Emergent BioSolutions Inc.
Form 10-Q
May 08, 2009

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, 2009

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files. 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 o Smaller reporting company (Do not check if a smaller reporting company)

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

As of April 30, 2009, the registrant had 30,261,642 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 perform under our contracts with the U.S. government for sales of BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, including the timing of deliveries;
- our plans for future sales of BioThrax, including our ability to obtain new contracts with the U.S. government;
- our plans to pursue label expansions and improvements for BioThrax;
- our ability to win a development award and procurement contract with the U.S. government for our recombinant protective antigen anthrax vaccine candidate, or rPA vaccine;
- 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, 2009 (Unaudited)	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,380	$ 91,473
Accounts receivable	74,136	24,855
Inventories	14,152	19,728
Note receivable	10,000	10,000
Prepaid expenses and other current assets	4,253	6,623
Total current assets	163,921	152,679
Property, plant and equipment, net	127,245	124,656
Deferred tax assets, net	11,245	12,073
Restricted cash	208	208
Other assets	1,163	1,172
Total assets	$ 303,782	$ 290,788
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 17,186	$ 18,254
Accrued expenses and other current liabilities	1,175	1,399
Accrued compensation	8,286	11,380
Indebtedness under line of credit	15,000	15,000
Long-term indebtedness, current portion	6,316	6,248
Income taxes payable	5,550	951
Deferred tax liabilities, net	466	557
Deferred revenue, current portion	227	232
Total current liabilities	54,206	54,021
Long-term indebtedness, net of current portion	35,208	35,935
Other liabilities	1,587	1,483
Total liabilities	91,001	91,439
Commitments and contingencies	-	-
Stockholders equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	-	-
Common Stock, $0.001 par value; 100,000,000 shares authorized, 30,241,241 and 30,159,546 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	30	30
Additional paid-in capital	110,877	109,170
Accumulated other comprehensive loss	(939)	(859)
Retained earnings	102,127	91,008
Total Emergent BioSolutions Inc. stockholders' equity	212,095	199,349
Noncontrolling interest in subsidiary	686	-
Total stockholders equity	212,781	199,349
Total liabilities and stockholders equity	$ 303,782	$ 290,788

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,	
	2009	**2008**
	(Unaudited)	
Revenues:		
Product sales	$ 61,678	$ 41,504
Contracts and grants	2,841	1,216
Total revenues	64,519	42,720
Operating expenses:		
Cost of product sales	15,368	8,010
Research and development	15,910	11,475
Selling, general and administrative	15,975	12,060
Income from operations	17,266	11,175
Other income (expense):		
Interest income	300	665
Interest expense	(4)	(1)
Other income (expense), net	(24)	(14)
Total other income (expense)	272	650
Income before provision for income taxes	17,538	11,825
Provision for income taxes	7,366	4,801
Net income	10,172	7,024
Net loss attributable to noncontrolling interest	947	-
Net income attributable to Emergent BioSolutions Inc.	$ 11,119	$ 7,024
Earnings per share - basic	$ 0.37	$ 0.24
Earnings per share - diluted	$ 0.35	$ 0.24
Weighted-average number of shares - basic	30,184,098	29,750,237
Weighted-average number of shares - diluted	31,454,456	29,819,727

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, 2009 (Unaudited)	2008
Cash flows from operating activities:		
Net income	$ 10,172	$ 7,024
Adjustments to reconcile to net cash used in operating activities:		
Stock-based compensation expense	860	230
Depreciation and amortization	1,262	1,081
Deferred income taxes	933	498
Non-cash development expenses from joint venture	1,633	-
Loss on disposal of property and equipment	25	10
Excess tax benefits from stock-based compensation	(196)	-
Changes in operating assets and liabilities:		
Accounts receivable	(49,281)	(2,701)
Inventories	5,576	(1,893)
Income taxes	4,599	(3,785)
Prepaid expenses and other assets	2,379	(405)
Accounts payable	(189)	(1,757)
Accrued compensation	(3,094)	(2,910)
Accrued expenses and other liabilities	(120)	(270)
Deferred revenue	(5)	(150)
Net cash used in operating activities	(25,446)	(5,028)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(4,755)	(6,931)
Issuance of note receivable	-	(3,500)
Net cash used in investing activities	(4,755)	(10,431)
Cash flows from financing activities:		
Proceeds from borrowings on long-term indebtedness and line of credit	15,000	15,000
Issuance of common stock subject to exercise of stock options	651	-
Principal payments on long-term indebtedness and line of credit	(15,659)	(12,708)
Excess tax benefits from stock-based compensation	196	-
Net cash provided by financing activities	188	2,292
Effect of exchange rate changes on cash and cash equivalents	(80)	184
Net decrease in cash and cash equivalents	(30,093)	(12,983)
Cash and cash equivalents at beginning of period	91,473	105,730
Cash and cash equivalents at end of period	$ 61,380	$ 92,747

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

EMERGENT BIOSOLUTIONS INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Summary of significant accounting policies

Basis of presentation and consolidation

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

The unaudited consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles 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, 2008, 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, 2009, results of operations for the three months ended March 31, 2009 and 2008, and cash flows for the three months ended March 31, 2009 and 2008. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Note receivable

In 2008, the Company entered into a loan and security agreement with Protein Sciences Corporation (PSC) to provide a loan to PSC of up to $10 million in conjunction with an agreement pursuant to which the Company would acquire substantially all of the assets of PSC. The loan is secured by substantially all of PSC s assets, including intellectual property. Under this loan agreement and a related promissory note, $10 million is outstanding as of March 31, 2009, and the Company has recorded this as a note receivable. The note was originally due and payable on December 31, 2008. On July 9, 2008, the Company initiated a lawsuit against PSC and PSC s senior management, alleging fraudulent conduct by PSC s senior management and breach of the terms of various agreements between PSC and the Company, including the loan and security agreement. Based on the event of default alleged by the Company, the promissory note was accelerated and became due and payable immediately. The Company has since agreed not to foreclose on the collateral securing the loan or to pursue other remedies relating to the loan prior to May 31, 2009. The note bears interest at an annual rate of 8% through December 31, 2008, and at 11% thereafter. As of March 31, 2009, the Company has recorded accrued interest on the note receivable of $809,000, included in prepaid expenses and other current assets. The Company has concluded that, in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 114, *Accounting by Creditors for Impairment of a Loan*, the $10 million note receivable is not impaired as of March 31, 2009, and therefore has not recorded a reserve against this note.

Capitalized interest

The Company capitalizes interest in accordance with 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, 2009 and 2008, the Company incurred interest expense of $501,000 and $890,000, respectively. Of these amounts, the Company capitalized $496,000 and $889,000, respectively.

Earnings per share

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

(in thousands, except share and per share data)	Three Months Ended March 31, 2009	2008
Numerator:		
Net income attributable to Emergent BioSolutions Inc.	$ 11,119	$ 7,024
Denominator:		
Weighted-average number of shares - basic	30,184,098	29,750,237
Dilutive securities - stock options	1,270,358	69,490
Weighted-average number of shares - diluted	31,454,456	29,819,727
Earnings per share - basic	$ 0.37	$ 0.24
Earnings per share - diluted	$ 0.35	$ 0.24

For the three months ended March 31, 2009 and 2008, outstanding stock options to purchase approximately 0 and 1,510,000 shares, respectively, of common stock are not considered in the diluted earnings per share calculation because the exercise price of these options is greater than the average per share closing price during the year.

Accounting for stock-based compensation

As of March 31, 2009, 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).

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 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, 2009	2008
Expected dividend yield	0%	0%
Expected volatility	55%	65%
Risk-free interest rate	1.4%	1.8%-2.7%
Expected average life of options	3.3	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 volatility of a peer group of companies at a similar stage of development to estimate expected volatility. The volatility of a peer group of companies ranged from approximately 40% to 80%, with an average estimated volatility of 55%. The Company used a rate of 55% for grants made in 2009.

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 in 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

SFAS No. 130, *Reporting Comprehensive Income,* requires the presentation of comprehensive income and its components as part of the financial statements. Comprehensive income is comprised of net income attributable to Emergent BioSolutions Inc. and other changes in equity that are excluded from net income. The Company includes gains and losses on intercompany transactions with foreign subsidiaries that are considered to be long-term investments and translation gains and losses incurred when converting its subsidiaries financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income. Comprehensive income for the three months ended March 31, 2009 and 2008 was $11.0 million and $7.2 million, respectively.

Recent accounting pronouncements

In November 2008, the Emerging Issues Task Force (the EITF) of the Financial Accounting Standards Board (the FASB) issued EITF Issue No. 08-8, *Accounting for an Instrument (or an Embedded Feature) with a Settlement Amount That Is Based on the Stock of an Entity s Consolidated Subsidiary* (EITF No. 08-8). EITF No. 08-8 applies to freestanding financial instruments and embedded features of such instruments for which the payoff to the counterparty is based, in whole or in part, on the stock of a consolidated subsidiary. EITF No. 08-8 applies to those instruments in the consolidated financial statements of the parent, whether the instrument was entered into by the parent or the subsidiary. Freestanding financial instruments and embedded features of such instruments for which the payoff to the counterparty is based, in whole or in part, on the stock of a consolidated subsidiary are not precluded from being considered indexed to the entity's own stock in the consolidated financial statements of the parent if the subsidiary is a substantive entity. If the subsidiary is not a substantive entity, the instrument would not be considered indexed to the entity's own stock. EITF No. 08-8 is effective for fiscal years beginning on or after December 15, 2008, and interim periods within those fiscal years. Early adoption is not permitted. EITF No. 08-8 was adopted by the Company effective January 1, 2009, and will impact the Company s financial statements to the extent that the Company has these types of instruments.

In November 2008, the EITF issued EITF Issue No. 08-7, *Accounting for Defensive Intangible Assets* (EITF No. 08-7). EITF No. 08-7 applies to acquired intangible assets in situations in which an entity does not intend to actively use the asset but intends to hold or lock up the asset to prevent others from obtaining access to the asset (a defensive intangible asset). EITF No. 08-7 states that a defensive intangible asset should be accounted for as a separate unit of accounting and should not be included as part of the cost of an entity's existing intangible asset(s) because the defensive intangible asset is separately identifiable. EITF No. 08-7 applies to intangible assets acquired on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. EITF No. 08-7 was adopted by the Company effective January 1, 2009, and will impact the Company s financial statements to the extent that the Company acquires a defensive intangible asset.

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. The Company adopted SFAS No. 141(R) effective January 1, 2009, and in accordance with the provisions of the standard, in January 2009 the Company expensed $1.4 million in previously capitalized costs associated with acquisitions that were in progress but not complete as of December 31, 2008. SFAS No. 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the acquiring entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS No. 141(R) was adopted by the Company effective January 1, 2009, and will further impact the Company s financial statements to the extent that the Company is party to a business combination.

2. Inventories

Inventories consist of the following:

(in thousands)	March 31, 2009	December 31, 2008
Raw materials and supplies	$ 2,811	$ 2,755
Work-in-process	9,674	14,459
Finished goods	1,667	2,514
Total inventories	$ 14,152	$ 19,728

3. Property, plant and equipment

Property, plant and equipment consist of the following:

(in thousands)	March 31, 2009	December 31, 2008
Land and improvements	$ 5,050	$ 5,050
Buildings and leasehold improvements	28,135	28,119
Furniture and equipment	22,686	22,657
Software	6,790	6,423
Construction-in-progress	85,451	82,518
	148,112	144,767
Less: Accumulated depreciation and amortization	(20,867)	(20,111)
Total property, plant and equipment, net	$ 127,245	$ 124,656

4. Stock options

As of March 31, 2009, the Company has two stock-based employee compensation plans, the 2006 Plan and the 2004 Plan (together, the Emergent Plans), under which the Company has granted options to purchase shares of its 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. As of March 31, 2009, an aggregate of 4,328,826 shares of Common Stock are authorized for issuance under the 2006 Plan, and a total of 434,404 options are available for issuance. Following the closing of the Company s initial public offering, the Company no longer granted 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 activity under the Emergent Plans:

	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, 2008	2,466,519	$	8.76	438,628	$	5.52		
Granted	1,241,637		18.90	-		-		
Exercised	(77,003)		7.65	(4,692)		13.26		
Forfeited	(14,333)		10.90	-		-		
Outstanding at March 31, 2009	3,616,820	$	12.26	433,936	$	5.43	$	15,249,452
Exercisable at March 31, 2009	770,798	$	8.91	378,794	$	4.58	$	6,968,762

5. Income taxes

The provision for income taxes consists of the following:

	Three Months Ended March 31,			
(in thousands)	**2009**		**2008**	
Current:				
Federal	$	4,550	$	4,040
State		2,069		263
International		11		-
Total current		6,630		4,303
Deferred:				
Federal		759		388
State		(23)		110
Total deferred		736		498
Total provision for income taxes	$	7,366	$	4,801

The Company s estimated effective annual tax rate on income before provision for income tax plus the net loss attributable to noncontrolling interest for the three months ended March 31, 2009 and 2008 was approximately 40% and 41%, respectively.

The Company s federal and state income tax returns for the tax years 2008 to 2005 remain open to examination. The Company s tax returns in the United Kingdom remain open to examination for the tax years 2008 to 2001, and tax returns in Germany remain open indefinitely. In July 2008,

the Company was notified by the U.S. Internal Revenue Service that the federal income tax return for the 2006 tax year has been selected for a limited scope audit.

6. Litigation

In 2008, the Company entered into a letter of intent, a loan and security agreement and related promissory note, and an asset purchase agreement with PSC, pursuant to which the Company agreed to acquire substantially all of PSC s assets and provide funding to PSC to enable PSC to continue operations through June 24, 2008, the anticipated closing date of the transactions contemplated by the asset purchase agreement.

In July 2008, the Company filed a lawsuit against PSC, Daniel D. Adams, PSC s Chief Executive Officer, and Manon M.J. Cox, PSC s Chief Operating Officer, in the Supreme Court of the State of New York asserting claims related to the letter of intent, the loan and security agreement, and the asset purchase agreement. On September 12, 2008, a stipulation of discontinuance was filed with the court regarding the claims against Mr. Adams and Ms. Cox, and, on October 3, 2008, the Company filed a separate suit against Mr. Adams and Ms. Cox in the United States District Court for the District of Connecticut, alleging fraud and unfair trade practices and seeking compensatory and punitive damages. On September 12, 2008, the Company filed an amended complaint against PSC, which remains pending in the Supreme Court of the State of New York, alleging fraud, breach of the letter of intent, the loan and security agreement and the asset purchase agreement, breach of the duty of good faith and fair dealing, unjust enrichment and unfair business practices. The Company is seeking from PSC money damages of no less than $13 million, punitive damages, declaratory judgment that the Company has no further funding obligations to PSC, injunctive relief to protect the collateral for the loan and other appropriate relief. PSC has moved to dismiss the New York action, and Mr. Adams and Ms. Cox have moved to dismiss the Connecticut action. Those motions remain pending. PSC, Mr. Adams, and Ms. Cox have not yet asserted any counterclaims, but PSC has stated that it may assert counterclaims for among other things, breach of contract, intentional misrepresentations, tortious interference with business relations and unfair trade practices.

Between March 2008 and June 2008, the Company provided PSC with $10 million in funding under the loan and security agreement and related promissory note. PSC s obligations under the loan and security agreement and related promissory note are secured by substantially all of PSC s assets, including intellectual property. The loan accrued interest at an annual rate of 8% through December 31, 2008 and currently accrues interest at an annual rate of 11%. Under the loan and security agreement and related promissory note, PSC was obligated to repay the $10 million principal plus accrued and unpaid interest and costs of collection upon the earlier of December 31, 2008 or an event of default under the loan and security agreement. In the lawsuit against PSC described above, the Company alleges that an event of default occurred under the loan and security agreement and that the loan was due and payable as of June 2008. In March 2009, the Company and PSC entered into a forbearance agreement, pursuant to which the Company agreed not to foreclose on the collateral securing the loan or to pursue other remedies relating to the loan prior to May 31, 2009. The Company intends to pursue full repayment under the loan and security agreement and related promissory note if the Company is not repaid as provided for under the forbearance agreement; if the Company is repaid pursuant to the forbearance agreement, the Company and PSC will subsequently enter into settlement agreements that provide for dismissal of the New York and Connecticut actions without prejudice. As of March 31, 2009, $10 million of principal was outstanding and $809,000 of interest was accrued and unpaid under the loan and security agreement and related promissory note.

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

7. Segment information

For financial reporting purposes, the Company reports financial information for two business segments: biodefense and commercial. In the biodefense segment, the Company develops, manufactures and commercializes vaccines and therapeutics for use against biological agents that are potential weapons of bioterrorism or biowarfare. Revenues in this segment relate primarily to the Company s FDA-licensed product, BioThrax. In the commercial segment, the Company develops vaccines and therapeutics for use against infectious diseases and other medical conditions 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 agreements, development contracts 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 primarily of cash and fixed assets.

(in thousands)	Reportable Segments		All Other	Total
	Biodefense	Commercial		
Three Months Ended March 31, 2009				

External revenue	$ 64,519	$ -	$ -	$ 64,519
Net income (loss) attributable to Emergent BioSolutions Inc.	24,283	(10,655)	(2,509)	11,119
Assets	209,975	22,927	70,880	303,782
	Three Months Ended March 31, 2008			
External revenue	$ 41,777	$ 797	$ 146	$ 42,720
Net income (loss) attributable to Emergent BioSolutions Inc.	20,628	(9,353)	(4,251)	7,024
Assets	143,435	20,233	109,973	273,641

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 former partner at WilmerHale, who did not participate in providing legal services to the Company. For the three months ended March 31, 2008, during which the spouse of the General Counsel was a partner at WilmerHale, the Company incurred fees for legal services of approximately $217,000. At March 31, 2009, $0 remained in accounts payable for these services.

The Company entered into a marketing arrangement in February 2009 with an entity controlled by family members of the Company s Chief Executive Officer to market and sell BioThrax. The agreement was effective November 2008, and requires a payment of 17.5% and reimbursement of certain expenses on net sales of biodefense products in Saudi Arabia, and 15% and reimbursement of certain expenses on net sales in Qatar and United Arab Emirates. No payments under this agreement have been triggered for the three months ended March 31, 2009.

The Company has entered into a consulting arrangement with a member of the Company s Board of Directors. At March 31, 2009, $15,000 remained in accounts payable for these services. During each of the three months ended March 31, 2009 and 2008, the Company paid approximately $45,000 under this agreement for strategic consultation and project support for the Company s marketing and communications group.

The Company has entered into a transportation arrangement with an entity owned by the Company s Chief Executive Officer. At March 31, 2009, $5,000 remained in accounts payable for these services. During each of the three months ended March 31, 2009 and 2008, the Company paid approximately $8,000 under this arrangement for transportation and logistical support.

9. Joint venture

In July 2008, the Company entered into a joint venture with the University of Oxford (Oxford) and certain Oxford researchers to conduct clinical trials in the advancement of a vaccine candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium (OETC). The Company has a 51% equity interest in OETC and controls the OETC Board of Directors. In addition, the Company has certain funding and services obligations of up to approximately $20 million related to its investment. In accordance with the provisions of FASB Interpretation No. 46(R), *Consolidation of Variable Interest Entities*, the Company has evaluated its variable interests in OETC and has determined that it is the primary beneficiary as it will absorb the majority of expected losses. Accordingly, OETC is consolidated in the Company s financial statements. As of March 31, 2009, assets of $544,000 and liabilities of $116,000 related to OETC are included within the Company s consolidated balance sheet. During the three months ended March 31, 2009, OETC incurred a net loss of $1.9 million, of which $986,000 is included in net income attributable to Emergent BioSolutions Inc. in the consolidated statement of operations.

In conjunction with the establishment of OETC, the Company granted a put option to Oxford and the Oxford researchers whereby the Company may be required to acquire all of the OETC shares held by Oxford and the Oxford researchers at the fair market value of the underlying shares. This put option is contingent upon the satisfaction of a number of conditions that must exist or occur subsequent to the grant of a marketing authorization for a tuberculosis vaccine by the European Commission. The Company accounts for the put option in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities,* and EITF Topic D-98, *Classification and Measurement of Redeemable Securities* (revised December 15, 2008). In accordance with this guidance, the Company has determined that the put option has a fair value of $0 as of March 31, 2009.

In January 2009, the Company adopted SFAS No. 160, *Noncontrolling Interest in Consolidated Financial Statements* (SFAS No. 160). Under the provisions of SFAS No. 160, recasting of prior excess losses is prohibited. The following pro forma table reflects the impact of recasting the

excess losses as if the Company had been subject to the provisions of Accounting Research Bulletin, No. 51, *Consolidated Financial Statements*:

(in thousands)	Three Months Ended March 31, 2009
Net income, under the provisions of SFAS No. 160	$ 11,119
Excess losses from the prior year (net of tax)	195
Net income, under the provisions of ARB No. 51	$ 11,314
Earnings per share - basic	$ 0.37
Earnings per share - diluted	$ 0.36

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

(in thousands)		Emergent BioSolutions Inc.		Noncontrolling Interest		Total
Stockholders' equity at December 31, 2008	$	199,349	$	-	$	199,349
Non-cash development expenses from joint venture		-		1,633		1,633
Net income (loss)		11,119		(947)		10,172
Other		1,627		-		1,627
Stockholders' equity at March 31, 2009	$	212,095	$	686	$	212,781

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 sections of this quarterly report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Product Portfolio

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

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

Our commercial segment focuses on vaccines and therapeutics for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved medical needs. Our product candidates in this segment include a tuberculosis vaccine, a typhoid vaccine, a hepatitis B therapeutic vaccine and a chlamydia vaccine.

Our biodefense segment has generated net income for each of the last five fiscal years. Our commercial segment has generated revenue through development contracts and grant funding. None of our commercial product candidates has received marketing approval and, therefore, our commercial segment has not generated any product sales revenues. As a result, our commercial segment has incurred a net loss for each of the last five fiscal years.

Product Sales

We have derived substantially all of our product sales revenues from BioThrax sales to the U.S. Department of Health and Human Services, or HHS, and U.S. Department of Defense, or DoD, and expect for the foreseeable future to continue to derive substantially all of our product sales revenues from the sales of BioThrax to the U.S. government. Our total revenues from BioThrax sales were $61.7 million and $41.5 million for the three months ended March 31, 2009 and 2008, respectively. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers domestically and internationally and pursuing label expansions and improvements for BioThrax.

Contracts and Grants

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

Product or Product Candidate	Funding Source
BioThrax post-exposure prophylaxis	HHS
Advanced anthrax vaccine	Biomedical Advanced Research and Development Authority and National Institute of Allergy and Infectious Dis
Anthrax immune globulin therapeutic	National Institute of Allergy and Infectious Diseases
Anthrax monoclonal antibody therapeutic	Biomedical Advanced Research and Development Authority and National Institute of Allergy and Infectious Dis
Typhella vaccine	The Wellcome Trust
Recombinant botulinum vaccine	National Institute of Allergy and Infectious Diseases

Additionally, our tuberculosis vaccine candidate is indirectly supported by grant funding provided to The University of Oxford by The Wellcome Trust and Aeras Global Tuberculosis Vaccine Foundation.

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

Manufacturing Infrastructure

We conduct our primary vaccine manufacturing operations at a multi-building campus on approximately 12.5 acres in Lansing, Michigan. To augment our existing manufacturing capabilities, we have constructed a new 50,000 square foot manufacturing facility on our Lansing campus. We have incurred costs of approximately $77 million through March 2009 for the building and associated capital equipment, as well as for validation and qualification activities required for regulatory approval and initiation of manufacturing. Although we have made progress on qualification and validation activities required for the commercial manufacture of BioThrax, we suspended the completion of those activities as we commenced a change-over process to use the facility for the manufacture of our rPA anthrax vaccine candidate under an anticipated HHS contract for the development and procurement of a recombinant anthrax vaccine. This change-over process is now substantially complete. We designed this facility to be campaignable subject to complying with appropriate change-over procedures, and we may seek permission from the FDA to use the facility for the manufacture of both BioThrax and our rPA anthrax vaccine candidate. In the event we are not awarded a contract for the development and procurement of our rPA anthrax vaccine candidate, we intend to use the facility for the manufacture of BioThrax and potentially additional products.

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 2009 related to initial engineering design and preliminary utility build out of one of these buildings. Moving forward with our plans for this building will be contingent on progress of our existing development programs or the acquisition of new product candidates. 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. However, we may elect to lease or sell one or both 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 U.S. 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 HHS and the DoD. Under our current contracts 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 were entitled to additional payments for development work under the collaboration. We recognized amounts received under this agreement over the estimated development period as we performed services. We recorded the amount of the upfront license fee as deferred revenue. Prior to the termination of this agreement in December 2008, we recognized this revenue over the estimated development period under the contract. Under the collaboration agreement, we were entitled to payments up to specified levels for development work we performed on behalf of Sanofi Pasteur. We invoiced Sanofi Pasteur monthly in arrears, and recognized revenue in the period in which the associated costs were incurred.

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 and recognize revenue upon incurring the reimbursable costs.

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 basis 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 on 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 No. 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.

Stock-based Compensation

We adopted SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS No. 123(R), on January 1, 2006. 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 attributable to Emergent BioSolutions Inc. and net income attributable to Emergent BioSolutions Inc. 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

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 Strategic National Stockpile, or 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 those specific doses. This discounted price does not apply to the final 13.25 million doses under the contract. The firm fixed price for the 18.75 million doses, including the discount, is $400 million in the aggregate. Through March 31, 2009, we have delivered approximately 16.5 million doses under this contract. If we receive FDA approval of our pending supplement to our biologics license application, or BLA, 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 final 13.25 million doses sold under this contract. 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 approximately $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. In December 2006, based on data generated from our ongoing stability studies, we submitted a supplement to our BLA for BioThrax to extend the expiry dating. We have received a complete response from the FDA which posed a number of questions. In responding to those questions, we submitted a separate supplement in December 2008 and submitted a response to the FDA's complete response in February 2009. We believe that our application will be approved in 2009.

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 us 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 2007.

On September 30, 2008, we entered into an agreement with HHS to supply up to an additional 14.5 million doses of BioThrax to HHS for placement into the SNS. The term of the agreement is from September 30, 2008 through September 30, 2011. Delivery of doses under the agreement will commence immediately following the anticipated completion of deliveries under our current 18.75 million dose supply contract with HHS, currently anticipated in September 2009, and continues through September 2011. Funds for the procurement of the first 5.7 million doses of BioThrax have been committed. Procurement of the remaining 8.8 million doses will be funded through the annual appropriations process for the SNS. If the FDA approves our pending application to extend the shelf life of BioThrax from three years to four years, and if four-year dated lots of BioThrax are available at the time of delivery of a particular lot or shipment, we must deliver four-year dated product to the SNS. In the event the FDA has not approved four-year expiry dating at the time of such delivery, we may instead deliver three-year dated product to the SNS. Four-year dated product will be invoiced at a higher price than three-year dated product. The total purchase price for the 14.5 million doses will be between $362.7 million and $402.8 million, depending on product dating. Under the agreement, we have agreed to provide all shipping services related to delivery of doses into the SNS over the term of the agreement, for which HHS has agreed to pay us approximately $1.9 million. We will invoice HHS under the agreement upon acceptance of each delivery of BioThrax doses to the SNS.

Pursuant to two supply agreements for BioThrax with the DoD, we supplied approximately 10 million doses of BioThrax for immunization of military personnel from 1997 through 2007. As a result of an October 2007 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, the DoD is procuring additional doses of BioThrax to satisfy ongoing requirements for its active immunization program directly from the SNS. Consequently, we are not currently party to a procurement contract with the DoD.

In September 2007, we received a development contract from the National Institute of Allergy and Infectious Disease, or NIAID, valued at up to $9.5 million, in support of non-clinical and clinical studies of our anthrax immune globulin therapeutic candidate. Under the terms of the development contract, we are using the funds to conduct various studies on this product candidate, including non-clinical efficacy studies and clinical trials. In July 2008, we were awarded two grants from NIAID, totaling over $4.5 million, to support development of our recombinant botulinum vaccine and advanced anthrax vaccine candidates. In September 2008, we received a $24 million development contract from NIAID and the Biomedical Advanced Research and Development Authority, or BARDA, to fund continued development of our anthrax monoclonal antibody therapeutic candidate, and a development contract with NIAID and BARDA, valued at up to approximately $30 million, to fund development of our advanced anthrax vaccine candidate.

In May 2006, we entered into a collaboration agreement with Sanofi Pasteur, which was amended in June 2008, under which we granted Sanofi Pasteur an exclusive, worldwide license under a proprietary technology to develop and commercialize a meningitis B vaccine candidate and received a $3.8 million upfront license fee. This agreement also provided for payments for development work under the collaboration. In December 2008, we and Sanofi Pasteur determined that the joint efforts on this collaboration had not identified a promising product candidate, and we mutually terminated the collaboration. Upon termination we recognized as revenue the unamortized portion of the upfront license fee.

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 performed under new and existing contracts and grants.

Cost of Product Sales

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

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

manufacturing capacity and the production yield for the period of production.

Research and Development Expenses

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

- salaries and related expenses for personnel;
- fees to professional service providers for, among other things, preclinical and analytical testing, independently monitoring our clinical trials and acquiring and evaluating data from our clinical trials and non-clinical studies;
- costs of contract manufacturing services for clinical trial material;
- costs of materials used in clinical trials and research and development;
- depreciation of capital assets used to develop our products; and
- operating costs, such as the operating 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 our product pipeline will increase as our product development activities continue based on ongoing advancement of our product candidates, and as we prepare for regulatory submissions and other regulatory activities. We expect that the magnitude of any increase in our research and development spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, the size, structure and duration of any follow on clinical programs that we may initiate, costs associated with manufacturing our product candidates on a large scale basis for later stage clinical trials, and our ability to use or rely on data generated by government agencies, such as the ongoing studies with BioThrax being conducted by the Centers for Disease Control and Prevention, or CDC.

In July 2008, we entered into a joint venture with the University of Oxford, or Oxford, and certain Oxford researchers to conduct clinical trials for the advancement of a vaccine candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium, or OETC. We have a 51% equity interest in OETC and control the OETC Board of Directors. In addition, we have certain funding and services obligations of up to approximately $20 million related to our investment through 2011 to support further development of the vaccine candidate and a Phase IIb proof of concept study in humans, primarily in the form of services to be performed by our personnel on behalf of the joint venture. As part of this arrangement, we have entered into a license agreement with the joint venture pursuant to which we obtained rights to develop, manufacture and commercialize pharmaceutical compositions intended to prevent or treat *Mycobacterium tuberculosis* in humans in developed countries. Oxford s contributions include support from the Wellcome Trust and the Aeras Global Tuberculosis Vaccine Foundation for the Phase IIb clinical trial in the form of cash and services.

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 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 primarily of interest income and interest expense. We earn interest income on our cash and cash equivalents, 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. 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, 2009 Compared to Quarter Ended March 31, 2008

Revenues

Product sales revenues increased by $20.2 million, or 49%, to $61.7 million for the three months ended March 31, 2009 from $41.5 million for the three months ended March 31, 2008. This increase in product sales revenues was primarily due to a 52% increase in the number of doses of BioThrax delivered. Product sales revenues for the three months ended March 31, 2009 consisted of BioThrax sales to HHS of $61.6 million and aggregate international and other sales of $54,000. 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.

Contracts and grants revenues increased by $1.6 million, or 134%, to $2.8 million for the three months ended March 31, 2009 from $1.2 million for the three months ended March 31, 2008. Contracts and grants revenues for the three months ended March 31, 2009 consisted of $2.8 million in development contract and grant revenue from NIAID and BARDA. 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.

Cost of Product Sales

Cost of product sales increased by $7.4 million, or 92%, to $15.4 million for the three months ended March 31, 2009 from $8.0 million for the three months ended March 31, 2008. This increase was attributable to a 52% increase in the number of doses of BioThrax delivered coupled with an increase in cost per dose sold associated with reduced production yield in the period during which the doses sold were produced.

Research and Development Expense

Research and development expenses increased by $4.4 million, or 39%, to $15.9 million for the three months ended March 31, 2009 from $11.5 million for the three months ended March 31, 2008. This increase reflects additional personnel and contract service costs, and includes increased expenses of $4.2 million on product candidates that are categorized in our biodefense segment and $827,000 in other research and development expenses, which are in support of technology platforms and central research and development activities, partially offset by a decrease of $612,000 on product candidates categorized in our commercial segment.

The increase in spending on biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials, coupled with increased spending on product candidates that we acquired in 2008. The spending for BioThrax enhancements was related to preparing for and conducting clinical and non-clinical efficacy studies to support applications for marketing approval of these enhancements. The spending for the recombinant protective antigen anthrax vaccine was related primarily to internal and external costs incurred to respond to a request for proposal from BARDA and the continued advancement of the product candidate. The decrease in spending in our advanced anthrax vaccine program resulted from the timing of feasibility studies and formulation development of product candidates. The increase in spending for our anthrax immune globulin therapeutic candidate was primarily due to the commencement of clinical and non-clinical studies in the first quarter of 2009. The increase in spending for

the anthrax monoclonal therapeutic candidate was primarily for manufacture of a working cell bank and formulation development and the conduct of non-clinical studies. The decrease in spending for our botulinum vaccine candidates resulted from scaling back our development efforts on our botulinum toxoid vaccine candidate pending the receipt of third party development funding.

The decrease in spending on commercial product candidates, detailed in the table below, was primarily attributable to the timing of development efforts. The spending for Typhella resulted from the manufacture of clinical material and conducting and completing a Phase IIb clinical trial in the U.S., which commenced in the second quarter of 2008. The decrease in spending for our hepatitis B therapeutic vaccine candidate resulted from the cessation of new patient enrollment from our ongoing Phase II clinical trial in the United Kingdom and Serbia as a result of patient recruitment difficulties because within this trial our product candidate was administered as a monotherapy. The decrease in spending for our group B streptococcus vaccine candidate resulted from our decision not to proceed with Phase I clinical trials for two of the protein components of the vaccine candidate. We expect that spending for our group B streptococcus vaccine candidate will continue to be minimal in the future. The spending for our tuberculosis vaccine candidate was related to the procurement of licenses, and preparation for a Phase IIb clinical trial. The decrease in spending for our chlamydia candidate, which is in preclinical development, was related to a decrease in development activities while seeking external funding.

The increase in other research and development expenses was primarily attributable to spending associated with the development of technology platforms.

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

Our principal research and development expenses for the three months ended March 31, 2009 and 2008 are shown in the following table:

(in thousands)	Three Months Ended March 31, 2009	2008
Biodefense:		
BioThrax enhancements	$ 2,757	$ 944
Recombinant protective antigen anthrax vaccine	1,824	-
Advanced anthrax vaccines	572	1,195
Anthrax immune globulin therapeutic	1,805	746
Anthrax monoclonal therapeutic	1,011	200
Botulinum vaccines	544	1,207
Total biodefense	8,513	4,292
Commercial:		
Typhella	2,332	2,292
Hepatitis B therapeutic vaccine	716	905
Group B streptococcus vaccine	153	2,171
Tuberculosis vaccine	2,123	-
Chlamydia vaccine	275	568
Meningitis B vaccine	126	401
Total commercial	5,725	6,337
Other	1,672	846
Total	$ 15,910	$ 11,475

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $3.9 million, or 32%, to $16.0 million for the three months ended March 31, 2009 from $12.1 million for the three months ended March 31, 2008. The increase in selling, general and administrative expenses primarily reflects an increase of approximately $2.6 million resulting from the addition of personnel and increased professional services to support the overall growth of our business, and a $1.4 million charge for previously capitalized costs associated with acquisitions that were in progress but not complete as of December 31, 2008, partially offset by a decrease of $134,000 in sales and marketing expenses. The majority of the expense is attributable to

the biodefense segment, in which selling, general and administrative expenses increased by $2.1 million, or 23%, to $11.4 million for the three months ended March 31, 2009 from $9.3 million for the three months ended March 31, 2008. Selling, general and administrative expenses related to our commercial segment increased by $1.8 million, or 64%, to $4.6 million for the three months ended March 31, 2009 from $2.8 million for the three months ended March 31, 2008.

Total Other Income (Expense)

Total other income decreased by $378,000, or 58%, to $272,000 for the three months ended March 31, 2009 from $650,000 for the three months ended March 31, 2008. This decrease resulted primarily from a decrease in interest income of $365,000 as a result of lower investment return on average invested cash balances related to a decline in interest rates.

Income Taxes

Provision for income taxes increased by $2.6 million, or 53%, to $7.4 million for the three months ended March 31, 2009 from $4.8 million for the three months ended March 31, 2008. The provision for income taxes for the three months ended March 31, 2009 resulted primarily from our income before provision for income taxes plus net loss attributable to noncontrolling interest of $18.5 million and an effective annual tax rate of approximately 40%. 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 approximately 41%. The decrease in the effective annual tax rate is due primarily to the research and development tax credit being renewed in October 2008. The provision for income taxes reflects research and development tax credits of $77,000 for the three months ended March 31, 2009 and $0 for the three months ended March 31, 2008.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest of $947,000 for the three months ended March 31, 2009 resulted from losses incurred by our joint venture with the University of Oxford, which was established in July 2008. This amount represents the portion of the loss incurred by the joint venture in the first quarter of 2009 that is attributable to Oxford.

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, 2009 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, 2008 and for each of the three months ended March 31, 2009 and 2008.

As of March 31, 2009, we had cash and cash equivalents of $61.4 million. Additionally, at March 31, 2009 our accounts receivable balance was $74.1 million. Of this balance, in excess of $70 million was received in April 2009.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2009 and 2008:

(in thousands)	**Three Months Ended March 31, 2009**	**2008**
Net cash provided by (used in):		
Operating activities(1)	$ (25,526)	$ (4,844)
Investing activities	(4,755)	(10,431)
Financing activities	188	2,292
Total net cash used	$ (30,093)	$ (12,983)

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

Net cash used in operating activities of $25.5 million for the three months ended March 31, 2009 was due principally to an increase in accounts receivable of $49.3 million due to amounts billed primarily to HHS but not collected as of March 31, 2009, partially offset by net income of $10.2 million, an increase in income taxes payable of $4.6 million due to the 2009 income tax liability and a decrease in inventories of $5.6 million reflecting the value of BioThrax lots delivered.

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 used in investing activities for the three months ended March 31, 2009 and 2008 of $4.8 million and $10.4 million, respectively, resulted principally from the purchase of property, plant and equipment and, in 2008, the issuance of a note receivable in the amount of $3.5 million. Capital expenditures for the three months ended March 31, 2009 and 2008 include $4.8 million and $6.9 million, respectively, in construction and related costs for our new manufacturing facility in Lansing, Michigan and infrastructure investments and other equipment.

Net cash provided by financing activities of $188,000 for the three months ended March 31, 2009 resulted primarily from $15.0 million in proceeds from borrowings under our revolving line of credit with Fifth Third Bank, $196,000 related to excess tax benefits from the exercise of stock options, and $651,000 in proceeds from stock option exercises, partially offset by $15.7 million in principal payments on long-term indebtedness, including $15.0 million in payments on our revolving line of credit with Fifth Third Bank.

Net cash provided by financing activities of $2.3 million for the three months ended March 31, 2008 resulted primarily from 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.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2008:

	Payments due by period						
(in thousands)	**Total**	**2009**	**2010**	**2011**	**2012**	**2013**	**After 2013**
Contractual obligations:							
Long-term indebtedness including current portion	$ 42,183	$ 6,248	$ 3,792	$ 15,643	$ 16,500	$ -	$ -
Operating lease obligations	11,073	1,972	1,317	1,300	1,268	1,288	3,928
Contractual settlement liabilities	-	-	-	-	-	-	-
Total contractual obligations	$ 53,256	$ 8,220	$ 5,109	$ 16,943	$ 17,768	$ 1,288	$ 3,928

The preceding table excludes contingent contractual payments that we may become obligated to make upon achievement of specified research, development and commercialization milestones and contingent contractual royalty payments. The amount of contingent contractual milestone payments that we may become obligated to make is variable based on the actual achievement and timing of the applicable milestones and the characteristics of any products or product candidates that are developed, including factors such as number of products or product candidates developed, type and number of components of each product or product candidate, ownership of the various components and the specific markets

affected.

Debt Financing

As of March 31, 2009, we had $56.5 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 our first facility in Frederick, Maryland;
- $6.3 million outstanding under a mortgage loan from PNC Bank used to finance the remaining portion of the purchase price for our first Frederick facility;
- $7.7 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance the purchase price for our second facility in Frederick, Maryland;
- $25.0 million outstanding under a term loan from HSBC Realty Credit Corporation used to finance a portion of the costs of constructing our new 50,000 square foot manufacturing facility in Lansing; and
- $15.0 million outstanding under a $15.0 million revolving line of credit with Fifth Third Bank, the balance of which was repaid in April 2009.

Tax Benefits

In connection with the construction of our 50,000 square foot manufacturing facility 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. The availability of these tax benefits is primarily based on our over $75 million investment in our Lansing manufacturing 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 and grant and development funding of our anthrax immune globulin therapeutic product candidate, recombinant botulinum vaccine candidate, anthrax monoclonal antibody therapeutic candidate and advanced anthrax vaccine candidate. Our ability to borrow additional amounts under our loan agreement 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 acquisition of new facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to our new manufacturing facility in Lansing, Michigan and, if we proceed, 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 extent to which we lend money to third parties;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- the extent to which we acquire or invest in 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.

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 November 2008, the Emerging Issues Task Force, or EITF, of the Financial Accounting Standards Board, or FASB, issued EITF Issue No. 08-8, *Accounting for an Instrument (or an Embedded Feature) with a Settlement Amount This at Is Based on the Stock of an Entity s Consolidated Subsidiary*, or EITF No. 08-8. EITF No. 08-8 applies to freestanding financial instruments and embedded features of such instruments for which the payoff to the counterparty is based, in whole or in part, on the stock of a consolidated subsidiary. EITF No. 08-8 applies to those instruments in the consolidated financial statements of the parent, whether the instrument was entered into by the parent or the subsidiary. Freestanding financial instruments and embedded features of such instruments for which the payoff to the counterparty is based, in whole or in part, on the stock of a consolidated subsidiary are not precluded from being considered indexed to the entity's own stock in the consolidated financial statements of the parent if the subsidiary is a substantive entity. If the subsidiary is not a substantive entity, the instrument would not be considered indexed to the entity's own stock. EITF No. 08-8 is effective for fiscal years beginning on or after December 15, 2008, and interim periods within those fiscal years. Early adoption is not permitted. EITF No. 08-8 was adopted by the Company effective January 1, 2009, and will impact our financial statements to the extent that we have these types of instruments.

In November 2008, the EITF issued EITF Issue No. 08-7, *Accounting for Defensive Intangible Assets,* or EITF No. 08-7. EITF No. 08-7 applies to acquired intangible assets in situations in which an entity does not intend to actively use the asset but intends to hold or lock up the asset to prevent others from obtaining access to the asset (a defensive intangible asset), except for intangible assets that are used in research and development activities. EITF No. 08-7 states that a defensive intangible asset should be accounted for as a separate unit of accounting and should not be included as part of the cost of an entity's existing intangible asset(s) because the defensive intangible asset is separately identifiable. EITF No. 08-7 applies to intangible assets acquired on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. EITF No. 08-7 was adopted by the Company effective January 1, 2009, and will impact our financial statements to the extent that we acquire a defensive intangible asset.

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. We adopted SFAS No. 141(R) effective January 1, 2009, and in accordance with the provisions of the standard, in January 2009 we expensed $1.4 million in previously capitalized costs associated with acquisitions that were in progress but not complete as of December 31, 2008. SFAS No. 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the acquiring entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS No. 141(R) was adopted by the Company effective January 1, 2009, and will further impact our financial statements in the future to the extent that we are party to a business combination.

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, and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, we 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, 2009. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2009, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the quarter ended March 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Litigation against Protein Sciences Corporation. In 2008, we entered into a letter of intent, a loan and security agreement and related promissory note, and an asset purchase agreement with Protein Sciences Corporation, or PSC, pursuant to which we agreed to acquire substantially all of PSC s assets and provide funding to PSC to enable PSC to continue operations through June 24, 2008, the anticipated closing date of the transactions contemplated by the asset purchase agreement.

In July 2008, we filed a lawsuit against PSC, Daniel D. Adams, PSC s Chief Executive Officer, and Manon M.J. Cox, PSC s Chief Operating Officer, in the Supreme Court of the State of New York asserting claims related to the letter of intent, the loan and security agreement, and the asset purchase agreement. On September 12, 2008, a stipulation of discontinuance was filed with the court regarding the claims against Mr. Adams and Ms. Cox, and, on October 3, 2008, we filed a separate suit against Mr. Adams and Ms. Cox in the United States District Court for the District of Connecticut, alleging fraud and unfair trade practices and seeking compensatory and punitive damages. On September 12, 2008, we filed an amended complaint against PSC, which remains pending in the Supreme Court of the State of New York, alleging fraud, breach of the letter of intent, the loan and security agreement and the asset purchase agreement, breach of the duty of good faith and fair dealing, unjust enrichment and unfair business practices. We are seeking from PSC money damages of no less than $13 million, punitive damages, declaratory judgment that we have no further funding obligations to PSC, injunctive relief to protect the collateral for the loan and other appropriate relief. PSC has moved to dismiss the New York action, and Mr. Adams and Ms. Cox have moved to dismiss the Connecticut action. Those motions remain pending. PSC, Mr. Adams, and Ms. Cox have not yet asserted any counterclaims, but PSC has stated that it may assert counterclaims for among other things, breach of contract, intentional misrepresentations, tortious interference with business relations and unfair trade practices.

Between March 2008 and June 2008, we provided PSC with $10 million in funding under the loan and security agreement and related promissory note. PSC s obligations under the loan and security agreement and related promissory note are secured by substantially all of PSC s assets, including intellectual property. The loan accrued interest at an annual rate of 8% through December 31, 2008 and currently accrues interest at an annual rate of 11%. Under the loan and security agreement and related promissory note, PSC was obligated to repay the $10 million principal plus accrued and unpaid interest and costs of collection upon the earlier of December 31, 2008 or an event of default under the loan and security agreement. In the lawsuit against PSC described above, we allege that an event of default occurred under the loan and security agreement and that the loan was due and payable as of June 2008. In March 2009, we and PSC entered into a forbearance agreement, pursuant to which we agreed not to foreclose on the collateral securing the loan or to pursue other remedies relating to the loan prior to May 31, 2009. We intend to pursue full repayment under the loan and security agreement and related promissory note if we are not repaid as provided for under the forbearance agreement; if we are repaid pursuant to the forbearance agreement, we and PSC will subsequently enter into settlement agreements that provide for dismissal of the New York and Connecticut actions without prejudice. As of March 31, 2009, $10 million of principal was outstanding and $809,000 of interest was accrued and unpaid under the loan and security agreement and related promissory note.

Other. We are, and may in the future become, subject to other legal proceedings, claims and litigation arising in the ordinary course of our business in connection with the manufacture, distribution and use of our products and product candidates. For example, Emergent BioDefense Operations Lansing Inc., or EBOL, 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. EBOL 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.

ITEM 1A. RISK FACTORS

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

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

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales of BioThrax, our FDA-approved anthrax vaccine and only marketed product, to the U.S. government. We are currently party to two contracts with the U.S. Department of Health and Human Services, or HHS, to supply doses of BioThrax for placement into the Strategic National Stockpile, or SNS. We are not currently party to a procurement contract with the U.S. Department of Defense, or DoD, which currently procures doses of BioThrax directly from the SNS. If the SNS priorities change, or if the DoD dose requirements from the SNS are reduced, our revenues could be substantially reduced.

Our existing and prior contracts with HHS and the DoD do not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government. HHS has issued a request for proposal for contracts to develop and procure a recombinant protective antigen based anthrax vaccine which we may not win. 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;
- the risk that third parties may submit protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; 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 Biomedical Advanced Research and Development Authority, or BARDA, has issued a request for proposal for the development and procurement of a recombinant protective antigen anthrax vaccine for the SNS. We have submitted a proposal responding to this request for proposal. We expect that our ability to secure an award will depend primarily on the technical merits of our recombinant protective antigen anthrax vaccine candidate, or rPA vaccine candidate. The U.S.

government may support the development of and purchase another company s product candidate instead of our rPA vaccine candidate, which would be a significant setback to our rPA program. 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. Purchases by the U.S. government of an rPA vaccine candidate, whether from us or another company, may further reduce future demand for BioThrax.

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

Our principal customer for BioThrax is the U.S. government. 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. For example, the sale of most supplied doses under our new contract with HHS is subject to the annual appropriations process. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, our business, revenues and operating results may suffer.

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

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

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

Our agreements with HHS to supply doses of BioThrax to HHS for placement into the SNS provide that if we receive FDA approval of an application to extend the expiry dating of BioThrax from three years to four years, HHS will increase the price per dose under the agreements. The regulatory approval process is complex and uncertain, and there is no guarantee that we will receive approval of four-year expiry dating. If approved, BioThrax will be the first vaccine to receive FDA approval of four-year dating. If we do not receive FDA approval of four-year expiry dating during the term of either agreement, we will not be entitled to receive the increased price per dose under the agreement with HHS and our revenues and operating results may suffer.

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

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

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

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

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including equitable price adjustments;
- cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- decline to exercise an option to renew a contract;

exercise an option to purchase only the minimum amount 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 contracts for BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the government s convenience. Under general principles of government contracting law, if the government terminates a contract for convenience, the terminated company may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination.

If the government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. One or more of our government contracts could be terminated under these circumstances. Some government contracts grant the government the right to use, for or on behalf of the U.S. government, any technologies developed by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the government.

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

Future legal proceedings could be costly to defend, and the results could reduce demand for BioThrax by the U.S. government. For example, a group of unnamed military personnel filed a lawsuit in 2003 seeking to enjoin the DoD from administering BioThrax on a mandatory basis without informed consent of the recipient or a Presidential waiver, and a federal court issued the requested injunction in 2004. In 2005, the FDA issued an order affirming the BioThrax license, and, as a result, an appellate court ruled in February 2006 that the injunction was dissolved. In October 2006, the DoD announced that it was resuming a mandatory vaccination program for BioThrax for designated personnel and contractors. In December 2006, the same counsel who brought the prior lawsuit filed a new lawsuit contending that the FDA's 2005 final order should be set aside and that BioThrax is not properly approved for use in the DoD s vaccination program. In February 2008, the federal district court in which that case was pending dismissed the action, concluding that FDA did not make a clear error of judgment in reaffirming the safety and efficacy of BioThrax. In April 2008, the plaintiffs filed a notice of appeal of this decision, and that appeal remains pending.

Although we are not a party to any 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 that may not be reimbursed by insurance carriers or covered by indemnification under existing contracts.

Risks Related to Our Financial Position and Need for Additional Financing

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

We commenced operations in 1998, and the FDA approved the manufacture of BioThrax at our renovated facilities in Lansing, Michigan in December 2001. Although we were profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. 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, 2009, we had $56.5 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 may undertake additional facility projects in the future.

As of March 31, 2009, we had $61.4 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 acquisition of new facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to our new manufacturing facility in Lansing, Michigan and, if we proceed, 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 extent to which we lend money to third parties;

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;

the extent to which we acquire or invest in companies, businesses, products and technologies;

our ability to obtain development funding from government entities and non-government and philanthropic organizations; and

our ability to establish and maintain collaborations.

Our committed external sources of funds consist of the borrowing availability under our revolving line of credit with Fifth Third Bank and grant and development funding of our anthrax immune globulin therapeutic product candidate, anthrax monoclonal antibody therapeutic candidate and advanced anthrax vaccine candidate. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Difficult economic conditions may make it difficult to obtain financing on attractive terms or at all. Lenders may be able to impose covenants on us that could be difficult to satisfy, which could put us at increased risk of defaulting on debt. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

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

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

Risks Related to Manufacturing and Manufacturing Facilities

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

We are currently evaluating alternatives for the manufacture of various product candidates. We may seek to acquire one or more additional facilities or sign agreements with contract manufacturing organizations. We have constructed a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus, which is designed to produce multiple fermentation-based vaccines, subject to developing, obtaining approval of, implementing and complying with appropriate change-over procedures. We also own two buildings in Frederick, Maryland that are available to address our future manufacturing requirements and have initiated initial engineering design and preliminary utility build out for these facilities.

Constructing and preparing a facility for manufacturing is a significant project. For example, the process for qualifying and validating our new facility in Lansing, for FDA licensure will be costly and time consuming, may result in unanticipated delays and may cost more than expected due to a number of factors, including regulatory requirements. The costs and time required to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements for sales of our products outside the U.S., may be significant. If qualification and validation activities of our new facility in Lansing are delayed, we may not be able to meet our obligations to the U.S. government, which may limit our opportunities for growth. Costs associated with constructing, qualifying and validating manufacturing facilities could require us to raise additional funds from external sources, and we may not be able to do so on favorable terms or at all.

We may seek permission from the FDA to use our new manufacturing facility in Lansing for the manufacture of both BioThrax and our rPA vaccine candidate. This could require approval from the FDA of change-over procedures. If approval of such change over procedures is delayed or not obtained, our ability to grow BioThrax revenues could be limited.

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

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

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

In addition, under our contacts with HHS, we are responsible for shipping. BioThrax and our product candidates 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, shipping deviations, spoilage or other loss during shipping could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

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

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

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

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

In addition, providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. For example, the U.S. government has designated our Lansing facility as a facility requiring additional security to protect against potential terrorist threats to the facility. Any disruption that impedes our ability to manufacture and ship BioThrax in a timely manner could reduce our revenues and materially harm our business, financial condition and operating results. 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. We have identified and contracted with an additional provider that we believe can handle our filling needs. Before this party may perform filling services for us, it must be qualified and licensed by the FDA. Such qualification and licensure may require use of a significant number of doses of BioThrax for consistency lots and stability testing that we may not be able to sell. If Hollister-Stier is unable to perform filling services for us, we would need to obtain FDA approval of our potential substitute filler, engage, qualify and license an alternative filling company or develop our own filling capabilities. Any new contract filling company or filling capabilities that we acquire or develop will need to 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 time and cost. As a result, we might not be able to deliver BioThrax orders on a timely basis and our revenues could decrease.

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

The timing and amount of customer demand is difficult to predict. We may not be able to scale-up our production quickly enough to fill any new customer orders on a timely basis. This could cause us to lose new business and possibly existing business. For example, we may not be able to scale-up manufacturing processes for our product candidates to allow production of commercial quantities at a reasonable cost or at all. Furthermore, if we overestimate customer demand, or choose to commercialize products for which the market is smaller than we anticipate, we could incur significant unrecoverable costs from creating excess capacity. In addition, if we do not successfully develop and commercialize any of our product candidates, we may never 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 vaccine and immune-related therapeutic product candidates that we require for preclinical and clinical development, including our anthrax immune globulin therapeutic, anthrax monoclonal therapeutic, Typhella vaccine, tuberculosis vaccine, hepatitis B therapeutic vaccine, and chlamydia 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. For example, the manufacturer of our anthrax monoclonal therapeutic recently informed us it is discontinuing contract manufacturing operations and we will need to secure alternative manufacturing resources. 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 anthrax immune globulin therapeutic product candidate and contract fill and finish operations and we rely on those manufacturers to comply with a wide variety of rules and regulations. If our contract manufacturers are unable to scale-up production to generate enough materials for commercial launch, if manufacturing is of insufficient quality, or if the costs of manufacturing are prohibitively high, the success of those products may be jeopardized. For example, we are currently evaluating manufacturing alternatives for Typhella in countries in which we believe manufacturing costs will be economical. 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 would require review and approval from the FDA and the applicable foreign regulatory agencies. 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.

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

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

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

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

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

Our development and manufacturing processes involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we are subject to federal, state, local and foreign laws and regulations governing the use, manufacture, distribution, storage, handling, disposal and recordkeeping of these materials. We are also subject to a variety of environmental laws in Michigan regarding underground storage tanks. One such tank on our Lansing campus has leaked in the past. The State of Michigan removed the tank, continues to monitor the situation and has agreed to indemnify us for any resulting liabilities. In the event that the State of Michigan does not indemnify us, or if our insurance does not cover the exposure of any remediation that may be necessary, we could spend significant amounts on remediation efforts. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the Centers for Disease Control and Prevention, or CDC, HHS and the DoD.

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

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

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

We hold a number of insurance policies in an effort to protect ourselves against extraordinary or unanticipated costs. Our general liability and excess insurance policies provide for coverage up to annual aggregate limits of $12 million, with coverage of $1 million per occurrence and $2 million in the aggregate for general liability and $10 million per occurrence and in the aggregate for excess liability. 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 $2 million annual aggregate limit and a $25,000 per claim deductible. We hold product liability insurance policies for each clinical trial that we are conducting, in amounts we deem appropriate to the product candidate and the scope of the applicable trial.

These policies are subject to deductibles, exclusions and coverage limitations. Additionally, we do not carry business interruption insurance. Circumstances may arise where we face liabilities that are not covered by these policies, or where our coverage is not adequate, which may expose us to significant liabilities and significantly and adversely affect our business or financial position.

Risks Related to Product Development

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

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

- successful development, formulation and cGMP scale-up of biological manufacturing that meets FDA requirements;
- successful development of animal models 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 will not be able to commercialize our product candidates if our preclinical development efforts are not successful, our clinical trials do not demonstrate safety or our clinical trials or animal studies do not demonstrate efficacy.

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

For example, in December 2008, we and Sanofi Pasteur determined that the joint efforts of our collaboration had not identified a viable product candidate, which effectively ended most material development activities under our meningitis B product development program.

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 vaccine and immune-related therapeutic product candidates in humans. If we are not successful in completing the development and commercialization of our vaccine and immune-related therapeutic product candidates, or if we are significantly delayed in doing so, our business will be materially harmed.

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

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;
- 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 impacted our ability to recruit participants for our Phase II clinical trial in the United Kingdom and Serbia because we administer our product candidate as a monotherapy, causing us to cease enrollment in this trial. If we are unable to recommence this trial in a region in which our enrollment efforts are successful, we will be unable to progress the clinical program for this candidate. 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 our clinical trials are not well designed, if we are unable to successfully complete our clinical trials or other testing, or if the results of these trials or tests are not positive, we may:

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

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

Under the Project BioShield Act, the Secretary of HHS can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA. However, our 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. Foreign governments in the past have requested that we submit an FDA certification of compliance. Such a certification may be difficult to obtain, potentially limiting our ability to make sales to foreign customers. In 2007, 2008 and for the three months ended March 31, 2009, 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 may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, many foreign governments require licensure of BioThrax in their jurisdiction before they will consider procuring doses. Additionally, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of BioThrax and related technology, the U.S. government may decide, particularly in the current environment of elevated concerns about global terrorism, to increase the scope of export prohibitions. These controls could limit our sales of BioThrax to foreign governments and other foreign customers. In addition, U.S. government demand for anthrax vaccine may limit supplies of BioThrax available for sale to non-U.S. government customers. For example, our efforts to develop domestic commercial and international sales may be impeded by the DoD s right under the Defense Production Act to require us to deliver doses that we do not currently anticipate.

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. To prepare for the event that we obtain significant orders for BioThrax from customers other than the U.S. government, we are exploring additional manufacturing alternatives that would enable us to increase our manufacturing capacity and, as a result, allow us to increase sales of BioThrax to customers other than the U.S. government. If we are successful in this effort, it could be several years until a facility is qualified and validated and able to produce saleable vaccine. If we are unsuccessful in this effort, our opportunities for growth could be limited.

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

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

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

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical studies and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. China is an example of one jurisdiction in which we are contemplating future expansion where we will need to exercise caution to ensure our compliance with the FCPA.

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

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

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

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

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

The use of vaccines carries a risk of adverse health effects. The adverse reactions that have been associated with the administration of BioThrax include local reactions, such as redness, swelling and 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 adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event. Serious adverse events, including diabetes, heart attacks, autoimmune diseases, including Guillian Barre syndrome, lupus, 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 from sales of these products. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects;
- the efficacy and potential advantages over alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;

the relative convenience and ease of administration;

the willingness of the target patient population to try new products and of physicians to prescribe these products;

the strength of marketing and distribution support; and

the sufficiency of coverage or reimbursement by third parties.

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

Products developed to treat diseases caused by or to combat the threat of bioterrorism 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 2006, members of the military and various activist groups who oppose mandatory inoculation with BioThrax petitioned the FDA and the federal courts to revoke the license for BioThrax and to terminate the DoD program for the mandatory administration of BioThrax to military personnel. Although the DoD has prevailed in those challenges to date, the actions of these groups have created negative publicity about BioThrax. 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 through a small, targeted sales and marketing group. We plan to continue to do so and expect that we will use a similar approach for sales to the U.S. government of any other biodefense product candidates that we successfully develop. However, to increase our sales of BioThrax to state and local governments and foreign governments and create an infrastructure for future sales of other biodefense products to these customers, we plan to expand our sales and marketing organization, which will be expensive and time consuming.

We may not be able to attract, hire, train and retain qualified sales and marketing personnel to build a significant or effective 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 vaccine and immune-related therapeutic products is highly competitive. We face competition with respect to BioThrax, our current product candidates and any products we may seek to develop or commercialize in the future from 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 vaccine and immune-related therapeutics are a number of pharmaceutical companies that have vaccine programs, including Merck & Co., which has agreed to merge with Schering-Plough Corporation, GlaxoSmithKline, Sanofi Pasteur, Wyeth and Novartis, as well as smaller more focused companies engaged in vaccine and immune-related therapeutic development, such as Crucell, Cangene, Human Genome Sciences, Dor BioPharma, Dynaport Vaccine Company L.L.C., Elusys, Bavarian Nordic and PharmAthene.

Any vaccine and immune-related therapeutic product candidate that we successfully develop and commercialize is likely to compete with currently marketed products, 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 product candidates. For example, HHS has awarded a development and SNS procurement contract to a competitor for an anthrax immune globulin therapeutic and is assisting this company in its production efforts by providing it with BioThrax doses that we delivered for placement into the SNS so that it can immunize donors and obtain plasma for its anthrax immune globulin therapeutic product candidate. HHS has awarded another development and SNS procurement contract to another competitor for an anthrax monoclonal antibody 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 U.S. and Europe. The Aeras Global Tuberculosis Vaccine Foundation is developing or supporting the development of five tuberculosis vaccine candidates in addition to ours, any of which could present competitive risks. Numerous companies have vaccine candidates in development that would compete with any of our commercial product candidates for which we are seeking to 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 competing for government funding and through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring products, product candidates and technologies complementary to, or necessary for, our programs or advantageous to our business.

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

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

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

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

In addition, although our prior contracts with DoD and HHS provided that the U.S. government would indemnify us for any damages resulting from product liability claims, our current contracts with HHS do not contain such indemnification, and we may not be able to negotiate similar indemnification provisions in future contracts. Also, the U.S. government may not honor its indemnification obligations. For example, although we have invoiced the DoD for reimbursement of our costs incurred with respect to the lawsuits filed against us by current and former members of the U.S. military claiming damages as the result of personal injuries allegedly suffered from vaccination with BioThrax, the DoD has not yet acted on our claim for indemnification for defense costs associated with those claims.

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

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

Under our prior BioThrax contracts with the DoD and HHS, the U.S. government indemnified 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. The collection process can be lengthy and complicated, and there is no guarantee that we will be able to recover these amounts from the U.S. government.

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

decreased demand for any product candidates or products that we may develop;

injury to our reputation;

withdrawal of clinical trial participants;

withdrawal of a product from the market;

costs to defend the related litigation;

substantial monetary awards to trial participants or patients;

loss of revenue; and

the inability to commercialize any products that we may develop.

We currently have product liability insurance for coverage up to a $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 statutory protections in addition to insurance to mitigate our liability exposure for BioThrax.

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

Our revenues and profits from any products that we successfully develop, other than with respect to sales of our biodefense products under government contracts, will depend heavily upon the availability of adequate reimbursement for the use of such products from governmental and

other third party payors, both in the U.S. and in other markets. Reimbursement by a third party payor may depend upon a number of factors, including the third party payor s determination that use of a product is:

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

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

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

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

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the Federal Acquisition Regulations, and agency-specific regulations supplemental to the Federal Acquisition Regulations, which comprehensively regulate the procurement, formation, administration and performance of government contracts;

the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act and the FCPA;

export and import control laws and regulations; and

laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

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

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

We have the right to use certain property and equipment that is owned by the U.S. government, referred to as government furnished equipment, or GFE, at our Lansing, Michigan site in the manufacture of BioThrax. We have the option to purchase all or part of the existing GFE from the government on terms to be negotiated with the government. If the government modifies the terms under which we use the GFE in a manner that is unfavorable to us, including substantially increasing the usage fee, or we are unable to reach an agreement with the government concerning the terms of the purchase of that part of the GFE necessary for our business, our business could be harmed. If the U.S. government were to terminate or fail to extend all BioThrax supply contracts with us, we potentially could be required to rent or 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 U.S. 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 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 our product candidates, we will be required to submit to the FDA a biologics license application, or BLA. Ordinarily, the FDA requires a sponsor to support a BLA application with substantial evidence of the product s safety and effectiveness in treating the targeted indication based on data derived from adequate and well controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted. However, our biodefense product candidates require slightly different treatment. Specifically, 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 use the FDA animal rule in pursuit of FDA approval for BioThrax as a post-exposure prophylaxis, our anthrax immune globulin therapeutic candidate, our recombinant botulinum vaccine candidate, our rPA anthrax vaccine, our anthrax monoclonal antibody therapeutic, and our advanced anthrax vaccine. 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.

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

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

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

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

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

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

After approving the renovated Lansing facilities in December 2001, the FDA conducted routine, biannual inspections of the Lansing facilities in September 2002, May 2004 and May 2006. Following each of these inspections, the FDA issued inspectional observations on Form FDA 483. We responded to the FDA regarding the inspectional observations relating to each inspection and, where necessary, implemented corrective action. In December 2005, the FDA stated in its final order on BioThrax that at that time we were in substantial compliance with all regulatory requirements related to the manufacture of BioThrax and that the FDA would continue to evaluate the production of BioThrax to assure compliance with federal standards and regulations.

The FDA conducted a routine, biannual inspection of the Lansing facility in March 2008. Following this inspection, the FDA issued inspectional observations on Form FDA 483. Some of the observations noted on the Form FDA 483 were significant. All observations from our 2008 inspection were closed out in November 2008. If in connection with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, or if the FDA is not satisfied with the corrective actions we take in connection with any such inspection, the FDA may undertake enforcement action against us.

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

- restrictions on the marketing or manufacturing of a product;
- warning letters;
- withdrawal of the product from the market;
- refusal to approve pending applications or supplements to approved applications;
- voluntary or mandatory product recall;

fines or disgorgement of profits or revenue;

suspension or withdrawal of regulatory approvals, including license revocation;

shut down, or substantial limitations of the operations in, manufacturing facilities;

refusal to permit the import or export of products;

product seizure; and

injunctions or the imposition of civil or criminal penalties.

If our competitors are able to obtain orphan drug exclusivity for their products that are the same as our products, we may 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 the FDA will grant such designation in the future. Even if we obtain orphan drug exclusivity for one or more indications for one of our product candidates, we may not be able to maintain it. For example, if a competitive product that is the same drug or biologic as our product is shown to be clinically superior to our product, any orphan drug exclusivity we may have obtained will not block the approval of that competitive product.

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

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

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

We intend to have some or all of our products marketed outside the U.S. 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 U.S., and we will depend on our collaborators to obtain these approvals. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval.

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

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

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

We do not have the ability to independently conduct the clinical 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, 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.

We expect to rely on data from clinical trials conducted by third parties seeking marketing approval for our product candidates. For example, our BLA supplement for a label expansion of BioThrax for a regimen of fewer doses is based on the 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 completion of all study reports.

Risks Related to Our Intellectual Property

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

Our success, particularly with respect to our commercial business, will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property covering or incorporated into our technology and products. This protection is very costly. The patent situation in the field of vaccine and immune-related therapeutic and other pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions.

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

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, patents generally expire, regardless of their date of issue, 20 years from the earliest claimed non-provisional filing date. As a result, the time required to obtain regulatory approval for a 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.

For example, under our licenses with the U.K. Health Protection Agency, or HPA, relating to our recombinant botulinum vaccine 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 and expect to enter into additional license agreements in the future. For example, we consider our license from the Oxford-Emergent Tuberculosis Consortium to our tuberculosis vaccine candidate to be material to our business. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

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

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for BioThrax or the label expansions and improvements that we are pursuing for BioThrax, our only intellectual property protection for BioThrax, other than the BioThrax trademark, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and biological starting materials. However, these types of trade

secrets can be difficult to protect. We seek to protect this confidential information, in part, with agreements with our employees, consultants and third parties.

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

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

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

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

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology and pharmaceutical industries. For example, Bavarian Nordic sued Acambis for patent infringement and other claims arising out of Acambis manufacture of the modified vaccinia Ankara virus, or MVA, as a smallpox vaccine for biodefense use by the U.S. government. We have a strain of MVA that we are evaluating as a platform technology and a tuberculosis vaccine candidate that is based on another strain of MVA, both of which are distinct from the Acambis strain. Bavarian Nordic claimed that its patents broadly covered the manufacture of MVA-based biological products and that Bavarian Nordic had rights in the biological materials used by Acambis. That litigation was terminated 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 U.S. its ACAM 3000 vaccine product, and further agreed not to challenge the validity or enforceability of certain Bavarian Nordic patents. Bavarian Nordic sued Oxford BioMedica PLC, Oxford BioMedica Ltd. and Biomedica Inc., collectively Oxford BioMedica, alleging that Oxford BioMedica has infringed certain Bavarian Nordic U.S. patents by making, using, and importing, and inducing others to use, Oxford BioMedica s experimental drug TroVax® which is an MVA-based therapeutic cancer vaccine. The original lawsuit against Oxford BioMedica was dismissed in January 2009. However, Bavarian Nordic has recently filed a new lawsuit against Oxford BioMedica that remains outstanding. Bavarian Nordic also has filed legal proceedings against the Bavarian State Ministry of the Environment, Public Health and Consumer Protection, or StMUGV, in which Bavarian Nordic is challenging StMUGV s ownership rights to the MVA in its possession. We have licensed from StMUGV rights to materials and technology related to MVA. Our MVA platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based on these rights.

Our ability to use our MVA platform technology, or to develop and manufacture MVA-based products such as our tuberculosis product candidate, could be negatively affected by pending or future patent infringement litigation or other legal actions brought by Bavarian Nordic or other parties challenging our rights to use MVA materials or technology. To protect our interests, we have filed oppositions in the European Patent Office against four of Bavarian Nordic s patents covering certain aspects of the MVA technology. We are also party to a trademark invalidation proceeding in a foreign trademark office and may in the future become party to additional trademark invalidation or interference proceedings. 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.

Since our inception we have pursued an acquisition strategy to build our business. 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 a significant portion of our pipeline of vaccine and therapeutic product candidates through our acquisition of ViVacs GmbH in 2006 and Microscience Limited in 2005 and our acquisition of substantially all of the assets of Antex Biologics, Inc. 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 vaccine and immune-related therapeutic field. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable products and product candidates include the following:

- we may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return on the 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 vaccine and immune-related therapeutic field to increase, which may result in fewer suitable acquisition opportunities for us as well as higher acquisition prices. If we are unable to successfully obtain rights to suitable products and product candidates, 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;
- prioritizing product portfolios;
- disruption of our ongoing business;
- difficulty and expense in assimilating and integrating the operations, products, technology, information systems or personnel of the acquired company;
- diversion of management s time and attention from other business concerns;
- inability to maintain uniform standards, controls, procedures and policies;

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

challenges and costs associated with reductions in work force; and

subsequent loss of key personnel.

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

Risks Related to Our Common Stock

Fuad El-Hibri, chief executive officer and chairman of our Board of Directors, has 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 among our significant stockholders. As of April 30, 2009, Mr. El-Hibri was the beneficial owner of approximately 45% of our outstanding common stock. Because Mr. El-Hibri has significant influence over the election of the members of our board, and because of his substantial control of our capital stock, Mr. El-Hibri will likely have the ability to delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

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

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

These provisions include:

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

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

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

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

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

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

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

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through April 30, 2009, our common stock has traded as high as $27.00 per share and as low as $4.40 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- decisions and procurement policies by the U.S. government affecting BioThrax and our biodefense product candidates;
- regulatory developments in the U.S. and foreign countries;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts reports or recommendations;
- general economic, industry and market conditions; and
- the other factors described in this Risk Factors section.

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 13.7 million shares of our common stock outstanding as of March 31, 2009 have the right to require us to register these shares of common stock under specified circumstances.

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

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

Not applicable.

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.

Date: May 7, 2009 **EMERGENT BIOSOLUTIONS INC.**

Date: May 7, 2009

By: /s/ Fuad El-Hibri

Fuad El-Hibri

Chief Executive Officer and

Chairman of the Board of Directors (Principal Executive Officer)

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 February 10, 2009 between Emergent BioDefense Operations Lansing Inc. and Intergen N.V. (Incorporated by reference to Exhibit 10.27 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008 (SEC File No. 001-33137))
31.1	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002