Emergent BioSolutions Inc.
Form 10-Q
May 07, 2008
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, 2008

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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

o Large Accelerated Filer	x Accelerated Filer	o Non-Accelerated Filer (do not check if a smaller reporting company)	o Smaller reporting Company

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

As of May 1, 2008, the registrant had 29,750,237 shares of common stock outstanding.

Emergent BioSolutions Inc.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our ability to obtain new contracts with the U.S. government for sales of BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, and our performance under those contracts, including the timing of deliveries;
- our plans for future sales of BioThrax;
- our plans to pursue label expansions and improvements for BioThrax;
- our plans to expand our manufacturing facilities and capabilities;
- the rate and degree of market acceptance and clinical utility of our products;
- our ongoing and planned development programs, preclinical studies and clinical trials;
- our ability to identify and acquire or in-license products and product candidates that satisfy our selection criteria;
- the potential benefits of our existing collaboration agreements and our ability to enter into selective additional collaboration arrangements;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property portfolio; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

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

You should read this quarterly report, including the documents that we have incorporated by reference herein and filed as exhibits hereto, completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2008 (Unaudited)	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 92,747	$ 105,730
Accounts receivable	21,518	18,817
Inventories	18,790	16,897
Notes receivable	3,500	-
Prepaid expenses and other current assets	3,074	2,866
Total current assets	139,629	144,310
Property, plant and equipment, net	115,421	110,218
Deferred tax assets, net	11,811	12,397
Restricted cash	5,200	5,200
Other assets	1,580	1,383
Total assets	$ 273,641	$ 273,508
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 17,863	$ 20,257
Accrued expenses and other current liabilities	1,499	1,778
Accrued compensation	6,592	9,502
Indebtedness under lines of credit	15,000	11,832
Long-term indebtedness, current portion	3,524	3,514
Income taxes payable	3,880	7,665
Deferred tax liabilities, net	123	211
Deferred revenue, current portion	900	902
Total current liabilities	49,381	55,661
Long-term indebtedness, net of current portion	41,702	42,588
Deferred revenue, net of current portion	2,325	2,473
Other liabilities	1,636	1,627
Total liabilities	95,044	102,349
Commitments and contingencies	-	-
Stockholders equity:		
Preferred Stock $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at March 31, 2008 and December 31, 2007.	-	-
Common Stock, $0.001 par value; 100,000,000 shares authorized, 29,750,237 shares issued and outstanding at March 31, 2008 and December 31, 2007	30	30
Additional paid-in capital	102,163	101,933
Accumulated other comprehensive loss	(946)	(1,130)
Retained earnings	77,350	70,326
Total stockholders equity	178,597	171,159
Total liabilities and stockholders equity	$ 273,641	$ 273,508

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,	
	2008 (Unaudited)	**2007 (Unaudited)**
Revenues:		
Product sales	$ 41,504	$ 25,446
Contracts and grants	1,216	1,002
Total revenues	42,720	26,448
Operating expense:		
Cost of product sales	8,010	5,516
Research and development	11,475	15,570
Selling, general and administrative	12,060	11,193
Income (loss) from operations	11,175	(5,831)
Other income (expense):		
Interest income	665	874
Interest expense	(1)	(26)
Other income (expense), net	(14)	177
Total other income (expense)	650	1,025
Income (loss) before provision for (benefit from) income taxes	11,825	(4,806)
Provision for (benefit from) income taxes	4,801	(2,116)
Net income (loss)	$ 7,024	$ (2,690)
Earnings (loss) per share - basic	$ 0.24	$ (0.10)
Earnings (loss) per share - diluted	$ 0.24	$ (0.10)
Weighted-average number of shares - basic	29,750,237	27,864,328
Weighted-average number of shares - diluted	29,819,727	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, 2008 (Unaudited)	2007 (Unaudited)
Cash flows from operating activities:		
Net income (loss)	$ 7,024	$ (2,690)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation expense	230	529
Depreciation and amortization	1,081	1,198
Deferred income taxes	498	2,400
Loss on disposal of property and equipment	10	-
Excess tax benefits from stock-based compensation	-	(1,597)
Changes in operating assets and liabilities:		
Accounts receivable	(2,701)	39,396
Inventories	(1,893)	(2,163)
Income taxes	(3,785)	(16,089)
Prepaid expenses and other assets	(405)	(292)
Accounts payable	(1,757)	(1,868)
Accrued compensation	(2,910)	(2,467)
Accrued expenses and other liabilities	(270)	(1,090)
Deferred revenue	(150)	(481)
Net cash provided by (used in) operating activities	(5,028)	14,786
Cash flows from investing activities:		
Purchases of property, plant and equipment	(6,931)	(16,490)
Issuance of notes receivable	(3,500)	-
Net cash used in investing activities	(10,431)	(16,490)
Cash flows from financing activities:		
Proceeds from borrowings on long term indebtedness and lines of credit	15,000	-
Issuance of common stock subject to exercise of stock options	-	890
Principal payments on long term indebtedness, notes payable to employees, and lines of credits	(12,708)	(9,386)
Excess tax benefits from stock-based compensation	-	1,597
Net cash provided by (used in) financing activities	2,292	(6,899)
Effect of exchange rate changes on cash and cash equivalents	184	(170)
Net decrease in cash and cash equivalents	(12,983)	(8,773)
Cash and cash equivalents at beginning of period	105,730	76,418
Cash and cash equivalents at end of period	$ 92,747	$ 67,645
Supplemental information on non-cash investing and financing activities:		
Purchases of property, plant and equipment unpaid at period end	$ 637	$ 5,511

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

EMERGENT BIOSOLUTIONS INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Summary of significant accounting policies

Basis of presentation and consolidation

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

The unaudited consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission.

In the opinion of the Company s management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of March 31, 2008, results of operations for the three month periods ended March 31, 2008 and 2007, and cash flows for the three month periods ended March 31, 2008 and 2007. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Notes receivable

The Company has entered into a loan and security agreement with a third party corporation (Borrower) to provide a loan to the Borrower of up to $10 million. The loan is secured by a first priority interest in the Borrower s accounts, equipment, contracts, and other agreements, documents and instruments, along with a leasehold mortgage for real property leased to the Borrower. Under this loan agreement and a related promissory note, the Borrower had drawn $3.5 million as of March 31, 2008, and the Company has recorded this as notes receivable. The note bears interest at an annual rate of 8%, and is due and payable on the earlier of December 31, 2008 or when the amount becomes due and payable under the terms of the note. In April 2008, the Company made an additional loan of $1.5 million to the Borrower under the same loan agreement.

Capitalized interest

The Company capitalizes interest in accordance with Statement of Financial Accounting Standards (SFAS) No. 34, *Capitalization of Interest Cost,* based on the cost of major ongoing capital projects which have not yet been placed in service. For the three months ended March 31, 2008 and 2007, the Company incurred interest expense of $890,000 and $703,000, respectively. Of these amounts, the Company capitalized $889,000

and $677,000, respectively.

Earnings per share

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

(in thousands, except share and per share data)	Three Months Ended March 31, 2008	2007
Numerator:		
Net income (loss)	$ 7,024	$ (2,690)
Denominator:		
Weighted-average number of shares basic	29,750,237	27,864,328
Dilutive securities stock options	69,490	-
Weighted-average number of shares diluted	29,819,727	27,864,328
Earnings (loss) per share-basic	$ 0.24	$ (0.10)
Earnings (loss) per share-diluted	$ 0.24	$ (0.10)

Accounting for stock-based compensation

Effective January 1, 2006, the Company adopted the fair value provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123(R)), using the modified prospective method. Under the fair value recognition provisions of SFAS No. 123(R), the Company recognizes stock-based compensation net of an estimated forfeiture rate. The Company accounts for equity instruments issued to non-employees in accordance with SFAS No. 123, *Accounting for Stock Based Compensation*, and Emerging Issues Task Force 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.*

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:

	Three Months Ended March 31, 2008
Expected dividend yield	0%
Expected volatility	65%
Risk-free interest rate	1.8%-2.7%
Expected average life of options	3.0

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 historical volatility of similar companies at a similar stage of development to estimate volatility. The volatility of these similar companies ranged from 40% to 89%, with an average estimated volatility of 68%. The Company chose a rate of 65%, approximately the mid-point of this range.

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 on which the option was granted.

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 Company s expectation of optionee exercise behavior subsequent to vesting of options.

Comprehensive income (loss)

SFAS No. 130, *Reporting Comprehensive Income,* requires the presentation of comprehensive income (loss) and its components as part of the financial statements. Comprehensive income (loss) is comprised of net income (loss) and other changes in equity that are excluded from net

income (loss). The Company includes gains and losses on intercompany transactions with foreign subsidiaries that are considered to be long-term investments and translation gains and losses incurred when converting its subsidiaries financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income (loss). Comprehensive income for the three months ended March 31, 2008 was $7,208. Comprehensive loss for the three months ended March 31, 2007 was $2,860.

Reclassifications

Certain amounts classified as accrued expenses and other current liabilities in the consolidated balance sheet as of December 31, 2007 have been reclassified as accounts payable to conform to current period presentation.

Recent accounting pronouncements

In March 2008, the Financial Accounting Standards Board (FASB) issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an Amendment of FASB Statement No* (SFAS No. 161). SFAS No. 161 states that entities are required to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under Statement No. 133 and its related interpretations and how derivative instruments and related hedged items affect an entity s financial position, financial performance, and cash flows. The provisions of SFAS No. 161 are effective for fiscal years beginning on or after November 15, 2008, with early adoption encouraged. The Company anticipates that the adoption of this statement will not have a material impact on its financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an Amendment of ARB No. 51* (SFAS No. 160). SFAS No. 160 clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements, requires consolidated net income to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest, establishes a single method of accounting for changes in a parent s ownership interest in a subsidiary that do not result in deconsolidation, and requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. The provisions of SFAS No. 160 are effective for fiscal years beginning on or after December 15, 2008. The Company is currently evaluating the impact of the adoption of this statement on its financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS No. 141(R)). SFAS No. 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values, changes the recognition of assets acquired and liabilities assumed arising from contingencies, changes the recognition and measurement of contingent consideration, and requires the expensing of acquisition-related costs as incurred. SFAS No. 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and it may not be applied before that date. The provisions of SFAS No. 141(R) will impact the Company s financial statements to the extent that the Company is party to a business combination after the pronouncement has been adopted.

2. Inventories

Inventories consist of the following:

(in thousands)	March 31, 2008	December 31, 2007
Raw materials and supplies	$ 2,635	$ 2,463
Work-in-process	15,364	11,483
Finished goods	791	2,951
Total inventories	$ 18,790	$ 16,897

3. Property, plant and equipment

Property, plant and equipment consist of the following:

(in thousands)	March 31, 2008	December 31, 2007
Land and improvements	$ 4,974	$ 4,974
Buildings and leasehold improvements	26,518	26,410
Furniture and equipment	20,257	19,626
Software	5,923	5,866
Construction-in-progress	76,587	71,129
	134,259	128,005
Less: Accumulated depreciation and amortization	(18,838)	(17,787)
Total property, plant and equipment, net	$ 115,421	$ 110,218

4. Stock options

As of March 31, 2008, the Company has two stock-based employee compensation plans, the Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the 2006 Plan) and the Emergent BioSolutions Employee Stock Option Plan (the 2004 Plan) (together, the Emergent Plans), under which the Company has granted options to purchase shares of Common Stock. The Emergent Plans have both incentive and non-qualified stock option features.

The 2006 Plan contains an evergreen provision that allows for increases in the number of shares authorized for issuance under the 2006 Plan in the first and third quarter of each year from 2007 through 2009. An aggregate of 2,976,932 shares of Common Stock are authorized for issuance under the 2006 Plan as of March 31, 2008, and options to purchase a total of 2,524,801 shares of Common Stock under the 2006 Plan are outstanding as of March 31, 2008. Following the closing of the Company s initial public offering in November 2006, the Company no longer grants options pursuant to the 2004 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:

	2006 Plan Number of Shares	Weighted-Average Exercise Price	2004 Plan Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2007	1,380,111	$ 9.77	666,519	$ 6.04	
Granted	1,214,690	7.02	-	-	
Exercised	-	-	-	-	
Forfeited	(70,000)	8.83	(19,181)	10.28	
Outstanding at March 31, 2008	2,524,801	$ 8.47	647,338	$ 5.92	$ 5,097,526
Exercisable at March 31, 2008	290,335	$ 10.41	526,024	$ 5.00	$ 2,279,214

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

	Three Months Ended March 31,	
(in thousands)	2008	2007
Cost of product sales	$ 18	$ 16
Research and development	93	85
Selling, general and administrative	119	428
Total stock-based compensation expense	$ 230	$ 529

5. Income taxes

Significant components of the provision for (benefit from) income taxes attributable to operations consist of the following:

	Three Months Ended March 31,	
(in thousands)	2008	2007
Current		
Federal	$ 4,040	$ (2,952)
State	263	34
Total current	4,303	(2,918)

Deferred		
Federal	388	775
State	110	27
Total deferred	498	802
Total provision for (benefit from) income taxes	$ 4,801	$ (2,116)

The estimated effective annual tax rate for the three months ended March 31, 2008 and 2007 was 41% and 44%, respectively. The decrease in the effective rate in 2008 from 2007 was due primarily to a decrease in the impact of foreign operations related to a change in tax rates effective in 2008.

The Company s federal and state income tax returns for the tax years 2007 to 2004 remain open to examination. The Company s tax returns in the United Kingdom remain open to examination for the tax years 2007 to 2001, and tax returns in Germany remain open indefinitely. A federal income tax audit of the Company's tax return for the 2005 tax year was completed in March 2008. As a result of this audit, the Company paid an assessment of $450,000, including $55,000 of interest.

6. Litigation

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

7. Segment information

The Company reports financial information for two business segments: biodefense and commercial. In the biodefense business, the Company develops, manufactures and commercializes products for use against biological agents that are potential weapons of bioterrorism. Revenues in this segment relate to the Company s FDA-approved product, BioThrax. In the commercial business, the Company develops products for use against infectious diseases that have resulted in significant unmet or underserved medical 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 Company and includes costs of the centralized services departments, which are not allocated to the other segments, as well as spending on product candidates or activities that are not classified as biodefense or commercial. The assets in this segment consist of cash and fixed assets.

		Reportable Segments				
(in thousands)		**Biodefense**	**Commercial**	**All Other**		**Total**
Three Months Ended March 31, 2008						
External revenue	$	41,777	$ 797	$ 146	$	42,720
Inter-segment revenue (expense)		-	-	-		-
Research and development		4,256	6,336	883		11,475
Interest income		-	-	665		665
Interest expense		-	-	(1)		(1)
Depreciation and amortization		708	262	111		1,081
Net income (loss)		20,628	(9,353)	(4,251)		7,024
Assets		143,435	20,233	109,973		273,641
Expenditures for long-lived assets		6,473	179	279		6,931
Three Months Ended March 31, 2007						
External revenue	$	25,446	$ 1,002	$ -	$	26,448
Inter-segment revenue		-	-	-		-
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. Related party transactions

The Company has engaged Wilmer Cutler Pickering Hale and Dorr LLP ("WilmerHale") to provide certain legal services to the Company. The Company's Senior Vice President, Legal Affairs and General Counsel is married to a partner at WilmerHale, who has not participated in providing legal services to the Company. The Company has incurred fees for legal services rendered by WilmerHale of approximately $217,000 for the three months ended March 31, 2008, all of which was in accounts payable at March 31, 2008.

The Company has entered into a marketing arrangement in 2008 with an entity controlled by family members of the Chief Executive Officer to market and sell BioThrax. The contract requires a payment of 17.5% of net sales and reimbursement of certain expenses for certain countries in the Middle East and North Africa, excluding countries to which export is prohibited by the U.S. government. No royalty payments under this agreement have been triggered for the three months ended March 31, 2008 and 2007.

The Company has entered into consulting and transportation arrangements with various persons or entities affiliated with the Chief Executive Officer and a member of the board of directors. At March 31, 2008 and 2007, there was $20,000 and $0, respectively, in accounts payable for these services. For the three months ended March 31, 2008 and 2007, the Company paid approximately $45,000 in each period to an entity affiliated with a member of our board of directors for corporate strategic issues consultation and directed project support to the marketing and communications group. For the three months ended March 31, 2008 and 2007, the Company paid approximately $8,000 and $9,000, respectively, to an entity owned by the Chief Executive Officer for transportation and logistical support.

9. Subsequent event

On May 2, 2008, the Company acquired all assets and rights related to a recombinant protective antigen anthrax vaccine product candidate and related technology from VaxGen, Inc., in exchange for consideration of $2 million upon execution of the definitive agreement, up to an additional $8 million in milestone payments, and specified percentages of future net 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 profitable multinational biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics, consisting of vaccines and therapeutics that assist the body s immune system to prevent or treat disease. We manufacture and market BioThrax®, the only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. We use internally generated cash flows from the sale of BioThrax to fund the development of a product pipeline that addresses a variety of infectious diseases and other medical conditions. We develop immunobiotics for use against infectious diseases that have resulted in significant unmet or underserved public health needs and against biological agents that are potential weapons of bioterrorism and biowarfare. We operate in two business segments, biodefense and commercial.

Our biodefense business focuses on immunobiotics for use against biological agents that are potential weapons of bioterrorism and biowarfare. Our product candidates targeted to the biodefense market are anthrax immune globulin therapeutic, next generation anthrax vaccine, botulinum vaccines and botulinum immune globulin therapeutic. Our commercial business focuses on immunobiotics for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. Our product candidates targeted to the

commercial market are typhoid vaccine, hepatitis B therapeutic vaccine, group B streptococcus vaccine and chlamydia vaccine. 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 and for the three months ended March 31, 2008. Our commercial business has generated revenue through development grant funding and an upfront license fee and additional payments for development work under a collaboration agreement with Sanofi Pasteur. None of our commercial product candidates have received marketing approval and, therefore, have not generated any product sales revenues. As a result, our commercial business has incurred a net loss for each of the last three fiscal years and for the three months ended March 31, 2008.

Product Sales

We have derived substantially all of our revenues from BioThrax sales to the Department of Defense, or DoD, and Health and Human Services, or HHS, and expect for the foreseeable future to continue to derive substantially all of our revenues from the sales of BioThrax to HHS. Our total revenues from BioThrax sales were $41.5 million for the three months ended March 31, 2008 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 advanced product portfolio includes an anthrax immune globulin therapeutic candidate for biodefense indications and a typhoid vaccine and hepatitis B therapeutic vaccine for commercial infectious disease indications. We are developing our anthrax immune globulin therapeutic in part with funding from the National Institute of Allergy and Infectious Diseases, or NIAID. The Wellcome Trust provided funding for the Phase I and Phase II clinical trials of our typhoid vaccine candidate. We typically advance development of our biodefense product candidates only with external funding, and may slow down or put development programs on hold during periods that are not covered by funding.

Our early stage product portfolio includes a next generation anthrax vaccine and botulinum vaccine and botulinum immune globulin therapeutic candidates for biodefense indications, and group B streptococcus and chlamydia vaccine candidates for commercial infectious disease indications. We have entered into collaboration agreements with the Health Protection Agency, or HPA, for the development of a recombinant botulinum vaccine candidate and a botulinum immune globulin candidate.

We are actively pursuing additional government sponsored development grants as well as encouraging both governmental and non-governmental agencies and philanthropic organizations to provide development funding, or to conduct clinical studies of these products. For example, the Wellcome Trust provided funding for the Phase I and Phase II clinical trials of our typhoid vaccine candidate, and NIAID is conducting and funding one of the Phase I clinical trials of our group B streptococcus vaccine candidate.

Manufacturing Infrastructure

We conduct our primary vaccine manufacturing operations at a multi-building campus on approximately 12.5 acres in Lansing, Michigan. To augment our existing manufacturing capabilities, we have constructed a new 50,000 square foot manufacturing facility on our Lansing campus. We expect the cost of this facility to be approximately $75 million, with approximately $55 million attributable to the building and associated capital equipment and the balance related to validation and qualification activities required for regulatory approval and initiation of commercial manufacturing.

We have incurred costs of approximately $67 million for these purposes through March 31, 2008. We completed construction of this facility in 2007 and currently are conducting validation and qualification activities required for regulatory approval. This new facility is a large scale manufacturing plant that we can use to produce multiple fermentation-based vaccine products, subject to complying with change-over procedures required by applicable regulations.

We also own two buildings in Frederick, Maryland that are available to support our future manufacturing requirements. We have incurred costs of approximately $4 million through March 31, 2008 related to initial engineering design and preliminary utility build out of one of these buildings. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that would be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project. We may elect to lease all or a substantial portion of, or sell, one of these facilities to third parties.

Critical Accounting Policies and Estimates

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

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

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

Revenue Recognition

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

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

We have generated BioThrax sales revenues under U.S. government contracts with the DoD and HHS. Under previous DoD contracts, we invoiced the DoD for progress payments upon reaching contractually specified stages in the manufacture of BioThrax. We recorded as deferred revenue the full amount of each progress payment invoice that we submitted to the DoD. Title to the product passed to the DoD upon submission of the first invoice. The earnings process was considered complete upon FDA release of the product for sale and distribution. Following FDA release of the product, we segregated the product for later shipment and recognized as period revenue all deferred revenue related to the released product in accordance with the bill and hold sale requirements under SAB 104. At that time, we also invoiced the DoD for the final progress payment and recognized the amount of that invoice as period revenue.

Under previous contracts with HHS, we invoiced HHS and recognized the related revenues upon delivery of the product to the government carrier, at which time title to the product passed to HHS. Under our current contract with HHS, we invoice HHS and recognize the related revenues upon acceptance by the government at the delivery site, at which time title to the product passes to HHS.

Under a collaboration agreement that we entered into with Sanofi Pasteur in May 2006 for our meningitis B vaccine candidate, we received an upfront license fee and are entitled to additional payments for development work under the collaboration and upon achieving contractually defined development and commercialization milestones.

We evaluated the various components of the collaboration in accordance with Emerging Issues Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables,* or EITF No. 00-21, which addresses whether, for revenue recognition purposes, there is one or several units of accounting in an arrangement. We concluded that under EITF No. 00-21, the upfront license fee, the development work and the milestone payments under our agreement with Sanofi Pasteur should be accounted for as a single unit of accounting. We recognize amounts received under this agreement over the estimated development period as we perform services. We recorded the amount of the upfront license fee as deferred revenue. We are recognizing this revenue over the estimated development period under the contract, currently estimated at seven

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

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

Inventories

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

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

Income Taxes

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

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

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

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

Stock-based Compensation

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

We value our share-based payment transactions using the Black-Scholes valuation model. We measure the amount of compensation cost based on the fair value of the underlying equity award on the date of grant. We recognize compensation cost over the period that an employee provides service in exchange for the award.

The effect of SFAS No. 123(R) on net income (loss) and net income (loss) per share in any period 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.

Financial Operations Overview

Revenues

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

On September 25, 2007, we entered into an agreement with HHS to supply 18.75 million doses of BioThrax to HHS for placement into the SNS. The term of the agreement is from September 25, 2007 through September 24, 2010. The first 5.5 million doses delivered under this contract were sold to HHS at a discounted price, as specified in the contract, due to the limited remaining shelf-life for these specific doses. This discounted price does not apply to the remaining 13.25 million doses that will be sold to HHS under the contract. The firm fixed price for the 18.75 million doses, including the discount, is $400 million in the aggregate.

If we receive FDA approval of our pending application to extend the expiry dating of BioThrax from three years to four years, HHS has agreed to increase the price per dose under the agreement for the remaining 13.25 million doses. In that event, HHS would make a lump sum payment to us reflecting an increase in the price per dose for specified doses delivered prior to such approval and pay an increased price per dose for doses delivered following the date of such approval. The aggregate value of such price adjustment is $34 million. If we do not receive FDA approval of four-year expiry dating during the term of the agreement there will be no adjustment in the price per dose under the agreement. We delivered over 8 million doses of BioThrax to HHS under this agreement through March 31, 2008. Under this agreement, we have also agreed to provide all shipping services related to delivery of doses into the SNS over the term of the agreement, for which HHS has agreed to pay approximately $2.2 million. We invoice HHS for each delivery upon acceptance of BioThrax doses delivered into the SNS. The agreement also provides for HHS to pay up to $11.5 million in milestone payments in connection with us advancing a program to obtain a post-exposure prophylaxis indication for BioThrax. These funds are payable upon achievement of specific program milestones. In October 2007, we achieved the initial milestone and invoiced HHS for $8.8 million. We received this payment from HHS and revenue was recognized in November 2007.

Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we have supplied approximately 10 million doses of BioThrax for immunization of military personnel. Our most recent contract with the DoD, as amended in October 2006, provided for the supply of a minimum of approximately 1.5 million doses of BioThrax to the DoD through September 2007. As a result of a further amendment of the DoD contract in June 2007, we completed delivery of all doses to the DoD under this contract prior to June 30, 2007. We are not currently party to a procurement contract with the DoD.

We believe that the DoD has a continued commitment to procure BioThrax for its active immunization program. We believe that, as a result of an October 2007 Presidential Directive that outlines that U.S. government s objective to enhance coordination and cooperation among federal agencies with respect to countermeasure procurement and stockpile management, in the future the DoD will likely procure additional doses of BioThrax to satisfy ongoing requirements for its active immunization program directly from HHS and not from us. We believe that these purchases by DoD from HHS may result in additional purchases by HHS from us.

In May 2006, we entered into a collaboration agreement with Sanofi Pasteur relating to the development and commercialization of our meningitis B vaccine candidate under which we granted Sanofi Pasteur an exclusive, worldwide license under our proprietary technology to

develop and commercialize our meningitis B vaccine candidate and received a $3.8 million upfront license fee. This agreement also provides for a series of milestone payments upon the achievement of specified development and commercialization objectives, payments for development work under the collaboration and royalties on net sales of this product. We defer the upfront license fee, milestone payments and development reimbursement payments under this agreement, and record revenue in accordance with our revenue recognition policies. We are currently in negotiations with Sanofi Pasteur to amend this agreement.

In September 2007, we received a development contract from NIAID, valued at up to $9.5 million, in support of non-clinical and clinical studies of our anthrax immune globulin therapeutic candidate. Under terms of the development contract, we will use the funds to conduct various studies on this product candidate, including animal efficacy studies and clinical trials. Through March 31, 2008, we have invoiced approximately $300,000 under this contract.

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

Cost of Product Sales

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

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

Research and Development Expenses

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

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

We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to be in a position to realize the potential of our product candidates. We expect that development spending for both our advanced stage products and earlier stage products will increase as our product development activities continue and we prepare for regulatory submissions and other regulatory activities. We expect that the magnitude of any increase in our research and development spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, the size, structure and duration of any follow on clinical program that we may initiate, costs associated with manufacturing our product candidates on a large scale basis for later stage clinical trials, our ability to use data generated by government agencies, such as the ongoing studies with BioThrax being conducted by the Centers for Disease Control and Prevention, or CDC, and our ability to rely upon and utilize clinical and non-clinical data, such as the data generated by CDC from use of the pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, sales and marketing, business development, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales or research and development expense and professional fees for legal and accounting services. We currently market and sell BioThrax directly to the 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 income on our cash, cash equivalents and short-term investments, and we incur interest expense on our indebtedness. We capitalize interest expense in accordance with SFAS No. 34, *Capitalization of Interest Cost,* based on the cost of major ongoing projects which have not yet been placed in service, such as our new manufacturing facility. Our total interest cost will increase in future periods as compared to prior periods as a result of the term loan that we entered into in June 2007, as well as any borrowings under our revolving line of credit. In addition, some of our existing debt arrangements provide for increasing amortization of principal payments in future periods. See Liquidity and Capital Resources Debt Financing for additional information.

Results of Operations

Quarter Ended March 31, 2008 Compared to Quarter Ended March 31, 2007

Revenues

Product sales revenues increased by $16.1 million, or 63%, to $41.5 million for the three months ended March 31, 2008 from $25.4 million for the three months ended March 31, 2007. This increase in product sales revenues was primarily due to a 68% increase in the number of doses of BioThrax delivered, partially offset by a 3% decrease in the average sales price per dose.

Product sales revenues for the three months ended March 31, 2008 consisted of BioThrax sales to HHS of $41.1 million and aggregate international and other sales of $394,000. 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.

Contracts and grants revenues increased by $214,000, or 21%, to $1.2 million for the three months ended March 31, 2008 from $1.0 million for the three months ended March 31, 2007. Contracts and grants revenues for the three months ended March 31, 2008 consisted of $798,000 from the Sanofi Pasteur collaboration, related to recognition of deferred revenue associated with the upfront payment received in 2006 as well as development service revenue, and $418,000 from the NIH. Contracts and grants 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 $2.5 million, or 45%, to $8.0 million for the three months ended March 31, 2008 from $5.5 million for the three months ended March 31, 2007. This increase was attributable to a 68% increase in the number of doses of BioThrax delivered, partially offset by decreased costs associated with improved production yield.

Research and Development Expense

Research and development expenses decreased by $4.1 million, or 26%, to $11.5 million for the three months ended March 31, 2008 from $15.6 million for the three months ended March 31, 2007. This decrease reflects lower contract service costs, and includes decreased expenses of $5.8 million on product candidates that are categorized in the biodefense segment, partially offset by increased expenses of $1.4 million on product candidates categorized in the commercial segment and $391,000 in other research and development expenses, which are in support of technology platforms and central research and development activities.

The decrease in spending on biodefense product candidates, detailed in the table below, was attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials. The spending for BioThrax enhancements is related to preparing for and conducting animal efficacy studies to support applications for marketing approval of these enhancements, which we expect to submit to the FDA in late 2008 or 2009. The decrease in spending in our immune globulin therapeutic development program of $4.3 million was primarily due to costs related to plasma extraction and fractionation incurred in early 2007 that did not recur in 2008. The spending for the recombinant botulinum vaccine program resulted from advancing this program to the process development stage and the manufacture of clinical trial material in early 2007. The spending for the next generation anthrax vaccine program resulted from feasibility studies and formulation development of product candidates. We continue to assess, and may alter, our future development plans for our products based on the interest of the U.S. government or other non-governmental organizations in providing funding for further development or procurement.

The increase in spending on commercial product candidates, detailed in the table below, primarily reflects additional personnel and contracted services. The spending for our typhoid vaccine candidate resulted from the ongoing Phase II study in Vietnam, which commenced in the first quarter of 2007. The spending for our hepatitis B therapeutic vaccine candidate resulted from preparing for and initiating our Phase II clinical trial, which commenced in 2007. The spending for our group B streptococcus vaccine candidate resulted from preparing for Phase I clinical trials for two of the protein components of the vaccine candidate, which the NIAID is conducting and funding. Both our chlamydia and meningitis B vaccine candidates are in preclinical development.

The increase in other research and development expenses was primarily attributable to spending associated with product development programs that we acquired in the acquisition of ViVacs GmbH, or Vivacs, in July 2006.

Our principal research and development expenses for the three months ended March 31, 2008 and 2007 are shown in the following table:

	Three Months Ended March 31,	
(in thousands)	**2008**	**2007**
Biodefense:		
BioThrax enhancements	$ 639	$ 2,029
Immune globulin therapeutic development	1,634	5,955
Recombinant bivalent botulinum vaccine	373	1,397
Next generation anthrax vaccine	1,609	710
Total biodefense	4,255	10,091
Commercial:		
Typhoid vaccine	2,348	1,785
Hepatitis B therapeutic vaccine	1,074	1,141
Group B streptococcus vaccine	2,095	1,149
Chlamydia vaccine	435	455
Meningitis B vaccine	384	456
Total commercial	6,336	4,986
Other	884	493
Total	$ 11,475	$ 15,570

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $867,000, or 8%, to $12.1 million for the three months ended March 31, 2008 from $11.2 million for the three months ended March 31, 2007. The increase in selling, general and administrative expenses was driven by an increase in our headquarters and staff organization to support our operations as a public company and to support the overall growth of our business, and primarily reflects an increase of approximately $731,000 resulting from the addition of personnel and increased legal and other professional services for our headquarters organization and an increase of $161,000 in sales and marketing expenses related to the growth of our staff and an increase in our sales and marketing activities. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses increased by $429,000, or 5%, to $9.3 million for the three months ended March 31, 2008 from $8.9 million for the three months ended March 31, 2007. Selling, general and administrative expenses related to our commercial segment increased by $438,000, or 16%, to $2.8 million for the three months ended March 31, 2008 from $2.3 million for the three months ended March 31, 2007.

Total Other Income (Expense)

Total other income (expense) decreased by $375,000, or 37%, to income of $650,000 for the three months ended March 31, 2008 from income of $1.0 million for the three months ended March 31, 2007. This decrease resulted primarily from a decrease in interest income of $209,000 as a

result of decreased average cash balances and a decrease in other income (expense) of $191,000.

Income Taxes

Provision for (benefit from) income taxes increased by $6.9 million to a provision for income taxes of $4.8 million for the three months ended March 31, 2008 from a benefit from income taxes of $2.1 million for the three months ended March 31, 2007. The provision for income taxes for the three months ended March 31, 2008 resulted primarily from our income before provision for income taxes of $11.8 million and an effective annual tax rate of 41%.

The benefit from income taxes for the three months ended March 31, 2007 resulted primarily from our loss before benefit from income taxes of $4.8 million and an effective annual tax rate of 44%. The decrease in the effective annual tax rate is due primarily to a decrease in the impact of foreign operations related to a change in tax rates effective in 2008. The benefit from income taxes for the three months ended March 31, 2007 also reflects research and development tax credits of $226,000.

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, 2008 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, the net proceeds from our initial public offering 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, 2007.

As of March 31, 2008, we had cash and cash equivalents of $92.7 million.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2008 and 2007:

	Three Months Ended March 31,	
(in thousands)	**2008**	**2007**
Net cash provided by (used in):		
Operating activities(1)	$ (4,844)	$ 14,616
Investing activities	(10,431)	(16,490)
Financing activities	2,292	(6,899)
Total net cash used	$ (12,983)	$ (8,773)

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

Net cash used in operating activities of $4.8 million for the three months ended March 31, 2008 resulted principally from a decrease in income taxes payable of $3.8 million due to the timing of payment of our 2007 income tax liability, a decrease in accrued compensation of $2.9 million related to the payment of 2007 annual bonuses in March 2008, an increase in billed but uncollected accounts receivable of $2.7 million and an increase in inventories of $1.9 million, reflecting the value of BioThrax lots being manufactured or awaiting delivery, partially offset by net income of $7.0 million for the quarter.

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 $16.1 million due to the timing of payment of our 2006 income tax liability, a decrease in accrued compensation of $2.5 million related to the payment of 2006 annual bonuses in March 2007, an increase in inventories of $2.2 million reflecting the value of BioThrax lots being manufactured or awaiting delivery, and our net loss of $2.7 million for the three months ended March 31, 2007.

Net cash used in investing activities for the three months ended March 31, 2008 and 2007 resulted principally from the purchase of property, plant and equipment and, in 2008, the issuance of notes receivable in the amount of $3.5 million. Capital expenditures of $6.9 million and $16.5 million for the three months ended March 31, 2008 and 2007, respectively, relate primarily to construction, validation and qualification activities for our new manufacturing facility in Lansing.

Net cash provided by financing activities of $2.3 million for the three months ended March 31, 2008 resulted primarily from the additional proceeds from a draw on our revolving line of credit with Fifth Third Bank of $15.0 million, partially offset by $12.7 million of principal payments on long-term indebtedness, including the repayment of $11.8 million under our revolving line of credit with Fifth Third Bank.

Net cash used in financing activities of $6.9 million for the three months ended March 31, 2007 resulted from $9.4 million in principal payments on long-term indebtedness, including the repayment of $8.9 million under our revolving line of credit with Fifth Third, 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.

Debt Financing

As of March 31, 2008, we had $60.2 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;
- $6.6 million outstanding under a mortgage loan from PNC Bank (formerly Mercantile Potomac Bank) used to finance the remaining portion of the purchase price for the first Frederick facility;
- $8.1 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;
- $28.0 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
- $15.0 million outstanding under a $15.0 million revolving line of credit with Fifth Third Bank. This balance was repaid in April 2008.

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 primarily based on our $75 million planned investment in our Lansing facility. In addition, we must maintain a specified number of employees in Lansing to continue to qualify for these tax benefits.

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures and debt service requirements from existing cash and cash equivalents, revenues from BioThrax product sales and other committed sources of funding. There are numerous risks and uncertainties associated with BioThrax product sales and with the development and commercialization of our product candidates.

We may seek to raise additional external debt financing to provide additional financial flexibility. Our committed external sources of funds consist of the borrowing availability under our revolving line of credit with Fifth Third Bank, development funding under our collaboration agreement with Sanofi Pasteur and funding from NIAID, including for studies related to our anthrax immune globulin therapeutic product candidate. 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 validation and qualification activities related to 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 March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an Amendment of FASB Statement No. 133,* or SFAS No. 161. SFAS No. 161 states that entities are required to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under Statement No. 133 and its related interpretations and how derivative instruments and related hedged items affect an entity s financial position, financial performance, and cash flows. The provisions of SFAS No. 161 are effective for fiscal years beginning on or after November 15, 2008, with early adoption encouraged. We anticipate that the adoption of this statement will not have a material impact on our financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an Amendment of ARB No. 51,* or SFAS No. 160. SFAS No. 160 clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements, requires consolidated net income to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest, establishes a single method of accounting for changes in a parent s ownership interest in a subsidiary that do not result in deconsolidation, and requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. The provisions of SFAS No. 160 are effective for fiscal years beginning on or after December 15, 2008. We are currently evaluating the impact of the adoption of this statement on our financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations,* or SFAS No. 141(R). SFAS No. 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values, changes the recognition of assets acquired and liabilities assumed arising from contingencies, changes the recognition and measurement of contingent consideration, and requires the expensing of acquisition-related costs as incurred. SFAS No. 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and it may not applied before that date. The provisions of SFAS No. 141(R) will impact our financial statements to the extent that we are party to a business combination after the pronouncement has been adopted.

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2008. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2008, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the fiscal quarter ended March 31, 2008 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. Between 2001 and 2003, over 100 individual plaintiffs filed a series of lawsuits in which they claimed damages resulting from personal injuries allegedly caused by vaccination with BioThrax by the DoD. In April 2006, the U.S. District Court for the Western District of Michigan entered summary judgment in our favor in four consolidated lawsuits brought by approximately 120 claimants. The District Court s ruling in these consolidated 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.

In 2005 and 2006, we were named as a defendant in three federal lawsuits, each filed on behalf of a single plaintiff claiming different injuries caused by DoD s immunization with BioThrax. Each plaintiff sought a different amount of damages. The plaintiff in one case alleged that the vaccine caused Bell s palsy and other related conditions and requested damages in excess of $75,000. The plaintiff in another case alleged that the vaccine caused a condition that originally was diagnosed as encephalitis related to a gastrointestinal infection and caused him to fall into a coma for many weeks and requested damages in excess of $10 million. The plaintiff in the last case alleged that the vaccine caused erosive rheumatoid arthritis and requested damages in excess of $1 million.

Two of these lawsuits were dismissed with prejudice in September 2007 and January 2008. The final case, in which the plaintiff alleged that the vaccine caused erosive rheumatoid arthritis, was dismissed for lack of personal jurisdiction in October 2006. The plaintiff appealed the dismissal to the U.S. Court of Appeals for the Ninth Circuit, and the Ninth Circuit affirmed the dismissal, without prejudice to file a new complaint in a jurisdiction in which personal jurisdiction is proper. If the case is re-filed in another jurisdiction, we intend to rely on defenses similar to those on which we prevailed in the cases that were filed between 2001 and 2003. We believe that we are entitled to indemnification under our contract with the DoD for legal fees and any damages associated with that case.

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

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

In October 2006, the DoD announced that it was resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency DoD civilian personnel and contractors. In December 2006, the same counsel who represented the plaintiffs in the 2003 litigation filed a new lawsuit against the government in the same federal court, on behalf of unnamed service members and the DoD civilian employees or contractors and purportedly on behalf of a class of similarly situated individuals. The suit contends on various grounds that the FDA's 2005 final order should be set aside as substantively and procedurally flawed and that BioThrax is not properly approved for use in the DoD s vaccination program. The plaintiffs seek a declaration that BioThrax is improperly licensed and is not approved for use against inhalation anthrax, an order vacating the FDA s 2005 final order, and an injunction prohibiting the DoD from using BioThrax in a mandatory vaccination program. In February 2008, the federal court in which that case was pending dismissed the action, concluding that FDA did not make a clear error of judgment in reaffirming the safety and efficacy of BioThrax. Although we are not a party to the lawsuits challenging DoD s mandatory anthrax vaccination program, if the District Court were to enjoin the mandatory use of BioThrax by DoD, the amount of future purchases of BioThrax by the U.S. government could be affected.

Other. We are, and may in the future become, subject to other legal proceedings, claims and litigation arising in the ordinary course of our business in connection with the manufacture, distribution and use of our products and product candidates. For example, Emergent BioDefense Operations is a defendant, along with many other vaccine manufacturers, in a series of lawsuits that have been filed in various state and federal courts in the United States alleging that thimerosal, a mercury-containing preservative used in the manufacture of some vaccines, caused personal injuries, including brain damage, central nervous system damage and autism. No specific dollar amount of damages has been claimed. Emergent BioDefense Operations is currently a named defendant in 40 lawsuits pending in two jurisdictions: three in California and 37 in Illinois. The products at issue in these lawsuits are pediatric vaccines. Because we are not currently and have not historically been in the business of manufacturing or selling pediatric vaccines, we do not believe that we manufactured the pediatric vaccines at issue in the lawsuits.

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

ITEM 1A. RISK FACTORS

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

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

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales of BioThrax, our FDA-approved anthrax vaccine and only marketed product. In 2006, 2007, and the three months ended March 31, 2008, we derived substantially all of our revenue from our BioThrax contracts with the DoD and HHS. In October 2007, the White House issued a Presidential Directive that outlines the U.S. government s objective to enhance coordination and cooperation among federal agencies with respect to countermeasure procurement and stockpile management. Also in October 2007, the U.S. Government Accountability Office, or GAO, issued a report that was critical of HHS for lacking an effective strategy to minimize waste in the SNS, citing concerns of large amounts of BioThrax that will become unusable each year due to shelf life expiration.

We believe that the DoD has a continued commitment to procure BioThrax for its active immunization program, but that in the future the DoD will likely procure additional doses of BioThrax to satisfy ongoing requirements for its active immunization program directly from HHS and not from us. It is possible that these purchases by DoD from HHS will not result in any additional purchases by HHS from us. Our existing and prior contracts with the DoD and HHS do not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government. HHS has issued an RFP for grants to develop and procure a recombinant protective antigen based anthrax vaccine. If we apply for the grant, we may not win the award. The development of our recombinant protective antigen product candidate could be harmed. Additionally, procurement by HHS of a recombinant protective antigen based anthrax vaccine could reduce demand for BioThrax. 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;
- the risk that the government will issue a request for proposal to which we would not be eligible to respond; 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, the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority, or BARDA, has issued a request for proposal for a recombinant protective antigen, or rPA, anthrax vaccine for the strategic national stockpile. If we are not successful in developing a qualifying rPA vaccine candidate and another company is successful in developing such a product, the U.S. government may purchase the other company s product candidate instead of BioThrax or one of our other anthrax vaccine candidates. 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 contract for BioThrax requires ongoing funding decisions by the government. The failure to fund this contract could cause our financial condition and operating results to suffer materially.

Our principal customer for BioThrax is the U.S. government. In addition, we anticipate that the U.S. government will be the principal customer for any other biodefense products that we successfully develop. Over its lifetime, a U.S. government program may be implemented through the award of many different individual contracts and subcontracts. The funding of some government programs is subject to Congressional appropriations, generally made on a fiscal year basis even though a program may continue for several years. Our government customers are subject to stringent budgetary constraints and political considerations. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, our business, revenues and operating results may suffer.

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

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

procurement integrity;

export control;

government security regulations;

employment practices;

protection of the environment;

accuracy of records and the recording of costs; and

foreign corrupt practices.

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

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

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

Our existing and prior contracts for the supply of BioThrax with the DoD and HHS have been fixed price contracts. We expect that our future contracts with the U.S. government for BioThrax as well as biodefense product candidates that we successfully develop also may be fixed price contracts. Under a fixed price contract, we are required to deliver our products at a fixed price regardless of the actual costs we incur and to absorb any costs in excess of the fixed price. Estimating costs that are related to performance in accordance with contract specifications is difficult. 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 to products, including intellectual property, developed under the contract;

take actions that result in a longer development timeline than expected;

direct the course of a development program in a manner not chosen by the government contractor;

suspend or debar the contractor from doing business with the government or a specific government agency;

pursue criminal or civil remedies under the False Claims Act and False Statements Act; and

control or prohibit the export of products.

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

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

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

In October 2006, the DoD announced that it was resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency DoD civilian personnel and contractors. In December 2006, the same counsel who brought the prior lawsuit filed a new lawsuit contending that the FDA's 2005 final order should be set aside and that BioThrax is not properly approved for use in the DoD s vaccination program. In February 2008, the federal court in which that case was pending dismissed the action, concluding that FDA did not make a clear error of judgment in reaffirming the safety and efficacy of BioThrax.

Although we are not a party to the lawsuits challenging the DoD s mandatory use of the vaccine, if a court were to again enjoin the DoD's use of BioThrax on a mandatory basis, the amount of future purchases of BioThrax by the U.S. government could be affected. Furthermore, contractual

indemnification provisions and statutory liability protections may not fully protect us from all related liabilities, and statutory liability protections could be revoked or amended to reduce the scope of liability protection. In addition, lawsuits brought directly against us by third parties, even if not successful, require us to spend time and money defending the related litigation.

Risks Related to Our Financial Position and Need for Additional Financing

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

We commenced operations in 1998, and the FDA approved the manufacture of BioThrax at our renovated facilities in Lansing in December 2001. Although we were profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. Our profitability is substantially dependent on revenues from BioThrax product sales. Revenues from BioThrax product sales have fluctuated significantly in recent quarters, and we expect that they will continue to fluctuate significantly from quarter to quarter based on the timing of our fulfilling orders from the U.S. government. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

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

As of March 31, 2008, we had $60.2 million principal amount of debt outstanding. We may seek to raise substantial external debt financing to provide additional financial flexibility. Our leverage could have significant adverse consequences, including:

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

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

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

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

As of March 31, 2008, we had $92.7 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, completion of validation and qualification activities related to our new manufacturing facility in Lansing, Michigan and the build out of our manufacturing facilities 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.

Our committed external sources of funds consist of the borrowing availability under our revolving line of credit with Fifth Third Bank, development funding under our collaboration agreement with Sanofi Pasteur, and funding from NIAID and BARDA including for studies related to our anthrax immune globulin therapeutic product candidate. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, which we may not be able to obtain when needed or on attractive terms, which would force us to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

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

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

Risks Related to Manufacturing and Manufacturing Facilities

We have initiated a manufacturing facility expansion program. Delays in completing and receiving regulatory approvals for these manufacturing facility projects could limit our potential revenues and growth.

We are spending significant amounts for the validation and qualification activities for our new 50,000 square foot manufacturing facility on our Lansing, Michigan campus, which has been designed and constructed to enable us to manufacture BioThrax on a large scale for our existing and potential future customers. This new facility is a large scale manufacturing plant that we can use to produce multiple vaccine products, subject to complying with change-over procedures required by applicable regulations.

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 completion of the Lansing facility and, if we proceed, the build out of the Frederick facilities, will involve substantial expenditures and likely require external sources of funds. Any delays in validation and qualification activities 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. 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 we can sell products manufactured in a new facility.

We expect to complete process validation, including the manufacture of five consistency lots of BioThrax, in our new large-scale manufacturing facility in Lansing in 2008. The Lansing manufacturing expansion project requires that we scale-up both fermentation and downstream processing compared to the levels employed at our existing production facility. We will be required to show that BioThrax manufactured in the new facility is comparable to BioThrax manufactured at our existing facility. Our current plan is to demonstrate comparability through non-clinical data. If the FDA approves our plan to rely on non-clinical data, we expect to submit a supplement to our biologics license application, or BLA, seeking marketing authorization for BioThrax manufactured in this new facility as early as 2009. If the FDA requires a human bridging trial to demonstrate comparability, then we will incur additional expenses associated with the clinical studies, and we may not file a BLA supplement until 2010 or later.

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 marketing approval for BioThrax manufactured in our new facility in Lansing is delayed, we may not be able to deliver sufficient quantities of BioThrax to allow us to increase sales of BioThrax to the U.S. government and other customers, which would limit our opportunities for growth. Cost overruns associated with constructing either our Lansing or Frederick facilities could require us to raise additional funds from external sources. We may not be able to do so on favorable terms or at all.

BioThrax and our immunobiotic product candidates are complex to manufacture, especially on a large scale commercial basis, which could cause us to delay product launches or experience shortages of products.

BioThrax and all our product candidates are biologics. Manufacturing biologic products, especially in large quantities, is complex. The products must be made consistently and in compliance with a clearly defined manufacturing process. Accordingly, it is essential to be able to validate and control the manufacturing process to assure that it is reproducible. Slight deviations anywhere in the manufacturing process, including obtaining materials, filling, labeling, packaging, storage and shipping and quality control and testing, some of which we experience from time to time, may result in lot failures, delay in the release of lots, product recalls or spoilage. We will not be able to sell any lots that fail to satisfy release testing specifications.

FDA approval is required for the release of each lot. We must provide the FDA with the results of potency testing before lots are released for sale. We have one mechanism for conducting this potency testing that is reliant on a unique animal strain for which we have no redundancy. In developing redundancy, we may face significant regulatory hurdles. In the event of a problem with this strain, if we have not developed redundancy, we would not be able to provide the FDA with required potency testing.

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

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

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

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

In addition, providers of bioterrorism 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. We do not carry business interruption insurance.

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

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

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

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

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

We currently rely on third parties to manufacture the supplies of our immunobiotic product candidates that we require for preclinical and clinical development, including our immune globulin therapeutic product candidates, typhoid vaccine, hepatitis B therapeutic vaccine, and group B streptococcus vaccine candidates. Any significant delay in obtaining adequate supplies of our product candidates could adversely affect our ability to develop or commercialize these product candidates. Although we recently commissioned a new pilot plant manufacturing facility on our Lansing campus 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 therapeutic 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 therapeutic 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 therapeutic candidate.

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

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

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

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

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

Our development and manufacturing processes involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we are subject to federal, state, local and foreign laws and regulations governing the use, manufacture, distribution, storage, handling, disposal and recordkeeping of these materials. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS and the DoD.

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

We also are subject to export control regulations governing the export of BioThrax and technology and materials used to develop and manufacture BioThrax and our product candidates. If we fail to comply with environmental, occupational health and safety, biosafety and export control laws, we could be held liable for fines, penalties and damages that result, and any such liability could exceed our assets and resources. In addition, we could be required to cease immediately all use of a select agent or toxin, and we could be prohibited from exporting our products, technology and materials. Our general liability and excess insurance policies provide for coverage up to annual aggregate limits of $12 million, with coverage of $1 million per occurrence and $2 million in the aggregate for general liability and $10 million per occurrence and in the aggregate for excess liability.

The general liability policy currently has a $15,000 per occurrence deductible. Both policies exclude coverage for liabilities relating to the release of pollutants. We do not currently hold insurance policies expressly providing for coverage relating to our use of hazardous materials other than storage tank liability insurance for our Lansing facility with a $1 million annual aggregate limit and a $10,000 per claim deductible. The insurance that we currently hold may not be adequate to cover all liabilities relating to accidental contamination or injury as a result of pollution conditions or other extraordinary or unanticipated events.

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 therapeutic 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 studies in approved animal models;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.
- successful completion of clinical trials;
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities;
- a determination by the Secretary of HHS that our biodefense product candidates should be purchased for the SNS prior to FDA approval;
- establishing commercial manufacturing processes of our own or arrangements with contract manufacturers;
- manufacturing stable commercial supplies of product candidates, including materials based on recombinant technology;
- launching commercial sales of the product, whether alone or in collaboration with others; and
- acceptance of the product by potential government customers, physicians, patients, healthcare payors and others in the medical community.

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

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

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

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

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;

we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;

regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;
the cost of our clinical trials could escalate and become cost prohibitive;

any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials; and

the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

For example, the standard of care for the treatment of patients infected with hepatitis B is affecting our ability to recruit participants for our Phase II clinical trial, causing us to consider expanding or moving the program to sites around the world. In addition, because some of our current and future vaccine candidates contain live attenuated viruses, our testing of these vaccine candidates is subject to additional risk. For example, there have been reports of serious adverse events following administration of live vaccine products in clinical trials conducted by other vaccine developers. Also, for some of our current and future vaccine candidates, we expect to conduct clinical trials in chronic carriers of the disease that our product candidate seeks to prevent. There have been reports of disease flares in chronic carriers following administration of live vaccine products.

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

be delayed in obtaining marketing approval for our product candidates;

not be able to obtain marketing approval; or

obtain approval for indications that are not as broad as intended.

In addition, our development plan for BioThrax as a post-exposure prophylaxis for anthrax infection provides for a non-human primate efficacy study. However, the timing of our non-human primate efficacy study depends upon the successful development of a non-human primate model by NIAID. If 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 foreign governments and state and local governments, which we expect will be interested in BioThrax to protect emergency responders such as police, fire and emergency medical personnel, multinational companies, non-governmental organizations and hospitals.

The market for sales of BioThrax to customers other than the U.S. government is 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 modest sales to these customers. In particular, we have supplied small amounts of BioThrax directly to several foreign governments. In 2007 and the three months ended March 31, 2008, our sales of BioThrax to customers other than the U.S. government represented a small portion of our revenue. If we fail to significantly increase our sales of BioThrax to these customers, our business and opportunities for growth could be materially harmed.

Government regulations and the terms of our U.S. government contract 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, 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 doses that we do not currently anticipate. If the DoD were to require delivery of additional doses, it could deplete BioThrax supplies that would otherwise be available for commercial sales. In addition, the DoD could either sell BioThrax directly to foreign governments at a lower price than we may offer or donate BioThrax to foreign governments under the DoD s Foreign Military Sales program.

Our ability to meet any potential increased demand that develops for sales of BioThrax to customers other than the U.S. government depends on our available production capacity. We use substantially all of our current production capacity at our facility in Lansing to manufacture BioThrax for sale to U.S. government customers. If FDA approval to sell BioThrax manufactured in 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 customers other than the U.S. government, which would limit our opportunities for growth.

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

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

In addition, notwithstanding favorable findings regarding the safety and efficacy of BioThrax by the FDA in its final ruling in December 2005, the GAO reiterated concerns regarding BioThrax in Congressional testimony in May 2006 that it had previously identified beginning in 1999. These concerns include the need for a six-dose regimen and annual booster doses, questions about the long-term and short-term safety of the vaccine, including how safety is affected by gender differences, and uncertainty about the vaccine s efficacy.

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

The use of vaccines carries a risk of adverse health effects. The adverse reactions that have been associated with the administration of BioThrax are similar to those observed following the administration of other adult vaccines and include local reactions, such as redness, swelling and limitation of motion in the inoculated arm, and systemic reactions, such as headache, fever, chills, nausea and general body aches. In addition, some serious adverse events have been reported to the vaccine adverse event reporting system database maintained by the CDC and the FDA

with respect to BioThrax. The report of any such adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event. These serious adverse events, including diabetes, heart attacks, autoimmune diseases, including Guillian Barre syndrome, lupus and multiple sclerosis, lymphoma and death, have not been causally linked to the administration of BioThrax.

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

- the prevalence and severity of any side effects;
- the efficacy and potential advantages over alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- the relative convenience and ease of administration;
- the willingness of the target patient population to try new products and of physicians to prescribe these products;
- the strength of marketing and distribution support; and
- the sufficiency of coverage or reimbursement by third parties.

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

Products developed to treat diseases caused by or to combat the threat of bioterrorism will be subject to changing political and social environments. The political and social responses to bioterrorism have been highly charged and unpredictable. Political or social pressures or changes in the perception of the risk that military personnel or civilians could be exposed to biological agents as weapons of bioterrorism may delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, which would harm our business.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Furthermore, lawsuits brought against us by third parties or activists, even if not successful, require us to spend time and money defending the related litigation. The need to address political and social issues may divert our management s time and attention from other business concerns. For example, between 2001 and 2004, members of the military and various activist groups who opposed mandatory inoculation with BioThrax petitioned the FDA and a federal court to revoke the license for BioThrax and to terminate the DoD program for the mandatory administration of BioThrax to military personnel. Although the DoD prevailed in the challenge to its mandatory vaccination program, the actions of these groups created negative publicity about BioThrax. Lawsuits or publicity campaigns could limit the demand for BioThrax and our biodefense product candidates and harm our future business.

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

To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We currently market and sell BioThrax directly to the DoD and HHS through a small, targeted marketing and sales group. We plan to continue to do so and expect that we will use a similar approach for sales to the U.S. government of any other biodefense product candidates that we successfully develop. However, to increase our sales of BioThrax to state and local governments and foreign governments and create an infrastructure for future sales of other biodefense products to these customers, we plan to expand our sales and marketing organization, which will be expensive and time consuming.

We may not be able to attract, hire, train and retain qualified sales and marketing personnel to build a significant or effective marketing and sales force for sales of biodefense product candidates to customers other than the U.S. government or for sales of our commercial product candidates.

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

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

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

Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. We believe that our most significant competitors in the area of immunobiotics are a number of pharmaceutical companies that have vaccine programs, including GlaxoSmithKline, Sanofi-Aventis, Wyeth, Merck and Novartis, as well as smaller more focused companies engaged in immunobiotic development, such as Cangene, Human Genome Sciences, Acambis, Avant Immunotherapeutics, Dor BioPharma, Dynport Vaccine Corporation, Elusys, Bavarian Nordic, Pharmathene and Avecia.

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

Although BioThrax is the only anthrax vaccine approved by the FDA for the prevention of anthrax infection, the government is funding the development of new products that could compete with BioThrax, and could eventually procure those new products in addition to, or instead of, BioThrax, potentially reducing our BioThrax revenues. We also face competition for our biodefense immunobiotic product candidates. For example, HHS has awarded a SNS supply contract to a competitor of ours for an anthrax immune globulin and is assisting this company in its production efforts by providing it with BioThrax doses that we delivered for placement into the SNS so that it can immunize donors and obtain plasma for its anthrax immune globulin therapeutic product candidate. HHS has awarded a SNS supply contract to another competitor of ours for a monoclonal antibody to anthrax as a post-exposure therapeutic for anthrax infection. Several companies have botulinum vaccines in early clinical or preclinical development. 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 contract with HHS and federal legislation enacted to protect manufacturers of biodefense and anti-terrorism countermeasures may limit our potential liability related to the manufacture, sale and use of BioThrax and our biodefense product candidates. However, these contractual provisions and legislation may not fully protect us from all related liabilities.

The Public Readiness and Emergency Preparedness Act, or PREP Act, which was signed into law in December 2005, creates general immunity for manufacturers of biodefense countermeasures, including security countermeasures, when the Secretary of HHS issues a declaration for their

manufacture, administration or use. A PREP Act declaration is meant to provide general immunity from all claims under state or federal law for loss arising out of the administration or use of a covered countermeasure.

Manufacturers are not entitled to this protection in cases of willful misconduct. Upon a declaration by the Secretary, a compensation fund is created to provide timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure. The covered injuries to which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer only after they have exhausted their remedies under the compensation program. However, a willful misconduct action could be brought against us if any individuals exhausted their remedies under the compensation program and thereby expose us to liability.

Our September 2007 contract with HHS provides that BioThrax in the SNS will not be administered in humans until the Secretary of HHS issues a PREP Act declaration applicable to BioThrax. We do not know, however, whether the PREP Act would provide adequate coverage or survive anticipated legal challenges to its validity.

In August 2006, the Department of Homeland Security approved our application under the Safety Act enacted by the U.S. Congress in 2002 for liability protection for sales of BioThrax. The Safety Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. In addition, the Safety Act provides a process by which an anti-terrorism technology may be certified as an approved product by the Department of Homeland Security and therefore entitled to a rebuttable presumption that the government contractor defense applies to sales of the product.

The government contractor defense, under specified circumstances, extends the sovereign immunity of the United States to government contractors who manufacture a product for the government. Specifically, for the government contractor defense to apply, the government must approve reasonably precise specifications, the product must conform to those specifications and the supplier must warn the government about known dangers arising from the use of the product. Although we are entitled to the benefits of the Safety Act, it may not provide adequate protection from any claims made against us.

In addition, although our prior contracts with DoD and HHS provided that the U.S. government would indemnify us for any damages resulting from product liability claims, our current contract with HHS does not contain such indemnification, and we cannot be certain that we will be able to negotiate similar indemnification provisions in future contracts or that the U.S. government will honor its indemnification obligations. For example, although we have notified the DoD of the lawsuits filed against us by current and former members of the U.S. military claiming damages as the result of personal injuries allegedly suffered from vaccination with BioThrax, the DoD has not yet acted on our claim for indemnification pending resolution of our claims under our product liability insurance. Members of Congress have proposed and may in the future propose legislation that reduces or eliminates the statutory liability protections for manufacturers of biodefense countermeasures.

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

We face an inherent risk of product liability exposure related to the sale of BioThrax and any other products that we successfully develop and the testing of our product candidates in clinical trials. For example, we currently are a defendant in two federal lawsuits filed on behalf of two individuals who alleged that they were vaccinated with BioThrax by the DoD and claimed damages resulting from personal injuries allegedly suffered because of the vaccinations. The plaintiffs in these lawsuits claimed different injuries and sought varying amounts of damages.

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

Under our BioThrax contracts with the DoD and HHS, the U.S. government indemnifies us against claims by third parties for death, personal injury and other damages related to BioThrax, including reasonable litigation and settlement costs, to the extent that the claim or loss results from specified risks not covered by insurance or caused by our grossly negligent or criminal behavior. As required under such contracts, we have notified the DoD of personal injury claims that have been filed against us as a result of the vaccination of U.S. military personnel with BioThrax and are seeking reimbursement from the DoD for uninsured costs incurred in defending these claims.

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, or if the U.S. government does not honor its indemnification obligations, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

We currently have product liability insurance for coverage up to a $10 million annual aggregate limit with a deductible of $75,000 per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Product liability insurance is difficult to obtain and increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. For example, from 2002 through February 2006, we were unable to obtain product liability insurance for sales of BioThrax on commercially reasonable terms. We do not believe that the amount of insurance we have been able to obtain for BioThrax is sufficient to manage the risk associated with the potential large scale deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on contractual indemnification provisions and statutory protections to limit our liability exposure for BioThrax.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, our growth will require us to hire a significant number of qualified scientific and commercial personnel, including clinical development, regulatory, marketing and sales executives and field sales personnel, as well as additional administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

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

Our business could be adversely affected by a negative audit by the U.S. government.

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

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

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

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

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

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

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

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

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

We have the right to use certain property and equipment owned by the DoD, referred to as government furnished equipment, or GFE, at our Lansing, Michigan site in the manufacture of BioThrax. We pay the DoD a small usage fee for the GFE based on the number of doses of BioThrax that we produce for sale to customers other than the U.S. government. We have the option to purchase all or part of existing GFE from

the DoD on terms to be negotiated with the DoD. If the DoD modifies the terms under which we use the GFE in a manner that is unfavorable to us, including substantially increasing the usage fee, or we are unable to reach an agreement with DoD concerning the terms of the purchase of that part of the GFE necessary for our business, our business could be harmed. If the U.S. government were to terminate or fail to extend all BioThrax supply contracts with us, we potentially could be required to rent or purchase that part of the GFE necessary for the continued production of BioThrax in our current manufacturing facility.

Risks Related to Regulatory Approvals

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

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have limited experience in preparing, filing and prosecuting the applications necessary to gain regulatory approvals and expect to rely on third party contract research organizations and consultants to assist us in this process. Securing FDA approval requires the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA to establish the product candidate s safety and efficacy. Our future products may not be effective, may be only moderately effective or may prove to have significant side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

In the United States, BioThrax, our biodefense product candidates and our commercial product candidates are regulated by the FDA as biologics. To obtain approval from the FDA to market these product candidates, other than biodefense products purchased by HHS for the SNS, we will be required to submit a BLA to the FDA. 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 intend to pursue FDA approval of BioThrax as a post-exposure prophylaxis, our immune globulin therapeutic candidates, our recombinant bivalent botulinum vaccine candidate, and a next generation anthrax vaccine under the FDA animal rule, as described above. We cannot guarantee that FDA will permit us to proceed with any of our products or product candidates under the animal rule. Even if we are able to proceed pursuant to the animal rule, FDA may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products.

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 analysis is complete, and we have submitted an amendment to our application. If the FDA does not find our response to be adequate, we might be required to conduct additional independent testing to continue to pursue the development of this reduced dosing regimen. Responding to the FDA s complete response letter will delay potential approval of our application. If we are unable ultimately to respond satisfactorily to the FDA, our application will not be approved.

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

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

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

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

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

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

After approving the renovated Lansing facilities in December 2001, the FDA conducted routine, biannual inspections of the Lansing facilities in September 2002, May 2004, May 2006 and March 2008. 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 March 2008 inspection, and are awaiting a response from the FDA. If in connection this inspection or with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, of if the FDA is not satisfied with the corrective actions we take in connect with any such inspection, the FDA may undertake enforcement action against us.

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

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

refusal to permit the import or export of products;

product seizure; and

injunctions or the imposition of civil or criminal penalties.

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.

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

The Fast Track designation for BioThrax as a post-exposure prophylaxis for anthrax infection may not actually lead to a faster development or regulatory review or approval process.

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

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

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

The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We and our collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Risks Related to Our Dependence on Third Parties

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

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

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

Any collaboration that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. It is likely that our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations. In particular, the successful development of our meningitis B vaccine candidate will initially depend on the success of our research collaboration with Sanofi Pasteur and whether Sanofi Pasteur selects one or more viable candidates pursuant to the collaboration for development of a product.

Thereafter, Sanofi Pasteur will have significant discretion in the development and commercialization of any such candidate. Sanofi Pasteur may choose not to pursue further development and commercialization of any candidate that it selects based on many factors outside our control. Sanofi Pasteur has the ability to suspend development of a candidate under the collaboration in various circumstances. The risks that we are subject to in our current collaborations, and anticipate being subject to in future collaborations, include the following:

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

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. For example, Sanofi Pasteur has the right to terminate our meningitis B vaccine collaboration at any time 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 therapeutic 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 therapeutic 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 or the label expansions and improvements that we are pursuing for BioThrax, our only intellectual property protection for BioThrax is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and biological starting materials. However, these types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, with agreements with our employees, consultants and third parties.

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

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

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

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

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology and pharmaceutical industries. For example, we monitored litigation between Bavarian Nordic and Acambis relating to the manufacture of the modified vaccinia Ankara virus, or MVA, as a smallpox vaccine for biodefense use by the U.S. government.

This litigation was terminated by a settlement and consent order filed by the parties with the U.S. International Trade Commission, or ITC, in August 2007 and subsequently published in the U.S. Federal Register. According to the published terms of the consent order, Acambis agreed not to import or sell within the United States its ACAM3000 vaccine product, and further agreed not to challenge the validity or enforceability of certain Bavarian Nordic patents. In addition, the consent order vacated the initial determination of the ITC that Bavarian Nordics patents were invalid, but if valid would have been infringed by importation or sale of ACAM3000 in the United States.

We have licensed from the Bavarian State Ministry of the Environment, Public Health and Consumer Protection, or StUMGV, rights to materials and technology related to MVA. Our MVA platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based on these rights. We are aware of litigation brought by Bavarian Nordic against StUMGV in which Bavarian Nordic is seeking information concerning StUMGV s ownership rights to the MVA in its possession. Our ability to use our MVA platform technology could be negatively affected by patent infringement litigation or other legal actions brought by Bavarian Nordic or other parties challenging our rights to use MVA materials or technology.

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

Risks Related to Our Acquisition Strategy

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

We have pursued an acquisition strategy since our inception to build our business of developing, manufacturing and commercializing immunobiotics. We commenced operations in September 1998 through an acquisition of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing and vaccine development and production know-how from the Michigan Biologic Products Institute. We acquired our pipeline of commercial vaccine candidates through our acquisition of ViVacs in 2006 and Microscience in 2005 and our acquisition of substantially all of the assets of Antex in 2003.

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

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

In addition, we expect competition for acquisition candidates in the immunobiotic field to increase, which may mean fewer suitable acquisition opportunities for us as well as higher acquisition prices. If we are unable to successfully obtain rights to suitable products and product

candidates, our business, financial condition and prospects for growth could suffer.

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

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

use of cash resources;

higher than anticipated acquisition costs and expenses;

potentially dilutive issuances of equity securities;

the incurrence of debt and contingent liabilities, impairment losses or restructuring charges;

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

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

challenges associated with managing an increasingly diversified business;

disruption of our ongoing business;

difficulty and expense in assimilating the operations, products, technology, information systems or personnel of the acquired company;

diversion of management s time and attention from other business concerns;

inability to maintain uniform standards, controls, procedures and policies;

the assumption of known and unknown liabilities of the acquired company, including intellectual property claims; and

subsequent loss of key personnel.

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

Risks Related to Our Common Stock

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

Mr. El-Hibri has the ability to control the election of the members of our Board of Directors through his ownership interests and voting arrangements among our significant stockholders. As of May 1, 2008, Mr. El-Hibri was the beneficial owner of a majority of our outstanding common stock. Because Mr. El-Hibri has the ability to control the election of the members of our board, and because of his substantial control of our capital stock, Mr. El-Hibri will likely have the ability to delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

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

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

These provisions include:

- the classification of our directors;
- limitations on changing the number of directors then in office;
- limitations on the removal of directors;
- limitations on filling vacancies on the board;
- limitations on the removal and appointment of the chairman of our Board of Directors;

following November 20, 2008, advance notice requirements for stockholder nominations for election of directors and other proposals;

the inability of stockholders to act by written consent;

the inability of stockholders to call special meetings; and

the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval.

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

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

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

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

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

If our stock price is volatile, purchasers of our common stock could incur substantial losses.

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through May 1, 2008, our common stock has traded as high as $17.75 per share and as low as $4.40 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

the success of competitive products or technologies;

results of clinical trials of our product candidates or those of our competitors;

decisions and procurement policies by the U.S. government affecting BioThrax and our biodefense product candidates;

regulatory developments in the United States and foreign countries;

developments or disputes concerning patents or other proprietary rights;

the recruitment or departure of key personnel;

variations in our financial results or those of companies that are perceived to be similar to us;

market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts reports or recommendations;

general economic, industry and market conditions; and

the other factors described in this Risk Factors section.

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

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

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 20.3 million shares of our common stock outstanding as of May 1, 2008 have the right to require us to register these shares of common stock under specified circumstances.

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

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

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

Through March 31, 2008, we have used approximately $16.0 million of the net proceeds from the offering to fund development of our product candidates, comprised of $2.1 million for label expansions and improvements for BioThrax, $1.7 million for a next generation anthrax vaccine candidate, $3.3 million for our anthrax immune globulin candidate, $4.4 million for our typhoid vaccine candidate and $4.5 million for our hepatitis B therapeutic vaccine candidate. Through March 31, 2008, we have used approximately $23.3 million of the net proceeds to fund a portion of the construction, installation, validation and qualification activities costs for our new manufacturing facility in Lansing. We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10 percent or more of our common stock or to any affiliate of ours. We have invested the balance of the net proceeds from the offering in short-term, investment grade, interest-bearing instruments. There has been no material change in our planned use of the balance of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

Not applicable.

ITEM 5. OTHER INFORMATION

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 7, 2008

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

Date: May 7, 2008

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

EXHIBIT INDEX

Exhibit Number	**Description**
10.1*	Amended and Restated Marketing Agreement, entered into on March 6, 2008, between Emergent BioDefense Operations Lansing Inc.and Intergen N
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 200
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

* Confidential Treatment Application has been filed with the Securities and Exchange Commission