports covering the work accomplished during each reporting period. These reports are subject to the technical inspection and requests for clarification by the Project Officer. These shall be brief and factual and prepared in accordance with the following format:

(1) Monthly Progress Reports: On the tenth of each month, the Contractor shall submit a monthly progress report to the Project Officer and the Contracting Officer. A monthly report will not be required for the period when the final report is due. The Contractor shall submit one copy of the monthly progress report electronically via e-mail. Any attachments to the e-mail report shall be submitted in Microsoft Word or WordPerfect 9 or compatible version. Such reports shall include the following specific information:

a. The contract number and title, the period of performance being reported, the contractor's name and address, the author(s), and the date of submission;
b. Section I – An introduction covering the purpose and scope of the contract effort;
c. Section II – The report shall detail, document, and summarize the results of work done in performance of

requirements of this contract during the period covered, and include a summary of work planned for the next reporting period. Production capacity assessment problems and recommendations to include:

i. Raw material procurement status;
ii. Inventory report of product manufactured and delivered to the USG under this contract;
iii. Quality control testing and purity;
iv. Quality control potency assessment;
v. FDA inspections and consultation results or recommendations;
vi Security assessment, problems and recommendations;
vii. Physical storage monitoring and calibration reports for manufactured products.
viii. Overall project assessment, problems encountered and recommended solutions, etc.
ix. Status of seeking a PEP indication
x. Status of seeking 4 year dating

d. Section III – An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if behind planned progress, what corrective steps are planned. The project plan and delivery schedule will be updated in each Quarterly Report and compared to the baseline plan and delivery schedule.

(2) Risk Mitigation Plan: The contractor shall submit a risk mitigation plan 90 days after contract award and shall update an updated plan on the anniversary of the contract award.

(3) Final Report: A final report is due 30 days prior to the end of the period of performance of the contract.

The Contractor shall deliver, within the time frames specified above, an original to the Contracting Officer and a copy to the Project Officer at the address shown on the face page of the contract, Block 9.

F.5 Excusable Delay

The contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. Furthermore, the Contractor will not be in default under this contract if it is unable to deliver AVA doses in accordance with any delivery schedule because of the action or inaction of the FDA, except to the extent that such action or inaction is a direct consequence of the negligence or willful misconduct of the Contractor. Additionally, the Contractor will not be in default of this contract in the event that deliveries are delayed as a result of another Government agency placing an order for AVA doses that is determined to have priority over this contract under the Defense Priority Allocation System or under any other reasonable legal justification. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement or any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch and shall promptly give written notice of the Contracting Officer of the cessation of such occurrence.

Section G – Contract Administration

G.1 Project Officer (Jul 1999)

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

Dr. Gerald R. Kovacs

Performance of the work hereunder shall be subject to the technical directions of the designated Project Officer for this contract.

As used herein, technical directions are directions to the Contractor, which fill in details, suggests possible lines of inquiry, or otherwise completes the general scope of work set forth herein. These technical directions must be within the general scope of work, and may not alter the scope of work or cause changes of such a nature as to justify an adjustment in the stated contract price/cost, or any stated limitation thereof. In the event that the Contractor feels that full implementation of any of these directions may exceed the scope of the contract, he or she shall notify the originator of the technical direction and the Contracting Officer in a letter separate of any required report(s) within two (2) weeks of the date of receipt of the technical direction and no action shall be taken pursuant to the direction. If the Contractor fails to provide the required notification within the said two (2) week period that any technical direction exceeds the scope of the contract, then it shall be deemed for purposes of this contract that the technical direction was within the scope. No technical direction, nor its fulfillment, shall alter or abrogate the rights and obligations fixed in this contract.

The Government Project Officer is not authorized to change any of the terms and conditions of this contract. Changes shall be made only by the Contracting Officer by properly written modification(s) to the contract. Any changes in Project Officer delegation will be made by the Contracting Officer in writing with a copy being furnished to the Contractor.

(End of Clause)

G.2 Payment by Electronic Funds Transfer – Central Contractor Registration or 52.232-33, Payment by Electronic Funds Transfer – Other than. (Mar 2004)

a) The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-34, Payment by Electronic Funds Transfer in Section I, requires the contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.
b) The contractor shall make the designation by submitting the form titled “ACH Vendor/Miscellaneous Payment Enrollment Form” to the address indicated below. Note: The form is either attached to this contract (see Section J, List of Attachments) or may be obtained by contacting the Contracting Officer.
c) In cases where the contractor has previously provided such designation, i.e., pursuant to a prior contract/order, and been enrolled in the program, the form is not required.
d) The completed form shall be mailed after award, but no later than 14 calendar days before an invoice is submitted, to the following address:

G.3 Invoice Submission (Jul 1999)

(a) The Contractor shall submit an original and three copies of contract invoices to the address shown below:

DHHS/OS/ASPR/BARDA
Attn.: Brian K. Goodger, Contracting Officer
330 Independence Ave., S.W.
Room G640
Washington, D.C. 20201

(b) The Contractor agrees to include (as a minimum) the following information on each invoice:

(1) Contractor’s Name & Address
(2) Contractor’s Tax Identification Number (TIN)
(3) Contract Number
(4) Invoice Number
(5) Invoice Date
(6) Contract Line Item Number
(7) Quantity
(8) Unit Price & Extended Amount for each line item
(9) Total Amount of Invoice
(10) Name, title and telephone number of person to be notified in the event of a defective invoice
(11) Payment Address, if different from the information in (c)(1).

(End of Clause)

G.4 Evaluation of Contractor Performance (Service) (Jan 2000)

(a) *Purpose:* In accordance with FAR 42.1502, the contractor's performance will be periodically evaluated by the government, in order to provide current information for source selection purposes. These evaluations will therefore be marked "Source Selection Information."

(b) *Performance Evaluation Period*: The contractor's performance will be evaluated at least annually.

(c) *Evaluators* : The performance evaluation will be completed jointly by the Project officer and the Contracting officer.

(d) *Performance Evaluation Factors*: The contractor's performance will be evaluated in accordance with the attachment listed in Section J titled Performance Evaluation Report.

(e) *Contractor Review*: A copy of the evaluation will be provided to the contractor as soon as practicable after completion of the evaluation. The contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 30 calendar days after receipt of the evaluation.

(f) *Resolving Disagreements Between the Government and the Contractor*: Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, contractor's response, and review comments, if any, will be retained as part of the evaluation.

(g) *Release of Contractor Performance Evaluation Information*: The completed evaluation will not be released to other than Government personnel and the contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the contractor being evaluated as well as impede the efficiency of Government operations.

(h) *Source Selection Information*: Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

(i) *Retention Period*: The agency will retain past performance information for a maximum period of three years after completion of contract performance for the purpose of providing source selection information for future contract awards.

(End of Clause)

G.5 Contracting Officer (Jul 1999)

(a) 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.

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

(End of Clause)

G.6 Contract Communications/Correspondence (Jul 1999)
The contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number from Page 1 of the contract.
(End of Clause)

G.7 Notice Prior to Publication

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Contracting Officer; provided however, that no such notice is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity; for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to 3rd parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. .

G.8 Press Releases

1. Pursuant to Public Law(s) cited in paragraph (2), below, 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: the percentage of the total costs of the program or project which will be financed with Federal money; the dollar amount of Federal funds for the project or program; and the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

2 Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-447 , Title V - General Provisions, Section 506	2007	10/1/06 - 9/30/07

G.9 Reporting Matters Involving Fraud, Waste, and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH 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

G.10 Notification of Utilization

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

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

Section H – Special Contract Requirements

H.1 Prohibition on the Use of Appropriated Funds for Lobbying Activities (Jul 1999)

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, 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.

(End of Clause)

H.2 Representations, Certifications and Other Statements of Offerors (Jul 1999)
The Representations, Certifications and Other Statements of Offerors submitted by Emergent BioDefense dated 8/6/07 are hereby incorporated by reference, with the same force and effect as if they were given in full text.

(End of Clause)

H.3 Privacy Act Applicability (Apr 2000)

(a) 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

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

(c) The contractor shall follow the Privacy Act guidance as contained in the Privacy Act system notice to be provided by the Government (See Section J, List of Attachments).

(End of Clause)

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

H.4 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.

(End of Clause)

H.5 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 Project Officer, which approval shall not be unreasonably withheld, conditioned, or delayed; provided, however, that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

(End of Clause)

H.6 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 relevant to this contract. The contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.7 Incorporation of Technical Proposal (May 1998)
The contractor's Technical Proposal included in its Final Proposal Revision dated 8/6/07, along with subsequent change pages dated 8/15/07 & 8/21/07 submitted in response to RFP HHS-OPHEMC-VB-07-02, and contractor's final proposal revision dated 9/24/07 is hereby incorporated into the contract by reference. The contractor shall perform the work substantially as set forth in the technical proposal. Any revisions to the technical proposal that would significantly alter the technical approach must be approved in writing by the Contracting Officer. In the event of a conflict between Section C, Statement of Work, and the Contractor's technical proposal, Section C will take precedence.
(End of Clause)

H.8 Year 2000 Compliance (Jul 1999)
Unless elsewhere exempted, information technology (if any) to be acquired under this contract/purchase order, which will be required to perform date/time processing involving dates subsequent to December 31, 1999, shall be Year 2000 compliant as defined in Federal Acquisition Regulation Part 39.002.

(End of Clause)

H.9 Security Plan Requirements

The work performed at the contractor's facility for manufacturing, storage, and distribution will be performed under a detailed security plan that ensures against theft, tampering or destruction of the BioThrax® and documents pertaining to the BioThrax®. The contractor shall develop a written Security Plan, for the protection of physical facilities, using for example, fencing, controlled access, surveillance equipment, 2-person integrity rule, tamper evident packaging, and armed guards. The Security Plan shall describe the procedures to be utilized to control the general internal operations of the firm and a description of contractor's facility(ies) in which the work will be performed-including any subcontractors. Also, the contractor shall submit to the government a list of all employees involved in production under this contract. This list shall include the employee's full name, date of birth, and Social Security number. The government shall retain this list in confidence, and use it only to compare the information contained therein against the government's list or lists of known or suspected terrorists or threats. The Security Plan shall also include the contractor's plans for conducting background investigations for all employees and subcontractors who will have access to the manufacturing and storage of the BioThrax®.

This plan shall ensure confidentiality and integrity of and timely access by authorized individuals to data, information and information technology systems, and consistent with OMB Circular A-130, Appendix III. This plan shall include the security measures to be used to protect the BioThrax® to be stored at the contractor's facility (e.g., refrigeration/freezer alarm systems, backup electrical power generator systems, etc.), and the contingency plan to accommodate any manufacturing and storage problems caused by natural or man-made disasters, power loss, refrigerant loss, equipment failures, etc.

Performance of work under this contract shall be in accordance with this written Security Plan.

H.10 Protection of Human Subjects

(a) No contract involving human subjects research shall be awarded until acceptable assurance has been given that the project or activity will be subject to initial and continuing review by an appropriate institutional review committee(s) as described in 45 CFR Part 46. Contracts involving human subjects will not be awarded to an individual unless the individual is affiliated with or sponsored by an institution that has an Office for Human Research Protections (OHRP) approved assurance of compliance in place and will assume responsibility for safeguarding the human subjects involved. The OHRP web site is: http://www.hhs.gov/ohrp. 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 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 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 performance of this contract, the Contracting Officer determines, in consultation with the OHRP, that the contractor if 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 such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing.

(d) 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, terminate this contract in whole or in part, and the contractor name may be removed from the list of those contractors with approved Health and Human Services Human Subject Assurances.

H.11 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. The USDA office contact information is available at http://www.aphis.usda.gov/ac/acorg.html . They are 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/usdaleg1.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 .

H.12 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 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.

H.13 Care of Live Vertebrate Animals

1	Before undertaking performance of any contract involving research on live, vertebrate animals, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30. The contractor shall furnish evidence of such registration to the Contracting Officer.
2	The contractor shall acquire animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2131-2157 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.
3	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 and 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 1-3). In case of conflict between standards, the more stringent standard shall be used.
4	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 (1) through (3) 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 Public Health Service Animal Welfare Assurances.

The contractor may request registration of its facility and a current listing of licensed dealers from the Animal Care Sector Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the sector 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: Animal Care Staff USDA/APHIS 4700 River Road, Unit 84 Riverdale, MD 20737 (301) 734-4980. Contractors proposing research that involves live, vertebrate animals will be contacted by OLAW and given detailed instructions on filing a written Animal Welfare Assurance with the PHS. Contractors are encouraged to visit the OLAW website at http://grants.nih.gov/grants/olaw/olaw.htm for additional information. OLAW may be contacted at the National Institutes of Health at (301) 594-2289.

H.14 Approval of Required Assurance by OLAW

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Office of Research & Development Coordination (ORDC) 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 independent 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/olawaddr.htm .

H.15 Liability Protection under the PREP Act

The Public Readiness & Emergency Preparedness Act (PREP Act), Pub. L. 109-148, Division C, 119 Stat. 2818 to 2832, amended the Public Health Service Act, 42, U.S.C. 243 et seq., to provide targeted liability protections. The Government agrees that the medical countermeasure delivered by the contractor under this contract will not be administered in humans, unless the Secretary executes a declaration in accordance with section 319F-3(b) of the Public Health Service Act, 42, U.S.C. 247-d-6d, that the medical countermeasure delivered under this contract is a covered countermeasure to which section 319-F3(a) applies subject to the terms and conditions of the declaration.

H.16 Manufacturing Standards

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

If at any time during the life of the contract, the Contractor fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by CBER and CDER, the contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such

material failure. If the contractor fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

H.17. Prohibition on Contractor Involvement with Terrorist Activities

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

H.18 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 OPHEMC, 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 individuals 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 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 – CONTRACT CLAUSES

Section I – CONTRACT CLAUSES

I.1. 52.212-4 Contract Terms and Conditions - Commercial Items (Jul 2005) is incorporated by reference.

I.2. 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (Jul 2005)

CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—COMMERCIAL ITEMS (JUNE 2007)

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

(1) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).
(2) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Pub. L. 108-77, 108-78)

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

[*Contracting Officer check as appropriate.*]

X (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Jul 1995), with Alternate I (Oct 1995) (41 U.S.C. 253g and 10 U.S.C. 2402).
__ (2) 52.219-3, Notice of Total HUB Zone Set-Aside (Jan 1999) (15 U.S.C. 657a).
__ (3) 52.219-4, Notice of Price Evaluation Preference for HUB Zone Small Business Concerns (July 2005) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
__ (4) removed
__ (ii) Alternate I (Mar 1999) of 52.219-5.
__ (iii) Alternate II (June 2003) of 52.219-5.
__ (5) (i) 52.219-6, Notice of Total Small Business Set-Aside (June 2003) (15 U.S.C. 644).
__ (ii) Alternate I (Oct 1995) of 52.219-6.
__ (iii) Alternate II (Mar 2004) of 52.219-6.
__ (6) (i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644).
__ (ii) Alternate I (Oct 1995) of 52.219-7.
__ (iii) Alternate II (Mar 2004) of 52.219-7.
X (7) 52.219-8, Utilization of Small Business Concerns (May 2004) (15 U.S.C. 637(d) (2) and (3).
X (8) (i) 52.219-9, Small Business Subcontracting Plan (July 2005) (15 U.S.C. 637(d) (4).
__ (ii) Alternate I (Oct 2001) of 52.219-9.
__ (iii) Alternate II (Oct 2001) of 52.219-9.
__ (9) 52.219-14, Limitations on Subcontracting (Dec 1996) (15 U.S.C. 637(a) (14).
__ (10) 52.219-16 Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637 (d)(4)(f)(i)
__ (11) (i) 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (July 2005) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323) (if the offeror elects to waive the adjustment, it shall so indicate in its offer).
__ (ii) Alternate I (June 2003) of 52.219-23.
__ (12) 52.219-25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting (Oct 1999) (Pub). L. 103-355, section 7102, and 10 U.S.C. 2323).
__ (13) 52.219-26, Small Disadvantaged Business Participation Program—Incentive Subcontracting (Oct 2000) (Pub). L. 103-355, section 7102, and 10 U.S.C. 2323).
__ (14) 52.219-27, Notice of Total Service-Disabled Veteran-Owned Small Business Set-Aside (May 2004).
__ (15) 52.219-28, Post Award Small Business Program Representative (June 2007) (15 U.S.C. 632(a)(2)
X (16) 52.222-3, Convict Labor (Jun 2003) (E.O. 11755)
X (17) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (June 2004) (E.O. 13126).
X (18) 52.222-21, Prohibition of Segregated Facilities (Feb 1999).
X (19) 52.222-26, Equal Opportunity (Apr 2002) (E.O. 11246).
X (20) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans

(Dec 2001) (38 U.S.C. 4212).

X (21) 52.222-36, Affirmative Action for Workers with Disabilities (Jun 1998) (29 U.S.C. 793).

(22) 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
X (Dec 2001) (38 U.S.C. 4212).

__ (23) 52.222-39, Notification of Employee Rights Concerning Payment of Union Dues or Fees (Dec 2004) (E.O. 13201).

(24) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (Aug 2000)
__ (42 U.S.C. 6962(c) (3) (A) (ii)).

__ (ii) Alternate I (Aug 2000) of 52.223-9 (42 U.S.C. 6962(i) (2) (C)).

__ (25) 52.225-1, Buy American Act—Supplies (June 2003) (41 U.S.C. 10a-10d).

(26) (i) 52.225-3, Buy American Act—Free Trade Agreements—Israeli Trade Act (Jan 2005) (41 U.S.C. 10a-10d,
__ 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, Pub. L. 108-77, 108-78, 108-286).

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

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

__ (27) 52.225-5, Trade Agreements (Jan 2005) (19 U.S.C. 2501, *et seq* ., 19 U.S.C. 3301 note).

(28) 52.225-13, Restrictions on Certain Foreign Purchases (Mar 2005) (E.o.s, proclamations, and statutes administered by the
__ Office of Foreign Assets Control of the Department of the Treasury).

___ (29) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (42 U.S.C. 5150)

___ (30) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area.

___ (31) 52.232-29, Terms for Financing of Purchases of Commercial Items (FEB 2002) (41 U.S.C. 255(f), 10 U.S.C. 2307 (f)

__ (32) 52.232-30, Installment Payments for Commercial Items (Oct 1995) (41 U.S.C. 255(f), 10 U.S.C. 2307(f)).

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

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

__ (35) 52.232-36, Payment by Third Party (May 1999) (31 U.S.C. 3332).

__ (36) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

__ (37) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Apr 2003)
(46 U.S.C. App. 1241 and 10 U.S.C. 2631).

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

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

[*Contracting Officer check as appropriate.*]

__ (1) 52.222 41, Service Contract Act of 1965, as Amended (July 2005) (41 U.S.C. 351, *et seq* .).
__ (2) 52.222 42, Statement of Equivalent Rates for Federal Hires (May 1989) (29 U.S.C. 206 and 41 U.S.C. 351, *et seq* .).
__ (3) 52.222 43, Fair Labor Standards Act and Service Contract Act—Price Adjustment (Multiple Year and Option Contracts) (May 1989) (29 U.S.C. 206 and 41 U.S.C. 351, *et seq* .).
__ (4) 52.222 44, Fair Labor Standards Act and Service Contract Act—Price Adjustment (Feb 2002) (29 U.S.C. 206 and 41 U.S.C. 351, *et seq* .).

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

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

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

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

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

(i) 52.219-8, Utilization of Small Business Concerns (May 2004) (15 U.S.C. 637(d) (2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(ii) 52.222-26, Equal Opportunity (Apr 2002) (E.O. 11246).

(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Dec 2001) (38 U.S.C. 4212).

(iv) 52.222-36, Affirmative Action for Workers with Disabilities (June 1998) (29 U.S.C. 793).

(v) 52.222-39, Notification of Employee Rights Concerning Payment of Union Dues or Fees (Dec 2004) (E.O. 13201).

(vi) 52.222-41, Service Contract Act of 1965, as Amended (July 2005), flow down required for all subcontracts subject to the Service Contract Act of 1965 (41 U.S.C. 351, *et seq* .).

(vii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Apr 2003) (46 U.S.C. App. 1241 and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64

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

Alt 1 (FEB 2000). As prescribed in 12.301(b)(4), delete paragraph (d) from the basic clause, re-designate paragraph (e) as paragraph (d), and revise the reference to "paragraphs (a), (b), (c), or (d) of this clause in the re-designated paragraph (d) to read "paragraphs (a), (b), and (c) of this clause".

I.2. HHSAR Addenda

Department of Health & Human Services Acquisition Regulation (HHSAR) (48 CFR CHAPTER 3) Clauses

HHSAR

Clause No.	Title	Date
1. HHSAR 352.202-1	Definitions	Jan-01
2. HHSAR 352.223-70	Safety and Health	Jan-06
3. HHSAR 352.224-70	Confidentiality of Information	Jan-06
4. HHSAR 352.232-9	Withholding of Contractor Payments	Apr-84
5. HHSAR 352.270-4	Pricing of Adjustments	Jan-01
6. HHSAR 352.270-5	Key Personnel	Jan-06
7. HHSAR 352.270-6	Publication & Publicity	Jul-91
8. HHSAR 352.270-7	Paperwork Reduction Act	Jul-91
9. HHSAR 352.270-8	Protection of Human Subjects	Jan-06

Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this clause.

10. HHSAR 352.270-9	Care of Live Vertebrate Animals	Jan-06
11. HHSAR 352.270-10	Anti-Lobbying	Jan-06

I.3. FAR Addenda

Federal Acquisition Regulation (FAR) (48 CFR CHAPTER 1) Clauses

FAR

Clause No.	Title	Date
1. FAR 52.243-1	Changes-Fixed Price	Aug-87
2. FAR 52.249-2	Termination for Convenience of the Government (fixed price)	May-04
3. FAR 52.249-8	Default (fixed price supply and Service) (over $100,000)	Apr-84

PART III – List of Documents, Exhibits, and other attachments

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

1 Summary of Related Activities
2 Protection of Human Subjects
3 Disclosure of Lobbying Activities
4 Invoice Instructions for Fixed Price Contracts
5 Performance Evaluation Report
6 Detailed Delivery Schedule
ACH Vendor/Miscellaneous Payment Enrollment
7 Form
8 Subcontracting Plan

Summary of Related Activities for Post-Exposure Prophylaxis Development Program

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

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

Name and Title/Position: [**]

Identifying Number	Agency	Effort Committed
1. 1 R34AI070321-01	NIH	15%
2. HHSN272200700034C	NIH	25%

Name and Title/Position: [**]

Identifying Number	Agency	Effort Committed
1. 1 U01AI060624-01	NIH	10%
2. HHSN272200700034C	NIH	10%

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

The following Key Personnel have no current obligations: [**]

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

Name and Title/Position: [**]

Identifying Number	Agency	Effort Committed
1. 1 R34AI072046-01	NIH	15%
2. 1 U01AI070486-01	NIH	5%

Name and Title/Position: [**]

Identifying Number	Agency	Effort Committed
1. 1 U01AI070486-01	NIH	5%

Name and Title/Position: [**]

Identifying Number	Agency	Effort Committed
1. 1 R34AI072046-01	NIH	10%
2. 1 U01AI070486-01	NIH	25%

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

The following Key Personnel have no current obligations.

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

Name	Title/Position	Proposed Effort
1. [**].	[**]	10%
2. [**]	[**]	10%
3. [**]	[**]	20%

Summary of Related Activities for Five Year Expiry Program

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

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

Name and Title/Position: [**]

Identifying Number	Agency	Effort Committed
1. DAMD17-97-D-0003	DoD	25%
2. W9113M-04-D-0002	DoD	25%

Name and Title/Position: [**]

Identifying Number	Agency	Effort Committed
1. DAMD17-97-D-0003	DoD	25%
2. W9113M-04-D-0002	DoD	25%

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

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

Name and Title/Position: [**]

Identifying Number	Agency	Effort Committed
1. W9113M-06-R-0016	DoD	25%

Name and Title/Position: [**]

Identifying Number	Agency	Effort Committed
1. W9113M-06-R-0016	DoD	25%

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

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

Name	Title/Position	Proposed Effort
1. [**]	[**]	10%
2. [**]	[**]	10%

OMB No. 0990-0263
Approved for use through 11/30/2008

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

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

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[X] ORIGINAL [ ] CONTINUATION [ ] EXEMPTION	[ ] GRANT [X] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:_____	FDA, IND# 13068 Western IRB, Olympia, Washington, IRB # 00000533
4. Title of Application or Activity Protocol AVA.005; Immunogenicity Study of A Three – Dose Subcutaneous Biothrax® Regimen for Post-Exposure Prophylaxis in Healthy Adults		5. Name of Principal Investigator, Program Director, Fellow, or Other Robert Hopkins, Program Director Peter Rogge MD, Principal Investigator Serena Mraz MD, Principal Investigator Scott Parker MD, Principal Investigator Richard Greenburg MD, Principal Investigator Frank Hampel, MD, Principal Investigator

6. Assurance Status of this Project *(Respond to one of the following)*

[ ] This Assurance, on file with Department of Health and Human Services, covers this activity.
Assurance Identification No._____, the expiration date_____ IRB Registration No. _____

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

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

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

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

[ ] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [X] Full IRB Review on (date of IRB meeting) 14 –June-2006 or [ ] Expedited Review on (date)
[ ] If less than one year approval, provide expiration date _____
[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments
FWA # was not requested as this clinical study as it is not federally funded. Registration of this study is filed with FDA, IND # 13068 and has been reviewed by, Western IRB, Olympia, Washington IRB review#: IRB00000553

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.		10. Name and Address of Institution Emergent BioSolutions, Inc. 300 Professional Drive, Suite 100 Gaithersburg, MD 20879
11. Phone No. *(with area code)*	301-994-0136	
12. Fax No. *(with area code)*	301-590-1252	
13. Email:	hopkinsr@ebsi.com	
14. Name of Official Robert Hopkins, MD, MPH & T.M.		15. Title Vice President, Clinical Development
16. Signature /s/ Robert Hopkins		17. Date 5/23/07

Authorized for local Reproduction Sponsored by HHS

Approved by OMB

0348-0046

Disclosure of Lobbying Activities

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352

(See reverse for public burden disclosure)

1. Type of Federal Action: __a__ a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	**2.** Status of Federal Action: __a___ a. bid/offer/application b. initial award c. post-award	**3.** Report Type: __a___ a. initial filing b. material change For material change only: Year _____ quarter _____ Date of last report_____
4. Name and Address of Reporting Entity: __x__ Prime _____ Subawardee Tier_____, if Known: Congressional District, *if known*: 4c	**5.** If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime: N/A Congressional District, *if known*:	
6. Federal Department/Agency: DHHS/OS/ASPR/OPHEMC	**7.** Federal Program Name/Description: CFDA Number, *if applicable*: _____	
8. Federal Action Number, *if known*: HHS-OPHEMC-VB-07-02	**9.** Award Amount, *if known*: $Under negotiation	
10. a. Name and Address of Lobbying Registrant *(if individual, last name, first name, MI)*: See Attached Schedule	b. Individuals Performing Services *(including address if different from No. 10a)* *(last name, first name, MI)*: See Attached Schedule	
11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.	Signature: /s/ Allen M. Shofe Print Name: Allen M. Shofe Title: Vice President, Public Affairs Telephone No.: 202-315-5113 Date: 09/20/2007	
Federal Use Only	Authorized for Local Reproduction Standard Form - LLL (Rev. 7-97)	

Schedule A to Form LLL
Solicitation Number HHS-OPHEMC-VB-07-02
September 20, 2007

Registrant	Lobbyists
Dalrymple & Associates 1926 N Street N.W. 3rd Floor Washington, DC 20007	Dalrymple, Dack
DC Navigators 901 7th Street, Ste. 200 Washington, DC 20001	Anderson, Philmore B. Christie, Ron Conda, Ceasar V. Cox, Christopher C. Pitts, Jim
Hecht, Spencer & Associates, Inc. 499 South Capitol Street, S.W., Ste 507 Washington, DC 20003	Hecht, William H. Hecht, Timothy P. Phifer Jr, Franklin C. Spencer, Stuart
The OB-C Group, LLC 1350 Eye Street, N.W. Washington, DC 20005	Johnson, Michael S. Keating, Thomas J. Marsh, Robert H. Mellody, Charles J.
Pillsbury Winthrop Shaw Pittman LLP 2300 N Street, N.W. Washington, DC 20037	Cannon, Joseph
McKenna Long & Aldridge LLP 1900 K Street Washington, DC 20006	Clerici, John Farry, Douglas Schwarz, David

Attachment # 04

INVOICE INSTRUCTIONS FOR FIXED-PRICE CONTRACTS.

General The contractor shall submit vouchers or invoices as prescribed herein.

Format Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form 1035, Public Voucher for Purchases and Services Other than Personal--Continuation Sheet, or the payee's letterhead or self-designed form should be used to submit claims for reimbursement.

Number of Copies As indicated in the contract.

Frequency Invoices submitted in accordance with the Payment Clause shall be submitted upon delivery of goods or services unless otherwise authorized by the contracting officer.

Preparation and Itemization of the Invoice The invoice shall be prepared as follows:

(a) Designated Billing Office and address:

HHS/OPHEP/ORDC
200 Independence Ave, Room 636G
Washington DC 20201
ATTN: Contract Specialist

(b) Invoice Number
(c) Date of Invoice
(d) Contract number and date
(e) Payee's name and address. Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.
(f) Description of goods or services, quantity, unit price, (where appropriate), and total amount.
(g) Charges for freight or express shipments other than F.O.B. destination. (If shipped by freight or express and charges are more than $25, attach prepaid bill.)
(h) Equipment If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain a statement indicating that no item of equipment was purchased or include a completed form HHS-565, Report of Capitalized Nonexpendable Equipment.

Currency Where payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States 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.

BioMedical Advanced Research & Development Authority (BARDA)
Contractor Performance Report

FINAL REPORT INTERIM REPORT

REPORTING PERIOD: (from) September 25, 2007 (to) September 24, 2008

CONTRACTING OFFICE (ICD, Location): DHHS/OS/ASPR/BARDA
Room G640
330 Independence Ave S.W.
Washington, D.C. 20201

CONTRACT NUMBER: HHSO100200700037C
CONTRACTOR'S NAME: Emergent BioDefense
ADDRESS: 3500 N. Martin Luther King, Jr. Blvd.
Lansing, MI 48906-2933
CONTRACT AWARD DATE: September 25, 2007

CONTRACT EXPIRATION DATE: September 24, 2010

CONTRACT VALUE: $446,650,001

DESCRIPTION OF REQUIREMENT (Title): "Anthrax Vaccine Adsorbed (AVA) for the S*trategic National Stockpile"*

RATINGS

Summarize contractor performance and Bold and Enlarge the number that corresponds to the rating for each rating category. (See attached Rating Guidelines) and provide comments to support the rating.

1. QUALITY OF PRODUCT OR SERVICE Rating 0 1 2 3 4 5

Comments:

2. COST CONTROL Rating 0 1 2 3 4 5
Comments:

3. TIMELINESS OF PERFORMANCE Rating 0 1 2 3 4 5

Comments:

4. BUSINESS RELATIONS Rating 0 1 2 3 4 5

Comments:

5. SUBCONTRACTS (Bold and Enlarge one)

Are subcontracts involved? Yes or No (bold one)

Comments:

6. KEY PERSONNEL

PROJECT MANAGER/PRINCIPAL INVESTIGATOR *(name)*:
Comments:

7. SMALL BUSINESS SUBCONTRACTING PLAN

Did the Contractor meet the goals set forth in its Subcontracting Plan? (See FAR 15.305(a)(2)(v) and FAR 19.7)
Yes No

Comments: (optional)

8. SMALL DISADVANTAGED BUSINESS GOALS

Did the Contractor meet its small disadvantaged business participation goals? (See FAR 15.305(a)(2)(v) and FAR 19.1202)
Yes No N/A

Comments: (optional)

9. CUSTOMER SATISFACTION (Bold and Enlarge one)

Is/Was the contractor committed to customer satisfaction?
Yes No *(Bold and Enlarge one)*

If this is the Final Report, would you recommend selection of this firm again? Yes No *(Bold and Enlarge one)*

Signature Page Follows

1. HHS PROJECT OFFICER *(name):* Dr. Gerry Kovacs

SIGNATURE: _____ Date _____

2. CONTRACTING OFFICER CONCURRENCE: *(Initial)* ___ Date:___

Brian Goodger

3. CONTRACTOR'S REVIEW:

Were comments or additional information provided?
Yes No *(Circle one)*

If yes, they are:

*On file in:*_____ _____
(Location) *(Phone)*

Attached: (Check if attached)

4. AGENCY REVIEW:

Were contractor comments reviewed at a level above the contracting officer? Yes No *(Circle one)*

If yes, Agency Decision is:

On file in: _____
(Location) *(Phone)*

Attached: (Check if attached)

5. SUMMARY RATINGS:

QUALITY:

COST CONTROL:

TIMELINESS OF PERFORMANCE:

BUSINESS RELATIONS:

7. CONTRACTING OFFICER *(name):*

SIGNATURE: _____ Date: _____
Phone: _____ FAX: _____
Internet Address: _____

Contractor Performance System (CPS)
Rating Guidelines

Quality of Product or Service

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Non-conformances are jeopardizing the achievement of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, it constitutes a significant impediment in consideration for future awards containing similar requirements.
Poor	Overall compliance requires significant Agency resources to ensure achievement of contract requirements.
Fair	Overall compliance requires minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or very minimal, quality problems, and the Contractor has met the contract requirements.
Excellent	There are no quality issues, and the Contractor has substantially exceeded the contract performance requirements without commensurate additional costs to the Government.
Outstanding	The contractor has demonstrated an outstanding performance level that was significantly in excess of anticipated achievements and is commendable as an example for others, so that it justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

Cost Control

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Ability to manage cost issues is jeopardizing performance of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, this level of ability to manage cost issues constitutes a significant impediment in consideration for future awards.
Poor	Ability to manage cost issues requires significant Agency resources to ensure achievement of contract requirements.
Fair	Ability to control cost issues requires minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or very minimal, cost management issues and the Contractor has met the contract requirements.
Excellent	There are no cost management issues and the Contractor has exceeded the contract requirements, achieving cost savings to the Government.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where the contractor achieved cost savings and performance clearly exceeds the performance levels described as "Excellent".

Timeliness of Performance

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Delays are jeopardizing the achievement of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, it constitutes a significant impediment in consideration for future awards.
Poor	Delays require significant Agency resources to ensure achievement of contract requirements.
Fair	Delays require minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or minimal, delays that impact achievement of contract requirements.
Excellent	There are no delays and the contractor has exceeded the agreed upon time schedule.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

Business Relations

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Response to inquiries and/or technical, service, administrative issues is not effective. If not substantially mitigated or corrected it should constitute a significant impediment in considerations for future awards.
Poor	Response to inquiries and/or technical, service, administrative issues is marginally effective.
Fair	Response to inquiries and/or technical, service, administrative issues is somewhat effective.
Good	Response to inquiries and/or technical, service, administrative issues is consistently effective.
Excellent	Response to inquiries and/or technical, service, administrative issues exceeds Government expectation.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

CONTRACTOR PERFORMANCE REPORT INSTRUCTIONS

Block 1: Check the appropriate block to indicate the type of report. The final evaluation of the contractor's performance will satisfy the reporting requirement stipulated in HHSAR 342.7002(c)(2)(iv).

Block 2: Indicate the period covered by the report.

Block 3: List the name of the contracting officer. Identify the contracting officer's Institute and the location of the contracting office.

Block 4: Identify the contract number of the contract being evaluated.

Block 5: List the name and address of the contractor. Identify the specific division or department being evaluated.

Block 6: Indicate the contract award date and contract expiration date.

Block 7: State the contract value, including any option amounts.

Block 8: Provide a brief description of the work being performed under the contract.

Block 9: Using the rating guidelines set forth on page 3, assign each area a rating of 0 (unsatisfactory), 1 (poor), 2 (fair), 3 (good), 4 (excellent), or 5 (outstanding). Provide a brief narrative for each of the categories to support the rating assigned.

Block 10: Indicate whether subcontracts were involved. Briefly summarize the performance of any subcontractors that have major responsibilities under the contract or are required to perform a significant part of the contract requirement.

Block 11: List the name of the principal investigator and the names of other key personnel. Briefly describe the performance of the key personnel listed.

Block 12: Circle the appropriate answer to indicate whether the contractor was successful in meeting the goals set forth in their subcontracting plan.

Block 13: Circle the appropriate answer to indicate whether the contractor met its small disadvantaged business participation goals.

Block 14: Circle the appropriate answer to indicate whether the contractor was committed to customer satisfaction. For the final report, indicate whether you would recommend selection of the firm again.

Block 15: The project officer signs in this block.

Block 16: The contracting officer initials in this block, indicating concurrence with the initial ratings and evaluation.

Block 17: Indicate whether the contractor submitted a rebuttal. Attach a copy of the contractor's rebuttal to this report, or indicate its location, if filed separately.

The contractor signs block 17, indicating review of the evaluation.

Block 18: If the contracting officer and the contractor are unable to agree on a final rating, the matter is to be referred to an individual one level above the contracting officer. Attach a copy of the agency's decision to this report, or indicate its location, if filed separately.

Block 19: Record the ratings from Block 9.

Block 20: The contracting officer signs the report when all actions are completed. If changes were made to the ratings or the narrative during the rebuttal process, a copy of the report, as revised, shall be promptly furnished to the contractor.

Estimated HHS Delivery Schedule 2007-2008

CLIN	Delivery #	Lot	QA Release	Estimated Delivery Date	Expiry Date*	Remaining Expiry (Days)*	Remaining Expiry (Months)*	Doses	Cum Doses	Avg Remaining Expiry Per Clin (Months)*	
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ACH Vendor/Miscellaneous Payment

ENROLLMENT FORM

This form is used for Automated Clearing House (ACH) payments, with an addendum record that contains payment related information processed through the Vendor Express Program. Recipients of these payments should bring this information to the attention of their financial institution when presenting this form for completion.

PRIVACY ACT

The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 U.S.C. 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to vendor's financial institution. Failure to provide the requested information may delay or prevent the receipt of payments through the Automated Clearing House Payment System.

AGENCY INFORMATION		
FEDERAL PROGRAM AGENCY		
AGENCY IDENTIFIER:	AGENCY LOCATION CODE (ALC):	ACH FORMAT:
ADDRESS:		
CONTACT PERSON NAME:		TELEPHONE NUMBER:
ADDITIONAL INFORMATION:		

PAYEE/COMPANY INFORMATION	
NAME Emergent BioDefense Operations Lansing, Inc.	SSN NO. OR TAXPAYER ID NO. 38-3412788
ADDRESS 3500 North Martin Luther King Jr. Boulevard	
Lansing, MI 48906-9910	
CONTACT PERSON NAME: Patrick Staam	TELEPHONE NUMBER: (517) 327-6886

FINANCIAL INSTITUTION INFORMATION	
NAME: Fifth Third Bank	
ADDRESS: 2501 Coolidge Road	
East Lansing, MI 48823	
ACH COORDINATOR NAME: Cheryl Gre isald	TELEPHONE NUMBER: (616) 653-5701
NINE-DIGIT ROUTING TRANSIT NUMBER: 0 1 2 1 0 0 0 5 2	
DEPOSITOR ACCOUNT TITLE: Emergent BioDefense Operation	
DEPOSITOR ACCOUNT NUMBER: [illegible]	LOCKBOX NUMBER:
TYPE OF ACCOUNT: ☒ CHECKING ☐ SAVINGS ☐ LOCKBOX	
SIGNATURE AND TITLE OF AUTHORIZED OFFICIAL: [illegible] ACH [illegible] Mark (illegible), Vice President	TELEPHONE NUMBER: (517) 351-6446

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
SMALL BUSINESS SUBCONTRACTING PLAN

Operating Division (OPDIV): Biomedical Advanced Research and Development Authority (BARDA)

DATE OF PLAN: September 24, 2007
CONTRACTOR: Emergent BioDefense Operations Lansing, Inc.

ADDRESS: 3500 N. Martin Luther King Jr. Blvd. Lansing, MI 48906-9910

DUNN & BRADSTREET NUMBER: [**]

SOLICITATION OR CONTRACT NUMBER: HHS-OPHEMC-VB-07-02

ITEM/SERVICE (Description): The supply of BioThrax® (Anthrax Vaccine Adsorbed) to meet the nation's urgent need to stockpile countermeasures to safeguard against the threat of a deliberate anthrax attack.

TOTAL CONTRACT AMOUNT:

$446,650,001 $446,650,001
Total Cost of Contract Base Period Cost

$ _____N/A_____ $_____N/A_____ $ _____N/A_____ $ ____N/A_____
Option #1 (if applicable) Option #2 (if applicable) Option #3 (if applicable) Option #4 (if applicable)

PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year): Sept 25, 2007 through Sep 24, 2010 (This contract period is equal to the Base Period)

TOTAL MODIFICATION AMOUNT, IF APPLICABLE $ _____N/A_____
TOTAL TASK ORDER AMOUNT, IF APPLICABLE $_____N/A_____
The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this outline has been designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable. **It is not intended to replace any existing corporate/commercial plan that is more extensive.**

Failure to include the essential information of FAR Subpart 19.7 may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor requesting supplies or services required for performance of the contract or subcontract.

If assistance is needed to locate small business sources, contact the OPDIV Small Business Specialist (SBS) at (_____) _____-_____, the Office of Small and Disadvantage Business Utilization (OSDBU) at (202) 690-7300, or visit the OSDBU website (http://www.hhs.gov/osdbu/staff.html). Also, sources may be obtained through the Central Contractor Registration (http://www.ccr.gov/) website.

Please note that the U.S. Department of Health and Human Services (HHS) has subcontracting goals of 25.1% for small business (SB), 5.50% for small disadvantaged business (SDB), 5.05% for women-owned business (WOSB), 3.03% for HubZone business (HUBZone) and 3.00% service disabled veteran-owned small business (SDVOSB) concerns for fiscal year 2007. For this procurement, HHS expects all proposed subcontracting plans to contain the following small business goals, a minimum, ____% for total SB, ____ % for SDB, _____% for WOSB, ____% for HubZone and _____% for SDVOSB concerns. These percentages shall be expressed as percentages of the total estimated subcontracting dollars. **The offeror is required to include an explanation for a category that has zero as a goal.**

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. The contractor must provide a copy of the initial agency approval and must enter an annual SSR into the electronic Subcontracting Reporting System (eSRS) with a breakout of subcontracting prorated for HHS and other Federal agencies.

2. Goals

State separate dollar and percentage goals for Small Business (SB), Small Disadvantaged Business (SDB), Woman-owned Small Business (WOSB), Historically Underutilized Business Zone (HUBZone) Small Business, Service-Disabled Veteran-owned Small Business (SDVOSB) and "Other than small business" (Other) as subcontractors, for the base year and each option year, as specified in FAR 19.704 (break out and append option year goals, if the contract contains option years) or project annual subcontracting base and goals under commercial plans.

a. Total estimated dollar value of ALL planned subcontracting, i.e., with ALL types of concerns under this contract is

$54,000,000 (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ ____N/A_____ $ ____N/A_____ $ ____N/A_____ $ _____N/A_____

b. Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES (including SDB, WOSB, HUBz and SDVOSB): (% of "a") $ 2,700,000 and 5.00% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ ____N/A_____ $ ____N/A_____ $ ____N/A_____ $ _____N/A_____

c. Total estimated dollar value and percent of planned subcontracting with SMALL DISADVANTAGED BUSINESSES: (% of "a") $ 540,000 and 1.00% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ ____N/A_____ $ ____N/A_____ $ ____N/A_____ $ _____N/A_____

d. Total estimated dollar value and percent of planned subcontracting with WOMAN-OWNED SMALL BUSINESSES: (% of "a") $ 1,620,000 and 3.00% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ ____N/A_____$ ____N/A_____$ ____N/A_____$ _____N/A_____

e. Total estimated dollar and percent of planned subcontracting with HUBZone SMALL BUSINESSES:

(% of "a") $ 270,000 and .5% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ ____N/A_____$ ____N/A_____$ ____N/A_____$ _____N/A_____

f. Total estimated dollar and percent of planned subcontracting with SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESSES: (% of "a") $ 270,000 and .5% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ ____N/A_____$ ____N/A_____$ ____N/A_____$ _____N/A_____

g. Total estimated dollar and percent of planned subcontracting with "OTHER THAN SMALL BUSINESSES"

(% of "a") $ 51,300,000 and 95% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ ____N/A_____$ ____N/A_____$ ____N/A_____$ _____N/A_____

Notes: 1. Federal prime contract goals are:
SB equals __5__%; SDB equals __1_%; WOSB equals _3__%; HUBZone equals _0.5_%; and SDVOSB equals _0.5__% may serve as objectives for subcontracting goal development.

2. SDB, WOSB, HUBZone and SDVOSB goals are subsets of SB and should be counted and reported in multiple categories, as appropriate.

3. If any contract has more four options, please attach additional sheets showing dollar amounts and percentages.

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	Professional Services	X	X		X		
2	Legal Expenses	X					
3	Animal and Animal Supplies	X	X				
4	Clothing and Uniforms	X					
5	Communications	X					
6	Insurance	X					
7	Office Expense	X	X				
8	Supplies	X	X	X	X	X	X
9	Utilities/Waste Mgmt	X					
10	Repairs and Maintenance	X	X		X		
11	Recruiting and Relocation	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.)

The subcontracting goals for small, HUBZone, small disadvantaged, women-owned small business concerns and service disabled veteran-owned small businesses were derived from current spending patterns by product and service area as of August 2007 and estimate of Supplier Diversity Program impact (Supplier Diversity Program). The product and service areas correspond to the major expense categories in EBOL's accounting software. Products and services exclude: Salaries and Benefits, Depreciation, License Fees, Taxes, Interest, and FAR non-allowable costs, capital costs, cGMP raw materials, and Travel, Meals and Entertainment. EBOL's procurement department seeks to obtain the lowest responsible and responsive bid for all goods and services. Competitive quotes from any sources must meet the business' specifications for all such requirements including quality, capability, service, competitive cost, performance expectations, and other relevant criteria.

j. Indirect costs have ____ have not _X__ 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:

_____

_____

_____

_____

3. Program Administrator:

NAME/TITLE: [**]_____

ADDRESS: 3500 N. Martin Luther King Jr. Blvd_____

Lansing, MI 48906-9910_____

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 indicate 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

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.

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 show compliance with the subcontracting plan; (3) submission of its Individual Subcontracting Report (ISR) and Summary Subcontract Report (SSR); and (4) ensuring that subcontractors agree to submit ISRs and SSRs. **The ISR and SSR 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	OF 312	30 days after completion

See FAR 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 cognizant awarding Contracting Officer's review and acceptance via the eSRS website https://esrs.symplicity.com/index?_tab=signin&cck=1 .

b. Currently, SSR (annually) must be submitted for the HHS eSRS Agency Coordinator review and acceptance via the eSRS website https://esrs.symplicity.com/index?_tab=signin&cck=1 . (***Note*** *:* Log onto the OSDBU website to view the HHS Agency Coordinator contact information (http://www.hhs.gov/osdbu/staff.html).

c. Contractors that do not use the eSRS to submit its reports must also submit a paper copy of the SSR to the appropriate Commercial Market Representative (contact the contracting official (CO) or the CO's eSRS Point of Contact).

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 item is not required on a *contract – by – contract basis* for company or division-wide commercial plans.)

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.

1) Implement a supplier diversity program, 2) Upgrade current vendor system software to allow for enhanced measurement of Small Business/Minority Business activities, 3) Attend Small Business seminars to identify qualified candidates, 4) Review all contract forms to ensure terms support the Small Business subcontracting goals

SIGNATURE PAGE

Signatures Required:

This subcontracting plan was submitted by:

Signature: /s/ Daniel J. Abdun-Nabi

Typed Name: ____DANIEL J. ABDUN-NABI_____

Title: ____Secretary_____

Date: ____September 24, 2007_____

This plan was reviewed by:

Signature: _____

Typed Name: _____

Title: Contracting Officer

Date: _____

This plan was reviewed by:

Signature: _____

Typed Name: _____

Title: Small Business Specialist (SBS)

Date: _____

This plan was reviewed by:

Signature: _____

Typed Name: _____

Title: Small Business Administration Procurement Center Representative (PCR)

Date: _____

Is Accepted By:

OPDIV: _____

Typed Name: _____

Title: _____

Date: _____

AMENDMENT TO
AMENDED AND RESTATED BY-LAWS OF
EMERGENT BIOSOLUTIONS INC.

Adopted by the Board of Directors October 30, 2007

The Amended and Restated By-laws of Emergent BioSolutions Inc. (the "By-laws") are hereby amended as follows:

1. ARTICLE IV, Section 4.2 of the By-laws is amended and restated in its entirety to read as follows:

4.2 Stock Certificates; Uncertificated Shares. The shares of the corporation shall be represented by certificates, provided that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Every holder of stock of the corporation represented by certificates shall be entitled to have a certificate, in such form as may be prescribed by law and by the Board of Directors, representing the number of shares held by such holder registered in certificate form. Each such certificate shall be signed in a manner that complies with Section 158 of the General Corporation Law of the State of Delaware.

Each certificate for shares of stock which are subject to any restriction on transfer pursuant to the Certificate of Incorporation, these By-laws, applicable securities laws or any agreement among any number of stockholders or among such holders and the corporation shall have conspicuously noted on the face or back of the certificate either the full text of the restriction or a statement of the existence of such restriction.

If the corporation shall be authorized to issue more than one class of stock or more than one series of any class, the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of each certificate representing shares of such class or series of stock, provided that in lieu of the foregoing requirements there may be set forth on the face or back of each certificate representing shares of such class or series of stock a statement that the corporation will furnish without charge to each stockholder who so requests a copy of the full text of the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

Within a reasonable time after the issuance or transfer of uncertificated stock, the corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to Sections 151, 202(a) or 218(a) of the General Corporation Law of the State of Delaware or, with respect to Section 151 of General Corporation Law of the State of Delaware, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

2. ARTICLE IV, Section 4.3 of the By-laws is amended and restated in its entirety to read as follows:

4.3 Transfers. Shares of stock of the corporation shall be transferable in the manner prescribed by law and in these By-laws. Transfers of shares of stock of the corporation shall be made only on the books of the corporation or by transfer agents designated to transfer shares of stock of the corporation. Subject to applicable law, shares of stock represented by certificates shall be transferred only on the books of the corporation by the surrender to the corporation or its transfer agent of the certificate representing such shares properly endorsed or accompanied by a written assignment or power of attorney properly executed, and with such proof of authority or the authenticity of signature as the corporation or its transfer agent may reasonably require. Except as may be otherwise required by law, by the Certificate of Incorporation or by these By-laws, the corporation shall be entitled to treat the record holder of stock as shown on its books as the owner of such stock for all purposes, including the payment of dividends and the right to vote with respect to such stock, regardless of any transfer, pledge or other disposition of such stock until the shares have been transferred on the books of the corporation in accordance with the requirements of these By-laws.

3. ARTICLE IV of the By-laws is amended by adding a new Section 4.6 to read as follows:

4.6 Regulations. The issue, transfer, conversion and registration of shares of stock of the corporation shall be governed by such other regulations as the Board of Directors may establish.

4. Except as aforesaid, the By-laws shall remain in full force and effect.

Adopted and approved by the Board of Directors of Emergent BioSolutions Inc.
on October 30, 2007

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)) 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) [Not applicable];

   (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 2, 2007

/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)) 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) [Not applicable];

   (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 2, 2007

/S/R. Don Elsey
R. Don Elsey
Senior Vice President Finance, Chief Financial Officer and Treasurer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the three months ended September 30, 2007 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 2, 2007

/s/Fuad El-Hibri
Fuad El-Hibri
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the three months ended September 30, 2007 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 2, 2007

/s/R. Don Elsey
R. Don Elsey
Senior Vice President Finance, Chief Financial Officer and Treasurer
(Principal Financial Officer)