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 March 31, 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 April 30, 2007, the registrant had 28,172,392 shares of common stock outstanding.

Emergent BioSolutions Inc.
Index to Form 10-Q

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 performance under existing sales contracts with the U.S. government for BioThrax (“BioThrax”) (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, including the timing of deliveries under these contracts;
- our ability to obtain new BioThrax sales contracts with the U.S. government;
- 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)

	December 31, 2006	March 31, 2007
		(Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 76,418	$ 67,645
Accounts receivable	43,331	3,935
Inventories	24,721	26,885
Income taxes receivable	869	3,255
Deferred tax assets	295	-
Prepaid expenses and other current assets	1,703	1,970
Total current assets	147,337	103,690
Property, plant and equipment, net	78,174	87,836
Deferred tax assets, net of current	11,477	11,074
Other assets	1,267	1,293
Total assets	$ 238,255	$ 203,893
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 27,366	$ 19,003
Accrued expenses and other current liabilities	3,253	2,907
Accrued compensation	7,190	4,723
Indebtedness under lines of credit	8,930	-
Long-term indebtedness, current portion	2,456	2,638
Notes payable to employees	17	-
Income taxes payable	13,703	-
Deferred tax liability	-	104
Deferred revenue, current portion	1,432	1,090
Total current liabilities	64,347	30,465
Long-term indebtedness, net of current portion	31,368	30,746
Deferred revenue, net of current portion	2,997	2,859
Other liabilities	1,071	1,802
Total liabilities	99,783	65,872
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred Stock $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2006 and March 31, 2007	-	-
Common Stock, $0.001 par value; 100,000,000 shares authorized, 27,596,249 and 28,038,348 shares issued and outstanding at December 31, 2006 and March 31, 2007, respectively	28	28
Additional paid-in capital	90,920	93,936
Accumulated other comprehensive loss	(473)	(643)
Retained earnings	47,997	44,700
Total stockholders' equity	138,472	138,021
Total liabilities and stockholders' equity	$ 238,255	$ 203,893

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

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

	Three Months Ended March 31,	
	2006	**2007**
	(Unaudited)	
Revenues:		
Product sales	$ 12,196	$ 25,446
Contracts and grants	27	1,002
Total revenues	12,223	26,448
Operating expense:		
Cost of product sales	2,861	5,516
Research and development	8,995	15,570
Selling, general and administrative	9,765	11,193
Loss from operations	(9,398)	(5,831)
Other income (expense):		
Interest income	203	874
Interest expense	(170)	(26)
Other income (expense), net	7	177
Total other income (expense)	40	1,025
Loss before benefit from income taxes	(9,358)	(4,806)
Benefit from income taxes	(4,722)	(2,116)
Net loss	$ (4,636)	$ (2,690)
Earnings (loss) per share - basic	$ (0.21)	$ (0.10)
Earnings (loss) per share - diluted	$ (0.21)	$ (0.10)
Weighted-average number of shares - basic	22,348,893	27,864,328
Weighted-average number of shares - diluted	22,348,893	27,864,328

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

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

	Three Months Ended March 31,	
	2006	**2007**
	(Unaudited)	
Cash flows from operating activities:		
Net loss	$ (4,636)	$ (2,690)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation expense	96	529
Depreciation and amortization	968	1,198
Deferred income taxes	635	2,400
Loss on disposal of property and equipment	4	-
Changes in operating assets and liabilities:		
Accounts receivable	59	39,396
Inventories	(4,661)	(2,163)
Income taxes	(6,615)	(17,686)
Prepaid expenses and other assets	(1,404)	(292)
Accounts payable	(2,294)	(2,735)
Accrued compensation	(472)	(2,467)
Accrued expenses and other liabilities	137	(223)
Deferred revenue	-	(481)
Net cash provided by (used in) operating activities	(18,183)	14,786
Cash flows from investing activities:		
Purchases of property, plant and equipment	(2,853)	(16,490)
Net cash used in investing activities	(2,853)	(16,490)
Cash flows from financing activities:		
Issuance of common stock subject to exercise of stock options	2	890
Redemption of Class B common stock	(200)	-
Principal payments on long term indebtedness, notes payable to employees, and lines of credits	(192)	(9,386)
Proceeds from excess tax benefits	-	1,597
Net cash used in financing activities	(390)	(6,899)
Effect of exchange rate changes on cash and cash equivalents	(94)	(170)
Net decrease in cash and cash equivalents	(21,520)	(8,773)
Cash and cash equivalents at beginning of period	36,294	76,418
Cash and cash equivalents at end of period	$ 14,774	$ 67,645
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 148	$ 644
Cash paid during the period for income taxes	$ 1,200	$ 12,500
Supplemental information on non-cash investing and financing activities:		
Purchases of property, plant and equipment unpaid at period end	$ 11,140	$ 5,511

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 accounting principles generally accepted in the United States 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, necessary to present fairly the financial position as of March 31, 2007, results of operations for the three month periods ended March 31, 2006 and 2007, and cash flows for the three month periods ended March 31, 2006 and 2007. Interim results are not necessarily indicative of results for the 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 March 31, 2006 and 2007, sales of BioThrax to the DoD and HHS comprised 95% and 96% of total revenues, respectively. As of March 31, 2007, 98% of the Company's receivable balance was comprised of amounts due from these customers. Unbilled accounts receivable, included in accounts receivable, totaling $1,690 and $172 as of March 31, 2006 and 2007, respectively, relate to various service contracts for which product has been delivered or work has been performed, though invoicing has not yet occurred. Accounts receivable are stated at invoice amounts and consist primarily 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 based on the cost of major ongoing capital projects which have not yet been placed in service. For the three months ended March 31, 2006 and 2007, the Company capitalized $0 and $677 of interest, respectively.

Earnings per share

Basic net income per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income 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. For the three months ended March 31, 2006 and 2007, 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

As of March 31, 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"), described more fully in Note 4 — Stockholders' Equity.

The Company accounts for equity instruments issued to non-employees in accordance with Statement of Financial Accounting Standards ("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").

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 2006 and 2007 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).

Based on options granted to employees as of March 31, 2007, total compensation expense not yet recognized related to unvested options is approximately $3,135, after tax. The Company expects to recognize that expense over a weighted average period of 3.0 years.

The Company has utilized 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 (no options were granted during the three months ended March 31, 2006):

	Three Months ended March 31, 2007
Expected dividend yield	0%
Expected volatility	50%
Risk-free interest rate	4.5%-4.8%
Expected average life of options	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 and other changes in equity that are excluded from net income. 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 loss for the three months ended March 31, 2006 and 2007 was $4,730 and $2,860, respectively.

Reclassifications

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

Recent accounting pronouncements

In February 2007, the Financial Accounting Standards Board ("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 has not yet determined the impact of adoption of this statement on its financial statements.

2. Inventories

Inventories consist of the following:

	December 31, 2006	March 31, 2007
Raw materials and supplies	$ 2,133	$ 2,222
Work-in-process	22,239	22,758
Finished goods	349	1,905
Total inventories	$ 24,721	$ 26,885

3. Property, plant and equipment

Property, plant and equipment consist of the following:

	December 31, 2006	March 31, 2007
Land and improvements	$ 5,173	$ 5,173
Buildings and leasehold improvements	25,074	25,081
Furniture and equipment	15,401	15,464
Software	4,499	4,554
Construction-in-progress	41,563	52,145
	91,710	102,417
Less: Accumulated depreciation and amortization	(13,536)	(14,581)
Total property, plant and equipment, net	$ 78,174	$ 87,836

4. 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 March 31, 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 the Common Stock. Holders of Common Stock are entitled to one vote for each share of Common Stock held on all matters as may be provided by law.

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 the Common Stock and the 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 March 31, 2007, the Company has two stock-based employee compensation plans, the 2006 Plan and the 2004 Plan, 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 Company established the 2006 Plan in connection with its initial public offering in November 2006. Under the 2006 Plan, the Company may grant options for a total of 503,500 shares of Common Stock, plus 585,961 shares of Common Stock reserved for issuance under the 2004 Plan that remained available for grant immediately prior to the initial public offering on November 14, 2006. Accordingly, the 2006 Plan initially authorized the issuance of up to 1,089,461 shares. In addition, the 2006 Plan contains an "evergreen provision" that allows for increases in the number of shares available for issuance under the 2006 Plan in the first and third quarter of each year from 2007 through 2009. 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 contractual life of no more than 10 years. In conjunction with the establishment of the 2006 Plan, as noted above, the shares reserved for issuance under the 2004 Plan that remained available for grant became available for grant under the 2006 Plan.

Each option granted under the Emergent Plans becomes exercisable as specified in the relevant option agreement, and no option can be exercised after ten years from the date of grant. The following is a summary of stock option plan 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	2,933,225	$	2.53	1,030,500	$	10.13	
Granted	-		-	78,200		14.52	
Exercised	(442,099)		2.02	-		-	
Forfeited	(287)		2.74	-		-	
Outstanding at March 31, 2007	2,490,839	$	2.62	1,108,700	$	10.44	$ 30,204,987
Exercisable at March 31, 2007	1,990,708	$	1.43	-	$	-	$ 23,868,589

The weighted average remaining contractual term of options outstanding as of December 31, 2006 and March 31, 2007 was 3.18 and 3.33 years, respectively. The weighted average remaining contractual term of options exercisable as of December 31, 2006 and March 31, 2007 was 1.06 and 0.98 years, respectively.

The weighted average grant date fair value of options granted during the three months ended March 31, 2007 was $5.46. The total intrinsic value of options exercised during the three months ended March 31, 2007 was $5,676. The total fair value of shares vested during the three months ended March 31, 2007 was $109.

Share-based compensation expense consists of the following:

	Three Months Ended March 31,	
	2006	2007
Cost of sales	$ -	$ 16
Research and development	-	85
General and administrative	96	428
Total share-based compensation expense	$ 96	$ 529

A summary of the status of the Company's non-vested stock options at March 31, 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	-	-	78,200	14.52
Exercised	-	-	-	-
Vested	(37,401)	8.41	-	-
Forfeited	-	-	-	-
Non-vested at March 31, 2007	500,131	$ 7.38	1,108,700	$ 10.44

During the three months ended March 31, 2007, the Company received a tax benefit from stock options exercised of approximately $1,522.

5. Income taxes

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

	Three months ended March 31,	
	2006	2007
Current		
Federal	$ (5,155)	$ (2,952)
State	100	34
Total current	(5,055)	(2,918)
Deferred		
Federal	301	775
State	32	27
Total deferred	333	802
Total provision for income taxes	$ (4,722)	$ (2,116)

The estimated effective annual tax rate for the three months ended March 31, 2006 and 2007 was 50% 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 June 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 $154 for the payment of interest and penalties as of March 31, 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 March 31, 2007, the Company accrued $19 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 March 31, 2007, $58 is classified as a current liability and $568 is classified as a non-current liability on the balance sheet. As of March 31, 2007, $415 of unrecognized tax benefits will reverse within the next twelve months.

The Company's federal and state income tax returns for the tax years 2003, 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. The Company is the subject of an ongoing federal income tax audit for the tax years ended December 31, 2004 and 2005. The financial statement impact of the audit has been estimated at approximately $862, including $102 of interest. This amount has been accrued as of March 31, 2007.

6. Litigation

From time to time, the Company is involved in product liability claims and other litigation considered normal in the nature of its business. The Company does not believe that any such proceedings would have a material, adverse effect on the results of its operations. For claims filed against the Company for use of BioThrax by the DoD, the Company expects to rely on contractual indemnification provisions with the DoD and statutory protections to limit its potential liability resulting from the pending lawsuits.

7. Segment information

The Company operates in two business segments: biodefense and commercial. In the biodefense business, the Company develops, manufactures and commercializes immunobiotics, consisiting 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 which 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**
Three Months Ended March 31, 2006				
External revenues	$ 12,196	$ 27	$ -	$ 12,223
Inter-segment revenues (expense)	-	-	-	-
Research and development	4,736	4,085	174	8,995
Interest income	-	-	203	203
Interest expense	-	-	(170)	(170)
Depreciation and amortization	763	174	31	968
Net income (loss)	138	(4,523)	(251)	(4,636)
Assets	48,667	10,067	31,839	90,573
Expenditures for long-lived assets	2,178	462	213	2,853
Three Months Ended March 31, 2007				
External revenues	$ 25,446	$ 1,002	$ -	$ 26,448
Inter-segment revenues	-	-	-	-
Research and development	10,091	4,986	493	15,570
Interest income	-	-	874	874
Interest expense	-	-	(26)	(26)
Depreciation and amortization	867	227	104	1,198
Net income (loss)	4,575	(5,697)	(1,568)	(2,690)
Assets	102,196	14,745	86,952	203,893
Expenditures for long-lived assets	15,170	445	875	16,490

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.

8. Subsequent event

On May 3, 2007, HHS issued a request for proposal ("RFP") for the procurement of 10.4 million doses of BioThrax during a base contract period from July 2007 through September 2010, with the option for HHS to acquire up to an additional 8.35 million doses of BioThrax during the same period. On May 7, 2007, the DoD issued an RFP for the manufacture, storage and delivery of BioThrax during a base contract period from October 2007 through September 2008, with three one-year option periods through September 2011. The RFP seeks a minimum of 1.0 million doses and a maximum of 3.6 million doses of BioThrax during the base year with options to purchase a minimum of 1.0 million doses and a maximum of 3.6 million doses in each of the three option periods. The RFP also seeks up to an additional 70,000 doses of BioThrax in the base year and in each of the three option years for foreign military sales.

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. We operate in two business segments: biodefense and commercial. We commenced operations as BioPort Corporation, or BioPort, in September 1998 through an acquisition from the Michigan Biologic Products Institute of rights to our marketed product, BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how. Following this acquisition, we completed renovations at the Lansing facilities that had been initiated by the State of Michigan. In December 2001, the FDA approved a supplement to our manufacturing facility license for the manufacture of BioThrax at the renovated facilities.

In June 2004, we completed a corporate reorganization in which we:

- issued 18,666,479 shares of class A common stock in exchange for 18,017,994 shares of BioPort class A common stock and 648,485 shares of BioPort class B common stock;
- repurchased and retired all other issued and outstanding shares of BioPort class B common stock; and
- assumed all outstanding stock options to purchase BioPort class B common stock and granted option holders replacement stock options to purchase an equal number of shares of our class B common stock.

As a result of the reorganization, BioPort became a wholly owned subsidiary of Emergent. We subsequently renamed BioPort as Emergent BioDefense Operations Lansing Inc. We acquired our portfolio of commercial vaccine candidates through our acquisition of Microscience Limited, or Microscience, in a share exchange in June 2005 and our acquisitions for cash of substantially all of the assets of Antex Biologics, Inc., or Antex, in May 2003 and ViVacs GmbH, or ViVacs, in July 2006. We subsequently renamed Microscience as Emergent Product Development UK Limited, Antex as Emergent Product Development Gaithersburg Inc. and ViVacs as Emergent Product Development Germany GmbH. 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 received no 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

In our biodefense business, we develop, manufacture and commercialize immunobiotics for use against biological agents that are potential weapons of bioterrorism or biowarfare. Our marketed product, BioThrax, is the only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. The U.S. Department of Defense, or the DoD, and the U.S. Department of Health and Human Services, or HHS, have been the principal customers for BioThrax. In addition, we have supplied small amounts of BioThrax directly to several foreign governments.

Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we have supplied over nine million doses of BioThrax through March 2007 for immunization of military personnel. Our most recent contract with the DoD, which was 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. We delivered to the DoD approximately 630,000 of these doses through March 2007, and we expect to deliver the balance by September 2007. The DoD's right to order additional doses of BioThrax under this contract expired in February 2007.

On May 7, 2007, the DoD issued an RFP for the manufacture, storage and delivery of BioThrax during a base contract period from October 2007 through September 2008, with three one-year option periods through September 2011. The RFP seeks a minimum of 1.0 million doses and a maximum of 3.6 million doses of BioThrax during the base year with options to purchase a minimum of 1.0 million doses and a maximum of 3.6 million doses in each of the three option periods. The RFP also seeks up to an additional 70,000 doses of BioThrax in the base year and in each of the three option years for foreign military sales.

Since May 2005, we have 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 $123.0 million and a modification for an additional 5.0 million doses for a fixed price of $120.0 million. We completed delivery of the first 5.0 million doses by February 2006, seven months earlier than required. We delivered approximately 4 million doses under the contract modification in 2006 and the balance in February 2007, more than two months earlier than required. On May 3, 2007, HHS issued an RFP for the procurement of another 10.4 million doses of BioThrax during a base contract period from July 2007 through September 2010, with the option for HHS to acquire up to an additional 8.35 million doses of BioThrax during the same period.

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenues from sales of BioThrax. Our total revenues from BioThrax sales were $127.3 million in 2005, $148.0 million in 2006 and $25.4 million for the three months ended March 31, 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 three biodefense product candidates in preclinical development. We are independently developing an anthrax immune globulin candidate, in part with funding from the National Institute of Allergy and Infectious Diseases, or the NIAID. We are collaborating with the U.K. Health Protection Agency, or HPA, in the development of a recombinant bivalent botulinum vaccine candidate and a new botulinum toxoid vaccine that we plan to use as the basis for 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

In our commercial business, we develop a range of immunobiotic product candidates that are designed to address significant unmet or underserved public health needs caused by infectious diseases. 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. In May 2006, we entered into a license and co-development agreement with Sanofi Pasteur under which we granted Sanofi Pasteur an exclusive, worldwide license under our proprietary technology to develop and commercialize our meningitis B vaccine candidate.

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 clinical trial of our typhoid vaccine candidate in Vietnam and is providing funding for the Phase II clinical trial of this vaccine candidate in Vietnam. In addition, the NIAID agreed to sponsor the Phase I clinical development of our group B streptococcus vaccine candidate.

Manufacturing Infrastructure

To augment our existing manufacturing capabilities, we are constructing a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus. We expect the construction of the facility to cost approximately $75 million, 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 incurred costs of approximately $46 million for these purposes through March 2007.

We substantially completed construction of this facility in 2006, and expect to conduct installation, validation and qualification activities required for regulatory approval during 2007 and 2008. We are constructing this new facility as a large scale manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures.

We anticipate that we will initiate large scale manufacturing of BioThrax for commercial sale at the new 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 for commercial sale at our new facility will be delayed and we will incur additional unanticipated costs.

We also own two buildings in Frederick, Maryland that are available to support our future manufacturing requirements. We incurred costs of approximately $1.5 million related to initial engineering design and preliminary utility build out of these facilities through March 2007. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that will 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 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 valuation of stock related to 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 cannot sell BioThrax to our customers without written FDA approval for each lot that we manufacture. As part of the FDA review process, we submit a detailed lot protocol for each BioThrax lot that we produce for sale. We also are required to submit product samples to the FDA for testing. Although we generally submit lot protocols and product samples promptly following the satisfactory completion of internal testing, we are permitted to submit product samples in advance of the lot protocols. The length of the FDA review process is approximately four to six weeks. However, individual lots may be released sooner or later depending on factors such as reviewer questions, license supplement approval, reviewer availability and whether our internal testing of product samples is completed before or concurrently with FDA testing. During the period covered by our financial statements included in this quarterly report, the FDA has not denied the sale of any BioThrax lots that we have submitted for approval.

We have generated BioThrax sales revenues under U.S. government contracts with the DoD and HHS. Under the DoD contract, we invoice the DoD for progress payments upon reaching contractually specified stages in the manufacture of BioThrax. We record as deferred revenue the full amount of each progress payment invoice that we submit to the DoD. Title to the product passes to the DoD upon submission of the first invoice. The earnings process is complete upon FDA release of the product for sale and distribution.

Following FDA release of the product, we segregate the product for later shipment and recognize 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 invoice the DoD for the final progress payment and recognize the amount of that invoice as period revenue.

Our contract with HHS does not provide for progress payments. We invoice HHS and recognize the related revenues upon delivery of the product to the government carrier, at which time title to the product passes to HHS. We do not record allowances for sales returns, rebates or special promotional programs for sales of BioThrax or provisions for sales made in prior periods.

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 evaluate the various components of a 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 elements 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 for 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. As services are completed, we 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.

Accounts Receivable

Accounts receivable are stated at invoice amounts and consist primarily 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. Because the prior collection history for receivables from these entities indicate that collection is likely, we do not currently record an allowance for doubtful accounts.

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.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service where we have not yet been invoiced or otherwise notified of actual cost. We make these estimates as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include:

- fees payable to contract research organizations in conjunction with clinical trials;
- fees payable to third party manufacturers in conjunction with the production of clinical trial materials; and
- professional service fees.

In accruing service fees, we estimate the time period over which services were provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify costs that have begun to be incurred or we underestimate or overestimate the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. We make judgments based upon the facts and circumstances known to us.

Income Taxes

We account for income taxes in accordance with Statement of Financial Accounting Standards 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 and 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 Statement of Financial Accounting Standards No. 123, or SFAS No. 123, *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 fair values. Pro forma disclosure is no longer an alternative.

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. Prior period operating results have not been restated. We measure the amount of compensation cost based on the fair value of the underlying common stock on the date of grant. We recognize compensation cost over the period that an employee provides service in exchange for the award.

As a result of our adoption of SFAS No. 123(R) effective January 1, 2006, we recorded stock-based compensation expense of $96,000 and $94,000 in the three months ended March 31, 2006 and 2007, respectively, related to stock options that were outstanding and had not completely vested as of January 1, 2006. During 2006 and the first quarter of 2007, we granted a total of 1,367,633 stock options. We recorded additional stock-based compensation expense of $435,000 related to these options in the three months ended March 31, 2007.

The effect of adopting SFAS No. 123(R) on net loss and net 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. Based on options granted to employees as of March 31, 2007, total compensation expense not yet recognized related to unvested options is approximately $3.1 million, after tax. We expect to recognize that expense over a weighted average period of 3.0 years. Based on options granted to employees as of March 31, 2007, we expect to recognize amortization of stock-based compensation, after tax, of approximately $1.1 million during the remainder of 2007, $1.1 million in 2008, $0.9 million in 2009, and $3,000 in 2010.

Financial Operations Overview

Revenues

We have generated substantially all of our revenues from sales of BioThrax. We delivered approximately 1.1 million total doses of BioThrax during the first quarter of 2007, representing 96% of our total revenues for the quarter. The DoD and HHS have been the principal customers for BioThrax. We also have had limited sales of BioThrax to foreign governments and private industry. In addition, we periodically realize revenues from grants from government entities and non-government and philanthropic organizations and from licensing fees, milestone payments and development reimbursement payments. These items accounted for 4% of our total revenues during the three months ended March 31, 2007. If our ongoing development efforts are successful, we would expect to generate revenues from sales of additional products and milestone payments, development payments and royalties on sales of products that we license to third parties.

In January 2004, we entered into a contract with the DoD for the delivery of a minimum number of doses of BioThrax over one base contract year plus two option periods for a minimum fixed price of approximately $91 million. Under the original terms of this contract, we were required to deliver a minimum of approximately 3.8 million total doses through September 2006. We delivered approximately 4.9 million total doses under this contract from 2004 through September 30, 2006 pursuant to the DoD purchase orders. Our most recent contract with the DoD was amended to provide for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. We delivered to the DoD approximately 630,000 of those doses through March 2007, and we expect to deliver the balance by September 2007. We have invoiced the DoD, as contemplated under this contract, for progress payments as doses of BioThrax are manufactured for sale to the DoD. In accordance with our revenue recognition policy, we record deferred revenue for invoiced amounts until the FDA releases the product for sale and delivery. As of December 31, 2006 and March 31, 2007, we had no deferred revenue for the DoD sales. On May 7, 2007, the DoD issued an RFP for the manufacture, storage and delivery of BioThrax during a base contract period from October 2007 through September 2008, with three one-year option periods through September 2011. The RFP seeks a minimum of 1.0 million doses and a maximum of 3.6 million doses of BioThrax during the base year with options to purchase a minimum of 1.0 million doses and a maximum of 3.6 million doses in each of the three option periods. The RFP also seeks up to an additional 70,000 doses of BioThrax in the base year and in each of the three option years for foreign military sales.

In May 2005, we entered into an agreement to supply 5.0 million doses of BioThrax to HHS for the SNS for a fixed price of $123 million. We completed delivery of all 5.0 million doses by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional 5.0 million doses of BioThrax for the SNS by May 2007 for a fixed price of $120 million. We delivered approximately 4.0 million of these doses in December 2006 and the balance in February 2007, more than two months earlier than required. On May 3, 2007, HHS issued an RFP for the procurement of 10.4 million doses of BioThrax during a base contract period from July 2007 through September 2010, with the option for HHS to acquire up to an additional 8.35 million doses of BioThrax during the same period.

In May 2006, we entered into a collaboration agreement with Sanofi Pasteur relating to the development and commercialization of 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 will record revenue in accordance with our revenue recognition policies.

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. We expect contracts and grant revenues to increase in 2007 compared to 2006 as we receive reimbursement for development expenses under our meningitis B collaboration with Sanofi Pasteur, funding from the Wellcome Trust for costs associated with our completed Phase I clinical trial and initiated Phase II clinical trial of our typhoid vaccine candidate in Vietnam and funding from the NIAID for costs associated with our animal efficacy studies for our anthrax immune globulin candidate.

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 expect our manufacturing costs to remain relatively stable during 2007.

We determine the cost of product sales for doses sold for a period based on the average manufacturing cost per dose for the period in which the doses sold were produced. We calculate the average manufacturing cost per dose by dividing the actual costs of manufacturing in the applicable 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 any period.

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 that development spending will increase 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 any increase in our research and development spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, the size, structure and duration of any follow on clinical program that we may initiate, cost 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. Furthermore, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

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. Our general and administrative expenses increased due to the addition of personnel to support the increased scale of our operations and to meet the reporting obligations applicable to public companies. 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 based on the cost of major ongoing projects which have not yet been placed in service, such as our new manufacturing facility. Our interest income may increase in future periods as a result of the investment of the net proceeds from our initial public offering. Our total interest cost will increase in future periods as compared to prior periods as a result of the mortgage loan that we entered into in April 2006 and the term loan that we entered into in August 2006, as well as any borrowings under our revolving lines 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 March 31, 2007 Compared to Quarter Ended March 31, 2006

Revenues

Product sales revenues in our biodefense segment increased by $13.3 million to $25.4 million for the three months ended March 31, 2007 from $12.2 million for the three months ended March 31, 2006. This increase in product sales revenues was primarily due to a 125% increase in the number of doses of BioThrax delivered, partially offset by a 7% decrease in average sales price per dose. Product sales revenues for the three months ended March 31, 2007 consisted of BioThrax sales to HHS of $21.7 million and sales to the DoD of $3.7 million. Product sales revenues for the three months ended March 31, 2006 consisted of BioThrax sales to HHS of $11.6 million and aggregate international and other sales of $630,000.

Contracts and grant revenues in our commercial segment increased by $975,000 to $1.0 million for the three months ended March 31, 2007 from $27,000 for the three months ended March 31, 2006. Contracts and grant revenues for the three months ended March 31, 2007 consisted of $1.0 million in amortization of the upfront payment received in 2006 and development program revenue from the Sanofi Pasteur collaboration.

Cost of Product Sales

Cost of product sales increased by $2.7 million, or 93%, to $5.5 million for the three months ended March 31, 2007 from $2.9 million for the three months ended March 31, 2006. This increase was attributable to a 125% increase in the number of doses sold, partially offset by improved utilization of our manufacturing capacity for BioThrax. The increase in the number of doses delivered resulted in an increase in costs of approximately $3.1 million. Manufacturing efficiencies resulted in a cost savings of approximately $400,000.

Research and Development Expense

Research and development expenses increased by $6.6 million to $15.6 million for the three months ended March 31, 2007 from $9.0 million for the three months ended March 31, 2006. This increase reflects increased expenses of $5.4 million in the biodefense segment, $900,000 in the commercial segment, and approximately $300,000 in other research and development expense.

The increase in biodefense spending, detailed in the table below, was attributable to increased efforts on all 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 increase in spending for BioThrax enhancements is related to preparing for animal efficacy studies to support applications for marketing approval of these enhancements, which we expect to submit to the FDA in late 2008 or early 2009. The increase in spending for our immune globulin candidate development related primarily to costs associated with our plasma collection program for our anthrax immune globulin. The increase in spending for the recombinant botulinum vaccine program, which is in preclinical development, resulted from advancing this program to the process development stage and the manufacture of clinical trial material. The increase in spending for the next generation anthrax vaccine program, which has product candidates in preclinical and Phase I clinical development, resulted from feasibility studies and formulation development of product candidates.

The increase in commercial spending, detailed in the table below, primarily reflects additional personnel and contract service costs. The spending for our typhoid vaccine candidate resulted from ongoing work for the Phase I clinical trial in Vietnam that we recently completed and preparing for our Phase II clinical trial in Vietnam that we initiated in the fourth quarter of 2006. The spending in 2007 for our hepatitis B therapeutic vaccine candidate resulted from preparing for our Phase II clinical trial, which we received regulatory clearance to commence in the fourth quarter of 2006. The spending in 2007 for our group B streptococcus vaccine candidate resulted from costs associated with our analysis of results from the Phase I clinical trial that we recently completed for one of the protein components of the vaccine candidate and preparation for Phase I clinical trials for two of the protein components of the vaccine candidate. In December 2006, we signed an agreement with the NIAID under which the NIAID has agreed to sponsor a Phase I clinical trial of each of the two components separately and the two-proteins in combination in healthy human volunteers. 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 three months ended March 31, 2007 and 2006 are shown in the following table:

(in thousands)	Three Months Ended March 31, 2006	2007
Biodefense:		
BioThrax enhancements	$ 1,745	$ 2,029
Immune globulin	2,531	5,955
Recombinant bivalent botulinum vaccine	460	1,397
Next generation anthrax vaccine	-	710
Total biodefense	4,736	10,091
Commercial:		
Typhoid vaccine	1,486	1,785
Hepatitis B therapeutic vaccine	1,049	1,141
Group B streptococcus vaccine	527	1,149
Chlamydia vaccine	409	455
Meningitis B vaccine	614	456
Total commercial	4,085	4,986
Other	174	493
Total	$ 8,995	$ 15,570

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $1.4 million, or 15%, to $11.2 million for the three months ended March 31, 2007 from $9.8 million for the three months ended March 31, 2006. Selling, general and administrative expenses related to our biodefense segment increased by $423,000, or 5%, to $8.9 million for the three months ended March 31, 2007 from $8.4 million for the three months ended March 31, 2006.

Selling, general and administrative expenses related to our commercial segment increased by $1.0 million, or 75%, to $2.3 million for the three months ended March 31, 2007 from $1.3 million for the three months ended March 31, 2006. The increase in both segments was primarily attributable to an increase in general and administrative expenses of approximately $1.2 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.

Total Other Income (Expense)

Total other income increased by $985,000 to $1.0 million for the three months ended March 31, 2007 from $40,000 for the three months ended March 31, 2006. This increase resulted primarily from an increase in interest income of $671,000 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 $144,000 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 an increase in other income of $170,000.

Income Taxes

Benefit from income taxes decreased by $2.6 million to $2.1 million for the three months ended March 31, 2007 from $4.7 million for the three months ended March 31, 2006. Our effective tax rate was 44% for the three months ended March 31, 2007 and 50% for the three months ended March 31, 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 $226,000 for the three months ended March 31, 2007 and $0 for the three months ended March 31, 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 March 31, 2007 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases, revenues under our collaboration agreement with Sanofi Pasteur, development funding from government entities and non-government and philanthropic organizations and, to a lesser extent, 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 March 31, 2007, we had cash and cash equivalents of $67.6 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 for the three months ended March 31, 2006 and 2007:

(in thousands)	Three Months Ended March 31, 2006	2007
Net cash provided by (used in):		
Operating activities(1)	$ (18,277)	$ 14,616
Investing activities	(2,853)	(16,490)
Financing activities	(390)	(6,899)
Total net cash used	$ (21,520)	$ (8,773)

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

Net cash provided by operating activities of $14.6 million for the three months ended March 31, 2007 resulted principally from $39.4 million received from the DoD and HHS relating to amounts billed in December 2006, partially offset by a decrease in income taxes payable of $17.7 million due to the timing of payment of our 2006 income tax liability, a decrease in accounts payable of $2.7 million related to timing of payments of construction and research and development costs recorded but unpaid at December 31, 2006 and our net loss of $2.7 million for the three months ended March 31, 2007.

Net cash used in operating activities of $18.3 million for the three months ended March 31, 2006 resulted principally from our net loss of $4.6 million, a non-cash benefit from income taxes of $6.6 million, reflecting our net loss before provision for income taxes for the period, and an increase in inventories of $4.7 million, reflecting the value of work in process for BioThrax lots being manufactured or awaiting delivery.

Net cash used in investing activities for the three months ended March 31, 2007 and 2006 resulted principally from the purchase of property, plant and equipment. Capital expenditures of $16.5 million for the three months ended March 31, 2007 relate primarily to construction of our new building in Lansing, Michigan. Capital expenditures of $2.9 million for the three months ended March 31, 2006 related primarily to $1.0 million for construction of our new building in Lansing, Michigan and approximately $1.9 million in infrastructure investments and other equipment.

Net cash used in financing activities of $6.9 million for the three months ended March 31, 2007 resulted primarily from the repayment of $8.9 million from our revolving line of credit with Fifth Third Bank, partially offset by $890,000 in proceeds from the exercise of stock options and $1.6 million related to excess tax benefits from the exercise of stock options.

Net cash used in financing activities of $390,000 for the three months ended March 31, 2006 resulted primarily from the redemption of Class B common stock of $200,000 and $192,000 related to the repayment of long-term debt.

Debt Financing

As of March 31, 2007, we had $33.4 million principal amount 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, Maryland;
- $6.9 million outstanding under a mortgage loan from Mercantile Potomac Bank used to finance the remaining portion of the purchase price for the Frederick facility;
- $8.3 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance the purchase price for the second facility on the Frederick site;
- $0.7 million outstanding under a term loan from Fifth Third Bank used to finance the purchase of an enterprise resource planning system;
- $10.0 million outstanding under a term loan from HSBC Realty Credit Corporation used to finance a portion of the costs of our facility expansion in Lansing, Michigan; and
- $5.0 million outstanding under a $5.0 million revolving line of credit with HSBC Realty Credit Corporation.

We also have a revolving line of credit for up to $10.0 million with Fifth Third Bank. We can borrow under this line of credit through May 2007.

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 fund our facility expansion in Lansing, Michigan and to provide additional financial flexibility. In addition to purchase obligations and orders under our contract with the DoD for BioThrax sales, our only committed external sources of funds are 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 animal efficacy studies of our anthrax immune globulin candidate, and funding from the Wellcome Trust for our Phase II clinical trial of our typhoid vaccine candidate in Vietnam. 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, Michigan and the build out of our manufacturing facility in Frederick, Maryland;
- 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 February 2007, the Financial Accounting Standards Board, or 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 have not yet determined the impact of the adoption of this statement on our 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 March 31, 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 March 31, 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 March 31, 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 alleged that they were vaccinated with BioThrax by the DoD and claimed damages resulting from personal injuries allegedly suffered because of the vaccinations. The plaintiffs in each of these three lawsuits claimed different injuries and sought varying amounts of damages. The first plaintiff alleged that the vaccine caused erosive rheumatoid arthritis and requested damages in excess of $1 million. The second plaintiff alleged that the vaccine caused Bell's palsy and other related conditions and requested damages in excess of $75,000. The third plaintiff 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.

We moved to dismiss these three lawsuits 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, another of these lawsuits was dismissed for lack of personal jurisdiction. The plaintiff in this lawsuit appealed that decision to the U.S. Court of Appeals for the Ninth Circuit. The appeal has not yet been fully briefed and oral argument is not scheduled. The court denied our motion in the third lawsuit. 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. On October 27, 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. On February 9, 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. On December 14, 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. On February 26, 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 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 41 lawsuits pending in two jurisdictions: four in California and 37 in Illinois. The products at issue in these lawsuits are pediatric vaccines and immune globulins. 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. One plaintiff in a thimerosal lawsuit alleges that he was injured by immune globulin containing thimerosal. We previously manufactured human immune globulin that contained thimerosal. 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 we are unable to obtain new contracts with, and deliver BioThrax to, these customers, 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 our only marketed product. In 2006 and for the three months ended March 31, 2007, we derived substantially all of our revenue from our BioThrax contracts with the DoD and HHS. Although the DoD has issued an RFP for the manufacture, storage and delivery of up to an additional 14.68 million doses of BioThrax through September 2011 and HHS has issued an RFP for the procurement of up to an additional 18.35 million doses of BioThrax through September 2010, neither the DoD nor HHS has awarded a new contract to us.

We may not be awarded a follow-on contract by either the DoD or HHS, or we may be awarded a contract on less favorable terms than our prior contracts with the DoD and HHS.

Our 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. We have sold BioThrax to the U.S. government under contracts with the DoD and HHS. In addition, we anticipate that the U.S. government will be the principal customer for any other biodefense products that we successfully develop. Accordingly, we are subject to a range of risks arising out of being a contractor to the U.S. government under U.S. government programs.

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. Congress generally appropriates funds on a fiscal year basis even though a program may continue for several years. For example, the DoD contracts for BioThrax have been structured with one base year during which the DoD agrees 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.

Government programs are often only partially funded initially, and additional funds are committed only as Congress makes further appropriations. The termination of a program or failure to commit funds to a program would result in a loss of anticipated future revenues attributable to that program, which could materially harm our business. 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.

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.

Historically, our contracts for the supply of BioThrax with the DoD and HHS were 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 October 2004, a federal court issued the requested injunction. In December 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 either of these lawsuits, 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. Lawsuits brought against us by third parties, even if not successful, require us to spend time and money defending the related litigation. 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.

Risks Related to Our Financial Position and Need for Additional Financing

We have a limited operating history and may not maintain profitability in future periods or on a consistent basis.

We have a limited operating history. We commenced operations in 1998, and the FDA approved the manufacture of BioThrax at our renovated facilities in Lansing, Michigan 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. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis. 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. If we are unable to maintain profitability on a consistent basis, the market price of our common stock may decline, and you could lose part or all of your investment.

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

As of March 31, 2007, we had $33.4 million principal amount of debt outstanding and remaining borrowing availability of $10.0 million under our revolving lines of credit. We may seek to raise substantial external debt financing to fund our facility expansion in Lansing, Michigan and 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. In addition, we incur significant commercialization expenses for BioThrax product sales, marketing and manufacturing. We expect these 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, Michigan. We expect the construction of the facility to cost approximately $75 million, 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 incurred approximately $46 million for these purposes through March 31, 2007. We also own two buildings in Frederick, Maryland that are available to support our future manufacturing requirements. We incurred approximately $1.5 million related to initial engineering design and preliminary utility build out for these facilities through March 31, 2007. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that will be necessary to complete this project.

We expect to continue to fund a significant portion of our development and commercialization costs for our product candidates with internally generated funds from sales of BioThrax. If we do not obtain future contracts with, and deliver BioThrax to, the DoD and HHS on terms consistent with our current expectations, we will be forced to find additional sources of funding. We will not be able to obtain this funding or otherwise be able to raise capital 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.

As of March 31, 2007, we had $67.6 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, Michigan and the build out of our manufacturing facility in Frederick, Maryland;
- 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.

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. In addition to remaining payment obligations under our most recent contract with the DoD for the additional doses of BioThrax to be delivered by September 30, 2007, our only committed external sources of funds are remaining borrowing availability under our revolving lines of credit, development funding under our collaboration agreement with Sanofi Pasteur, funding from the NIAID for animal efficacy studies of our anthrax immune globulin candidate and funding from the Wellcome Trust for our Phase II clinical trial of our typhoid vaccine candidate in Vietnam.

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 construction of a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus, which is being designed to enable us to manufacture BioThrax on a large scale for our existing and potential future customers. We are also constructing 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, Maryland that are available to address our future manufacturing requirements and have initiated initial engineering design and preliminary utility build out for these facilities. The construction of the Lansing facility and the upgrade of the Fredrick facilities, if we proceed, will involve substantial expenditures and likely require external sources of funds. Any delays in the construction or regulatory approval may adversely affect our ability to manufacture our commercial product candidates for clinical trials or commercial sale.

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 construction or regulatory approval of our new facility in Lansing is 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. FDA approval is required for the release of each lot. 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 filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. From time to time, we experience deviations during the manufacturing process of BioThrax that can affect our release of the production lot according to our release protocols and other acceptance criteria. 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. Lot failures, 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 or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business. We will not be able to sell any lots that in the future fail to satisfy release testing specifications or that are not released for sale by the FDA.

We are conducting a comparability program in connection with our plans to scale-up and manufacture BioThrax in our new large scale manufacturing facility in Lansing, Michigan. We are also conducting BioThrax characterization activities to identify the material proteins and components of BioThrax.

The purpose of these initiatives is to demonstrate that BioThrax to be produced in our new facility will be bioequivalent to BioThrax as produced in our currently licensed manufacturing facility. We expect to present this data to the FDA, upon review of the data that we present, may require additional testing of, or manufacturing processes for, BioThrax that may be difficult to perform or that could affect our ability to obtain approval for our new large scale manufacturing facility. In addition, because our immune globulin product candidates are produced from human plasma, we must immunize human donors and collect plasma on a regular basis to generate sufficient volumes of plasma to manufacture the immune globulin product. If we are unable to recruit and retain donors, we may be unable to continue to manufacture our immune globulin product candidates in commercial quantities or at all.

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

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

- equipment malfunctions or failures;
- technology malfunctions;
- work stoppages or slow downs;
- protests, including by animal rights activists;
- damage to or destruction of the facility due to natural disasters;
- 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 are spending for construction of 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 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, Michigan 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., which is in the process of being acquired by Jubilant Organosys Ltd. Our contract with Hollister-Stier expires on December 31, 2007. The fact that we have successfully negotiated a contractual relationship with Hollister-Stier does not necessarily mean that we will be successful in negotiating a new contract, or an extension of our existing contract, after the closing of the acquisition by Jubilant. 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 or we are unable to enter into a new contract with Hollister-Stier or amend our current contract with Hollister-Stier, 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. In addition, our development plans for our botulinum immune globulin candidate require the development of a new botulinum toxoid vaccine that we would use to vaccinate individuals who would then donate plasma for use in our botulinum immune globulin candidate. If the development of this new botulinum toxoid vaccine is delayed or not completed, for regulatory or other reasons, we may not be able to successfully develop our botulinum immune globulin candidate.

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.

For example, the FDA could require us to conduct additional clinical development in our botulinum immune globulin program that we currently do not plan to conduct. We expect to rely on safety and immunogenicity data from a pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan in the development of a new bivalent botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin candidate. We plan to conduct a Phase I clinical trial to evaluate the safety of the botulinum toxoid vaccine. If the results are favorable, we expect that the Phase I clinical trial will provide data sufficient to support an acceptable dose for the vaccine and the optimal dosing schedule. As a result, we anticipate that the FDA will not require us to conduct a Phase II clinical trial for the botulinum toxoid vaccine before permitting us to initiate a donor stimulation program for our botulinum immune globulin candidate. However, the FDA has not approved our plan to proceed directly to a donor stimulation program without conducting a Phase II clinical trial for the botulinum toxoid vaccine and may not do so. If the FDA requires us to conduct a Phase II clinical trial for the botulinum toxoid vaccine, the development plans for our botulinum immune globulin candidate will be delayed.

In addition, our development plan for BioThrax as a post-exposure prophylaxis for anthrax infection contemplates that we will conduct 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, Michigan to manufacture BioThrax for sale to U.S. government customers. We substantially completed construction of our new manufacturing facility in Lansing in 2006, and expect to conduct installation, validation and qualification activities required for regulatory approval during 2007 and 2008. We anticipate that we will initiate large scale manufacturing of BioThrax for commercial sale at the new facility in 2008. We anticipate that we will be able to demonstrate in non-clinical studies that BioThrax manufactured at our new facility is comparable to BioThrax manufactured at our existing facility.

As a result, we expect 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. 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 for commercial sale at our new facility will be delayed and we will incur additional unanticipated costs. Until the new manufacturing facility is available for commercial use, we will not have sufficient available production capacity to allow us to significantly increase sales of BioThrax to customers other than the U.S. government.

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. For example, in 2004, HHS issued a request for proposals for the supply of anthrax vaccine for the SNS. The HHS request was limited to a recombinant anthrax vaccine. Because BioThrax is not a recombinant vaccine, BioThrax was precluded from consideration under that procurement program.

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 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.

The use of vaccines carries a risk of adverse health effects that must be weighed against the expected health benefit of the product. 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. As a result of the federal court proceedings, the DoD was enjoined from administering BioThrax to military personnel on a mandatory basis without informed consent of the recipient or a Presidential waiver. In 2006, after the FDA issued a final order that BioThrax is safe, effective and not misbranded, the court injunction was dissolved and the DoD announced that it was resuming mandatory vaccination with BioThrax for designated military personnel and emergency DoD civilian personnel and contractors. Although DoD prevailed in the challenge to its mandatory vaccination program, the actions of these groups created negative publicity about BioThrax. In December 2006, the same counsel who brought the prior lawsuit filed a new lawsuit contending that the FDA's 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. These and other 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.

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. Expanding our internal sales and marketing capability will be expensive and time consuming and could delay any product launch. 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. The 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. Although we may petition the Secretary to make such a declaration with respect to anthrax generally and BioThrax specifically, we do not know if any such petition would be successful or that, if successful, the PREP Act will 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 existing and prior contracts with the DoD and HHS provide that the government will indemnify us for any damages resulting from product liability claims, we cannot be certain that we will be able to continue to negotiate similar rights in future contracts or that the U.S. government will honor this obligation. 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.

In addition, members of Congress have proposed and may in the future propose legislation that reduces or eliminates these and other 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. In late 2005 and early 2006, we were named as a defendant in three federal lawsuits filed on behalf of three 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 each of these three lawsuits claimed different injuries and sought varying amounts of damages. The first plaintiff alleged that the vaccine caused erosive rheumatoid arthritis and requested damages in excess of $1 million. The second plaintiff alleged that the vaccine caused Bell's palsy and other related conditions and requested damages in excess of $75,000. The third plaintiff 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. 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 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. Insurance coverage is 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 deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on contractual indemnification provisions and statutory protections to limit our liability 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 nongovernmental, 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 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 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 Fuad El-Hibri, chief executive officer and chairman of our board of directors; Daniel J. Abdun-Nabi, president and secretary; R. Don Elsey, chief financial officer and treasurer; Edward J. Arcuri, chief operating officer; and Robert G. Kramer, president and chief executive officer of Emergent BioDefense Operations, to be key to our BioThrax operations and our efforts to develop and commercialize our product candidates. 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.

Our BioThrax supply contract with the DoD grants us the right to use property and equipment owned by the DoD in the manufacture of BioThrax. This property and equipment, referred to as government furnished equipment, is in service at our Lansing site. Some of this government furnished equipment is important to our business. We pay the DoD a small usage fee for the government furnished equipment 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 the government furnished equipment at any time during the contract period for approximately $21 million. If the DoD modifies the terms under which we use the government furnished equipment in a manner unfavorable to us, including raising the usage fee, our business could be harmed. If DoD terminated our contract, we could be required to rent or purchase all or a part of the government furnished equipment to continue production of BioThrax in our current 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 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, Michigan in 1998 from the Michigan Biologic Products Institute, we spent significant amounts of time and money renovating those facilities before the FDA approved a supplement to our manufacturing facility license in December 2001. The State of Michigan had initiated renovations after the FDA issued a notice of intent to revoke the FDA license to manufacture BioThrax in 1997. The notice of intent to revoke cited significant deviations by the Michigan Biologic Products Institute from cGMP requirements, including quality control failures. In March 2007, the FDA notified us that our manufacturing facility license is no longer subject to the notice of intent to revoke. After approving the renovated Lansing facilities in December 2001, the FDA conducted routine, biannual inspections of the Lansing facilities in September 2002, May 2004 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 would 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 are aware of and are monitoring 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.

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 is based on these licensed rights, could potentially be used as a viral vector for delivery of several vaccine antigens for different disease-causing organisms, including influenza, using recombinant technology. As a result, our licensed rights and our ability to use our MVA platform technology could be negatively affected by the outcome of this ongoing litigation. It also is possible that we could be named as a defendant in future similar litigation relating to MVA. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference and reexamination proceedings declared by the U.S. Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and 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, Michigan 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 April 30, 2007, Mr. El-Hibri was the beneficial owner of approximately 80% 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% 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 April 30, 2007, our common stock has traded as high as $17.75 per share and as low as $9.75 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 your sole source of gain 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 22.3 million shares of our common stock outstanding as of April 30, 2007 have the right to require us to register these shares of common stock under specified circumstances, subject to lock-up agreements signed in connection with our initial public offering.

In addition, as of April 30, 2007, options exercisable for approximately 1,474,498 shares of our common stock will expire if not exercised prior to July 1, 2007. Because these options have exercise prices ranging from $0.09 to $2.74 per share, which is less than the current market price of our common stock, we expect that the holders of these options will exercise the options prior to their expiration date and then promptly sell a substantial portion of the shares of our common stock issued upon exercise of the options. We have filed with the SEC a registration statement on Form S-8 registering the sale of all the shares of our common stock subject to outstanding options and options and other awards issuable pursuant to our equity incentive plans. Shares registered under this registration statement on Form S-8 are available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements signed in connection with our initial public offering that are applicable to these shares.

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 March 31, 2007, we have used approximately $1.7 million of the net proceeds from the offering to fund development of our biodefense product candidates, comprised of approximately $450,000 for label expansions and improvements for BioThrax, approximately $280,000 for a next generation anthrax vaccine candidate and approximately $1.0 million for our anthrax immune globulin candidate; approximately $820,000 of the net proceeds to fund development of our commercial product candidates, comprised of approximately $360,000 for our typhoid vaccine candidate and approximately $460,000 for our hepatitis B therapeutic vaccine candidate; and approximately $6.9 million of the net proceeds to fund a portion of the construction, validation and qualification costs for our new manufacturing facility in Lansing, Michigan. 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

Not applicable.

ITEM 6. EXHIBITS

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

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

Date: May 10, 2007	By:	/s/Fuad El-Hibri Fuad El-Hibri Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)
Date: May 10, 2007	By:	/s/R. Don Elsey R. Don Elsey Vice President Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description
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

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: May 10, 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: May 10, 2007

/S/R. Don Elsey
R. Don Elsey
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 March 31, 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: May 10, 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 March 31, 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: May 10, 2007

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