Emergent BioSolutions Inc.
Form 10-Q
November 07, 2008
U.S.

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2008

OR

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

For the transition period from ___ to ____

Commission file number: **001-33137**

EMERGENT BIOSOLUTIONS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**14-1902018**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
2273 Research Boulevard, Suite 400	
Rockville, Maryland	**20850**
(Address of Principal Executive Offices)	(Zip Code)

(301) 795-1800

(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. [X] Yes o No

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

o Large accelerated filer x Accelerated filer o Non-accelerated filer 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 October 31, 2008, the registrant had 29,921,107 shares of common stock outstanding.

Emergent BioSolutions Inc.

Index to Form 10-Q

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2008 (Unaudited)	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 104,688	$ 105,730
Accounts receivable	14,070	18,817
Inventories	17,516	16,897
Note receivable	10,000	-
Prepaid expenses and other current assets	5,700	2,866
Total current assets	151,974	144,310
Property, plant and equipment, net	120,898	110,218
Deferred tax assets, net	12,598	12,397
Restricted cash	200	5,200
Other assets	1,726	1,383
Total assets	$ 287,396	$ 273,508
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 16,673	$ 20,257
Accrued expenses and other current liabilities	1,463	1,778
Accrued compensation	10,378	9,502
Indebtedness under line of credit	15,000	11,832
Long-term indebtedness, current portion	3,739	3,514
Income taxes payable	2,898	7,665
Deferred tax liabilities, net	597	211
Deferred revenue, current portion	820	902
Total current liabilities	51,568	55,661
Long-term indebtedness, net of current portion	39,651	42,588
Deferred revenue, net of current portion	1,853	2,473
Other liabilities	1,495	1,627
Total liabilities	94,567	102,349
Commitments and contingencies	-	-
Stockholders equity:		
Preferred Stock $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2008 and December 31, 2007	-	-
Common Stock, $0.001 par value; 100,000,000 shares authorized, 29,850,411 and 29,750,237 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	30	30
Additional paid-in capital	104,288	101,933
Accumulated other comprehensive loss	(1,040)	(1,130)
Retained earnings	89,551	70,326
Total stockholders equity	192,829	171,159
Total liabilities and stockholders equity	$ 287,396	$ 273,508

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	**2007**	**2008**	**2007**
	(Unaudited)		**(Unaudited)**	
Revenues:				
Product sales	$ 55,478	$ 41,786	$ 139,308	$ 89,750
Contracts and grants	1,121	1,858	3,496	3,528
Total revenues	56,599	43,644	142,804	93,278
Operating expense:				
Cost of product sales	10,519	11,407	27,211	22,765
Research and development	16,627	12,777	45,308	41,689
Selling, general and administrative	14,115	15,038	41,212	38,889
Income (loss) from operations	15,338	4,422	29,073	(10,065)
Other income (expense):				
Interest income	476	472	1,598	1,945
Interest expense	2	(7)	(4)	(54)
Other income (expense), net	(1)	(14)	183	164
Total other income (expense)	477	451	1,777	2,055
Minority interest in subsidiary	428	-	428	-
Income (loss) before provision for (benefit from) income taxes	16,243	4,873	31,278	(8,010)
Provision for (benefit from) income taxes	5,857	2,028	12,051	(3,205)
Net income (loss)	$ 10,386	$ 2,845	$ 19,227	$ (4,805)
Earnings (loss) per share - basic	$ 0.35	$ 0.10	$ 0.65	$ (0.17)
Earnings (loss) per share - diluted	$ 0.34	$ 0.10	$ 0.64	$ (0.17)
Weighted-average number of shares - basic	29,818,994	29,739,797	29,777,852	28,741,380
Weighted-average number of shares - diluted	30,590,950	29,900,571	30,151,940	28,741,380

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

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

	Nine Months Ended September 30,	
	2008	**2007**
	(Unaudited)	
Cash flows from operating activities:		
Net income (loss)	$ 19,227	$ (4,805)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation expense	1,733	1,895
Depreciation and amortization	3,547	3,597
Deferred income taxes	185	9,418
Gain on disposal of property and equipment	(182)	-
Excess tax benefits from stock-based compensation	-	(6,708)
Minority interest in subsidiary	(428)	-
Changes in operating assets and liabilities:		
Accounts receivable	4,747	1,318
Inventories	(619)	(901)
Income taxes	(4,767)	(25,820)
Prepaid expenses and other assets	(2,749)	(1,109)
Accounts payable	(1,165)	1,521
Accrued expenses and other liabilities	876	(1,512)
Accrued compensation	(447)	426
Deferred revenue	(702)	(1,015)
Net cash provided by (used in) operating activities	19,256	(23,695)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(16,464)	(36,197)
Issuance of a note receivable	(10,000)	-
Net cash used in investing activities	(26,464)	(36,197)
Cash flows from financing activities:		
Proceeds from borrowings on long term indebtedness and line of credit	45,000	15,333
Issuance of common stock subject to exercise of stock options	620	2,474
Principal payments on long term indebtedness and line of credit	(44,544)	(11,131)
Excess tax benefits from stock-based compensation	-	6,708
Restricted cash release (deposit)	5,000	(5,000)
Net cash provided by financing activities	6,076	8,384
Effect of exchange rate changes on cash and cash equivalents	90	(644)
Net decrease in cash and cash equivalents	(1,042)	(52,152)
Cash and cash equivalents at beginning of period	105,730	76,418
Cash and cash equivalents at end of period	$ 104,688	$ 24,266

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, as amended, for the year ended December 31, 2007, as filed with the Securities and Exchange Commission.

In the opinion of the Company s management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of September 30, 2008, results of operations for the three and nine month periods ended September 30, 2008 and 2007, and cash flows for the nine month periods ended September 30, 2008 and 2007. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Note receivable

The Company has 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, PSC had drawn $10 million as of September 30, 2008, and the Company has recorded this as a note receivable. The note bears interest at an annual rate of 8%, and is due and payable on the earlier of December 31, 2008 or when the amount becomes due and payable under the terms of the note. As of September 30, 2008, the Company has recorded accrued interest on the note receivable of $336,000, included in prepaid expenses and other current assets.

On July 9, 2008, the Company initiated a lawsuit against PSC and PSC s senior management, alleging fraudulent conduct by the senior management and breach of the terms of PSC s agreements with the Company. Based on the event of default alleged by the Company, the promissory note has been accelerated and is due and payable immediately. The Company has concluded that, according to 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 September 30, 2008, and 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 month periods ended September 30, 2008 and 2007, the Company incurred interest of $676,000 and $899,000, respectively. Of these amounts, the Company capitalized $674,000 and $890,000, respectively. For the nine months ended September 30, 2008 and 2007, the Company incurred interest of $2.3 million and $2.2 million, respectively. Of these amounts, the Company capitalized $2.2 million in each period.

Earnings per share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except share and per share data)	**2008**	**2007**	**2008**	**2007**
Numerator:				
Net income (loss)	$ 10,386	$ 2,845	$ 19,227	$ (4,805)
Denominator:				
Weighted-average number of shares basic	29,818,994	29,739,797	29,777,852	28,741,380
Dilutive securities stock options	771,956	160,774	374,088	-
Weighted-average number of shares diluted	30,590,950	29,900,571	30,151,940	28,741,380
Earnings (loss) per share-basic	$ 0.35	$ 0.10	$ 0.65	$ (0.17)
Earnings (loss) per share-diluted	$ 0.34	$ 0.10	$ 0.64	$ (0.17)

Accounting for stock-based compensation

Effective January 1, 2006, the Company adopted the fair value provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123(R)), using the modified prospective method. Under SFAS No. 123(R), the Company recognizes stock-based compensation net of an estimated forfeiture rate. The Company accounts for equity instruments issued to non-employees in accordance with Emerging Issues Task Force (EITF) Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services.*

The Company has utilized the Black-Scholes valuation model for estimating the fair value of all stock options granted. The fair value of each option is estimated on the date of grant. Set forth below are the weighted-average assumptions used in valuing the stock options granted and a discussion of the Company s methodology for developing each of the assumptions used:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	**2007**	**2008**	**2007**
Expected dividend yield	0%	0%	0%	0%
Expected volatility	65%	50%	65%	50%
Risk-free interest rate	2.75%	4.01-4.95%	1.78-2.75%	4.01-5.09%
Expected average life of options	3.0 Years	3.0 Years	3.0 Years	3.0 Years

Expected dividend yield The Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.

Expected volatility Volatility is a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company analyzed the historical volatility of similar companies at a similar stage of development to estimate volatility. The volatility of these similar companies ranged from 40% to 89%, with an average estimated volatility of 68%. The Company chose a rate of 65%, approximately the mid-point of this range.

Risk-free interest rate This is the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date on which the option was granted.

Expected average life of options This is the period of time that the options granted are expected to remain outstanding. This estimate is based primarily on the Company s expectation of optionee exercise behavior subsequent to vesting of options.

Comprehensive income (loss)

SFAS No. 130, *Reporting Comprehensive Income,* requires the presentation of comprehensive income (loss) and its components as part of the financial statements. Comprehensive income (loss) is comprised of net income (loss) and other changes in equity that are excluded from net income (loss). The Company includes gains and losses on intercompany transactions with foreign subsidiaries that are considered to be long-term investments and translation gains and losses incurred when converting its subsidiaries financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income (loss). Comprehensive income for the three and nine months ended September 30, 2008 was $10.6 million and $19.3 million, respectively. Comprehensive income for the three months ended September 30, 2007 was $2.7 million. Comprehensive loss for the nine months ended September 30, 2007 was $5.4 million.

Reclassifications

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

Recent accounting pronouncements

In May 2008, the Financial Accounting Standards Board (FASB) issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS No. 162). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the U.S. SFAS No. 162 is effective 60 days following the Securities and Exchange Commission approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles.* The Company anticipates that the adoption of this statement will not have a material impact on its financial statements.

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

In February 2008, the FASB issued a one-year deferral for non-financial assets and liabilities to comply with SFAS No. 157, *Fair Value Measurements* (SFAS No. 157). The Company adopted SFAS No. 157 for financial assets and liabilities effective January 1, 2008. There was no material effect upon adoption of this accounting pronouncement on the Company s consolidated results of operations or financial position. The Company does not expect the adoption of SFAS No. 157 as it pertains to non-financial assets and liabilities to have a material impact on its financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an Amendment of ARB No. 51* (SFAS No. 160). SFAS No. 160 clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements, requires consolidated net income (loss) to be reported at amounts that

include the amounts attributable to both the parent and the noncontrolling interest, establishes a single method of accounting for changes in a parent s ownership interest in a subsidiary that do not result in deconsolidation, and requires that a parent recognize a gain or loss in net income (loss) when a subsidiary is deconsolidated. The provisions of SFAS No. 160 are effective for fiscal years beginning on or after December 15, 2008. The Company anticipates that the adoption of this statement will not have a material impact on its financial statements.

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

In November 2007, the EITF issued EITF No. 07-1, *Accounting for Collaborative Arrangements* (EITF No. 07-1). EITF No. 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The provisions of EITF No. 07-1 are effective for fiscal years beginning on or after December 15, 2008 and interim periods within those fiscal years. EITF No. 07-1 shall be applied to all periods presented for all collaborative arrangements existing as of the effective date. The Company is currently evaluating the impact of the adoption of this statement on its financial statements.

2. Inventories

Inventories consist of the following:

(in thousands)	September 30, 2008	December 31, 2007
Raw materials and supplies	$ 2,854	$ 2,463
Work-in-process	12,150	11,483
Finished goods	2,512	2,951
Total inventories	$ 17,516	$ 16,897

3. Property, plant and equipment

Property, plant and equipment consist of the following:

(in thousands)	September 30, 2008	December 31, 2007
Land and improvements	$ 4,914	$ 4,974
Buildings and leasehold improvements	28,105	26,410
Furniture and equipment	22,955	19,626
Software	6,297	5,866
Construction-in-progress	78,095	71,129
	140,366	128,005
Less: Accumulated depreciation and amortization	(19,468)	(17,787)
Total property, plant and equipment, net	$ 120,898	$ 110,218

4. Stock options

As of September 30, 2008, the Company has two stock-based employee compensation plans, the Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the 2006 Plan) and the Emergent BioSolutions Employee Stock Option Plan (the 2004 Plan) (together, the Emergent Plans),

under which the Company has granted options to purchase shares of Common Stock. The Emergent Plans have both incentive and non-qualified stock option features.

The 2006 Plan contains an evergreen provision that allows for increases in the number of shares authorized for issuance under the 2006 Plan in the first and third quarter of each year from 2007 through 2009. As of September 30, 2008, an of 3,424,040 shares of Common Stock are authorized for issuance under the 2006 Plan, and options to purchase a total of 2,575,517 shares of Common Stock under the 2006 Plan are outstanding. Following the closing of the Company s initial public offering in November 2006, the Company no longer grants options pursuant to the 2004 Plan.

Each option granted under the Emergent Plans becomes exercisable as specified in the relevant option agreement, and no option can be exercised after ten years from the date of grant. The following is a summary of stock option plan activity:

	2006 Plan Number of Shares	Weighted-Average Exercise Price	2004 Plan Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2007	1,380,111	$ 9.77	666,519	$ 6.04	
Granted	1,444,140	7.37	-	-	
Exercised	(32,201)	9.85	(67,973)	4.45	
Forfeited	(216,533)	8.60	(19,181)	10.28	
Outstanding at September 30, 2008	2,575,517	$ 8.52	579,365	$ 6.09	$ 15,933,634
Exercisable at September 30, 2008	367,010	$ 10.12	521,826	$ 5.50	$ 5,088,724

5. Income taxes

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2008**	**2007**	**2008**	**2007**
Current:				
Federal	$ 5,504	$ 1,931	$ 12,120	$ (6,025)
State	(472)	214	(257)	317
Total current	5,032	2,145	11,863	(5,708)
Deferred:				
Federal	(663)	(114)	(1,560)	2,229
State	1,488	(3)	1,748	274
Total deferred	825	(117)	188	2,503
Total provision for (benefit from) income taxes	$ 5,857	$ 2,028	$ 12,051	$ (3,205)

The estimated effective annual tax rate for the nine months ended September 30, 2008 and 2007 was approximately 39% and 40%, respectively.

The Company s federal and state income tax returns for the tax years 2007 to 2005 remain open to examination. The Company s tax returns in the United Kingdom remain open to examination for the tax years 2007 to 2001, and tax returns in Germany remain open indefinitely.

In July 2008, the Company was notified by the Internal Revenue Service that the federal income tax return for the 2006 tax year has been selected for a limited scope audit. A federal income tax audit of the Company's tax return for the 2005 tax year was completed in March 2008. As a result of that audit, the Company paid an assessment of $450,000, including $55,000 of interest.

6. Litigation

On July 9, 2008, the Company filed suit against PSC, Daniel D. Adams (Adams), PSC s Chief Executive Officer, and Manon M.J. Cox (Cox), PSC s Chief Operating Officer, in the Supreme Court of the State of New York raising claims in connection with the letter of intent, asset purchase agreement and related loan agreement entered into by the Company and PSC. On September 12, 2008, a stipulation of discontinuance was filed with the court regarding the claims against Adams and Cox. Also on September 12, 2008, the Company filed a first amended complaint against PSC. As amended, the complaint alleges fraud, breach of the asset purchase agreement, loan agreement and related letter of intent, breach of the duty of good faith and fair dealing, unjust enrichment, and unfair business practices. The Company is seeking monetary damages of no less than $13 million, punitive damages, declaratory judgment that the Company has no further funding obligations to PSC, injunctive relief associated with PSC's misappropriation of funds provided by the Company, injunctive relief to protect the collateral for the loan, a declaratory judgment that the asset purchase agreement remains in effect and injunctive relief barring PSC s breach of the no-shop provision, and other appropriate relief. On October 3, 2008, the Company filed a separate suit against Adams and Cox in the U.S. District Court for the District of Connecticut, alleging fraud and unfair trade practices and seeking compensatory and punitive damages.

On July 29, 2008, PSC announced that it had terminated the asset purchase agreement for alleged breach of the Company s obligation to continue to provide funding and to preserve confidentiality. PSC has since reiterated its position that the asset purchase agreement is terminated in a September 2008 letter to shareholders. Additionally, PSC asserted in an earlier communication to the Company that the Company is liable for a break-up fee of $1.5 million, that this liability reduces the balance of the loan due to the Company from $10 million to $8.5 million and that PSC does not believe that the note is due until December 31, 2008. The Company disputes PSC's position and contends that PSC has defaulted on the loan, breached the contract, has no right to terminate the asset purchase agreement and is required to repay the $10 million loan immediately.

From time to time, the Company is involved in product liability litigation and other lawsuits that arise in the ordinary course of its business. The Company does not believe that any pending proceedings will have a material, adverse effect on the results of its operations. There are currently no pending claims against the Company arising out of the use of BioThrax by the U.S. government. If such cases occur, the Company plans to rely on a combination of contractual indemnification provisions, the government contractor defense, statutory protections and product liability insurance to limit its potential liability.

7. Segment information

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 immune related biologics consisting of 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 immune related biologics consisting of vaccines and therapeutics for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. Revenues in this segment consist predominantly of milestone payments and development and grant revenues received under collaboration, 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 Biodefense	Commercial	All Other	Total
	Three Months Ended September 30, 2008			
External revenue	$ 56,132	$ 467	$ -	$ 56,599
Net income (loss)	26,311	(13,423)	(2,502)	10,386
Assets	143,610	23,946	119,840	287,396
	Three Months Ended September 30, 2007			
External revenue	$ 42,679	$ 965	$ -	$ 43,644
Net income (loss)	16,767	(10,591)	(3,331)	2,845
Assets	156,695	19,738	50,318	226,751

(in thousands)	Reportable Segments Biodefense	Commercial	All Other	Total
	Nine Months Ended September 30, 2008			
External revenue	$ 140,615	$ 2,043	$ 146	$ 142,804
Net income (loss)	58,719	(33,148)	(6,344)	19,227
Assets	143,610	23,946	119,840	287,396
	Nine Months Ended September 30, 2007			
External revenue	$ 90,643	$ 2,635	$ -	$ 93,278
Net income (loss)	26,120	(24,124)	(6,801)	(4,805)
Assets	156,695	19,738	50,318	226,751

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

8. Related party transactions

The Company has engaged Wilmer Cutler Pickering Hale and Dorr LLP ("WilmerHale") to provide certain legal services to the Company. The Company's Senior Vice President, Legal Affairs and General Counsel is married to a former partner at WilmerHale, who did not participate in providing legal services to the Company. The Company has incurred fees for legal services rendered by WilmerHale of approximately $735,000 and $760,000, respectively, for the nine months ended September 30, 2008 and 2007. Of this amount, approximately $505,000 and $318,000, respectively, remained in accounts payable at September 30, 2008 and 2007.

The Company entered into a marketing arrangement in 2008 with an entity controlled by family members of the Chief Executive Officer to market and sell BioThrax. The contract requires a payment of 17.5% of net sales and reimbursement of certain expenses for certain countries in the Middle East and North Africa, excluding countries to which export is prohibited by the U.S. government. No royalty payments under this agreement have been triggered for the nine months ended September 30, 2008 and 2007. During the nine months ended September 30, 2008, the Company paid the same entity a $70,000 settlement related to a previously terminated agreement.

The Company has entered into the consulting and transportation arrangements outlined in this paragraph with various persons or entities affiliated with a member of the Company s Board of Directors and the Chief Executive Officer. At September 30, 2008 and 2007, $19,000 and $15,000, respectively, remained in accounts payable for these services. For the nine months ended September 30, 2008 and 2007, the Company paid approximately $137,000 and $155,000, respectively, to an entity affiliated with a member of the Company s Board of Directors for strategic consultation and project support for the marketing and communications group. For the nine months ended September 30, 2008 and 2007, the Company paid approximately $23,000 and $22,000, respectively, to an entity owned by the Chief Executive Officer for transportation and logistical support.

9. Asset purchase agreement

On May 2, 2008, the Company and VaxGen, Inc. (VaxGen) entered into an asset purchase agreement in which the Company acquired all assets and rights related to a recombinant protective antigen anthrax vaccine product candidate and related technology from VaxGen, in exchange for consideration of $2 million upon execution of the definitive agreement, up to an additional $8 million in milestone payments, and specified percentages of future net sales. The $2 million was paid to VaxGen in May 2008, and a $1 million milestone payment was paid in August 2008. These amounts have been recorded as research and development expense.

10. Joint venture

In July 2008, the Company entered into a joint venture with the University of Oxford and certain University of 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 Limited. As part of this arrangement, the Company has entered into a license agreement with the joint venture pursuant to which the Company obtained rights to develop, manufacture and commercialize pharmaceutical compositions intended to prevent or treat *mycobacterium tuberculosis* in humans in developed countries. The Company consolidates the joint venture in accordance with Accounting Research Bulletin No. 51, *Consolidated Financial Statements.* The income/(loss) attributable to the minority interest is recorded as minority interest in subsidiary on the income statement.

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

We are a biopharmaceutical company focused on the development, manufacture and commercialization of immune related biologics products, consisting of vaccines and therapeutics that assist the body s immune system to prevent or treat disease. We develop vaccines and therapeutics for use against biological agents that are potential weapons of bioterrorism and biowarfare and against infectious diseases that have resulted in significant unmet or underserved public health needs. 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. We use internally generated cash flows from the sale of BioThrax to substantially fund the development of our product pipeline. We also seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties. 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 botulinum. Within our anthrax product portfolio, in addition to our marketed vaccine, BioThrax, we are developing a recombinant protective antigen anthrax vaccine acquired in May 2008 from VaxGen, Inc., next generation anthrax vaccines, an anthrax immune globulin therapeutic and a recombinant anthrax monoclonal antibody therapeutic. Within our botulinum 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 public health needs. Our product candidates in this segment include a typhoid vaccine, a tuberculosis vaccine, a hepatitis B therapeutic vaccine, a chlamydia vaccine and a group B streptococcus vaccine.

We continue to negotiate with the non-management members of the board of directors of Protein Sciences Corporation, or PSC, an acquisition of PSC that would add a flu vaccine candidate and technology platform to our portfolio. Based on the proposal currently being negotiated, we do not anticipate completing this acquisition on the terms originally agreed to, and any transaction may be based on a different structure and on substantially different terms from what we announced.

Our biodefense segment has generated net income for each of the last five fiscal years and for the nine months ended September 30, 2008. Our commercial segment has generated revenue through development contracts and grant funding. None of our commercial product candidates have 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 and for the nine months ended September 30, 2008.

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 $139.3 million and $89.8 million for the nine months ended September 30, 2008 and 2007, 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 by leveraging external funding. 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:

- post-exposure prophylaxis for BioThrax from HHS;
- anthrax immune globulin therapeutic candidate from National Institute of Allergy and Infectious Diseases, or NIAID;
- recombinant botulinum vaccine candidate from NIAID;
- anthrax monoclonal antibody therapeutic candidate from NIAID and the Biomedical Advanced Research and Development Authority, or BARDA;
- next generation anthrax vaccine candidate from NIAID and BARDA;
- tuberculosis vaccine candidate from the Wellcome Trust and the Aeras Global TB Vaccine Foundation through our collaboration with the University of Oxford; and
- typhoid vaccine candidate from the Wellcome Trust.

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 BioThrax 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 completed construction of the building and installation of the associated capital equipment, and current spending is related to qualification and validation activities required for regulatory approval and initiation of commercial manufacturing of BioThrax. We expect the facility to cost approximately $75 million when complete, including approximately $55 million for the building and equipment, with the balance related to qualification and validation. We have incurred costs of approximately $72 million for these purposes through September 30, 2008.

This new facility is a large scale manufacturing plant that is intended to be used to produce multiple fermentation-based vaccine products, subject to complying with appropriate change-over procedures. We have made significant progress on qualification and validation activities required for the commercial manufacture of BioThrax, but in connection with the development of our recombinant protective antigen, or rPA, anthrax vaccine product candidate, we are currently evaluating facility requirements for the manufacture of rPA and whether our new Lansing facility would meet those requirements. The plant may ultimately be used for the manufacture of either BioThrax or rPA, or potentially both.

We are currently evaluating alternatives for the manufacture of various product candidates, and may seek to acquire one or more additional facilities or sign agreements with contract manufacturing organizations. We may also manufacture some product candidates, such as our hepatitis B product candidate, in China or India. One alternative we continue to evaluate is the utilization of our two buildings in Frederick, Maryland. We have incurred costs of approximately $4 million through September 30, 2008 related to initial engineering design and preliminary utility build out of one of these buildings. Because we are in the preliminary stages of evaluating our alternatives, we cannot reasonably estimate the timing and costs that would be necessary to complete this project. We may also elect to sell or lease all or a substantial portion of 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 the DoD and HHS. Under previous DoD contracts, we invoiced the DoD for progress payments upon reaching contractually specified stages in the manufacture of BioThrax. We recorded as deferred revenue the full amount of each progress payment invoice that we submitted to the DoD. Title to the product passed to the DoD upon submission of the first invoice. The earnings process was considered complete upon FDA release of the product for sale and distribution. Following FDA release of the product, we segregated the product for later shipment and recognized as period revenue all deferred revenue related to the released product in accordance with the bill and hold sale requirements under SAB 104. At that time, we also invoiced the DoD for the final progress payment and recognized the amount of that invoice as period revenue.

Under previous contracts with HHS, we invoiced HHS and recognized the related revenues upon delivery of the product to the government carrier, at which time title to the product passed to HHS. Under our current 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 are entitled to additional payments for development work under the collaboration. We evaluated the various components of the collaboration in accordance with Emerging Issues Task Force Issue, or EITF, No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables,* or EITF No. 00-21, which addresses whether, for revenue recognition purposes, there is one or several units of accounting in an arrangement. We concluded that under EITF No. 00-21, the license fee and the development work under our agreement with Sanofi Pasteur should be accounted for as a single unit of accounting. We recognize amounts received under this agreement over the estimated development period as we perform services. We recorded the amount of the upfront license fee as deferred revenue. We are recognizing this revenue over the estimated development period under the contract, currently estimated at seven years, as adjusted from time to time for any delays or acceleration in the development of the product candidate. Under the collaboration agreement, we are entitled to payments up to specified levels for development work we perform on behalf of Sanofi Pasteur. We invoice Sanofi Pasteur monthly in arrears, and recognize revenue in the period in which the associated costs are incurred. To date, we have not identified a meningitis B product candidate suitable for commercialization.

From time to time, we are awarded reimbursement contracts for services and development grant contracts with government entities and non-government and philanthropic organizations. Under these contracts, we typically are reimbursed for our costs in connection with specific development activities and may also be entitled to additional fees. We record the reimbursement of our costs and any associated fees as contracts and grants revenue and the associated costs as research and development expense. We issue invoices under these contracts after we incur the reimbursable costs. We recognize revenue upon 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 48, *Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109, Accounting for Income Taxes*or FIN 48. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Under FIN 48, we recognize in our financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure.

Stock-based Compensation

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

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

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

Financial Operations Overview

Revenues

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

On September 25, 2007, we entered into an agreement with HHS to supply 18.75 million doses of BioThrax to HHS for placement into the SNS. The term of the agreement is from September 25, 2007 through September 24, 2010. The first 5.5 million doses delivered under this contract were sold to HHS at a discounted price, as specified in the contract, due to the limited remaining shelf-life for 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 September 30, 2008, we have delivered approximately 11 million doses under this contract. If we receive FDA approval of our pending application to extend the expiry dating of BioThrax from three years to four years, HHS has agreed to increase the price per dose under the agreement for 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.

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 November 2007.

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

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 is scheduled to commence in September 2009, immediately following the scheduled completion of deliveries under our current 18.75 million dose supply contract with HHS, and continue 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 supplement to our biologics license 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 completion of each delivery of BioThrax doses to the SNS.

In September 2007, we received a development contract from NIAID, valued at up to $9.5 million, in support of non-clinical and clinical studies of our anthrax immune globulin therapeutic candidate. Under the terms of the development contract, we will use 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 next generation anthrax vaccine candidates. In September 2008, we received a $24 million development contract from NIAID and BARDA to fund continued development of our anthrax monoclonal antibody therapeutic candidate. Also in September 2008, we signed a development contract with NIAID and BARDA, valued at up to approximately $30 million, to fund development of our next generation 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. To date, this collaboration has not yielded a product candidate suitable for commercialization. We have deferred recognition of the upfront license fee and development reimbursement payments, and record revenue in accordance with our revenue recognition policies.

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

Cost of Product Sales

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

We determine the cost of product sales for doses sold during a reporting period based on the average manufacturing cost per dose 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;
- 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 program that we may initiate, costs associated with manufacturing our product candidates on a large scale basis for later stage clinical trials, on 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 and certain University of 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 Limited. 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. We anticipate contributing approximately $21 million to the joint venture over the next three years to support the 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, with approximately $4 million in cash being contributed over the three-year period. The Wellcome Trust and the Aeras Global TB Vaccine Foundation are also providing financial support for the Phase IIb clinical trial.

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 principally 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. Our total interest cost will increase in future periods as compared to prior periods as a result of the term loan that we entered into in June 2007, as well as any borrowings under our revolving line of credit. In addition, some of our existing debt arrangements provide for increasing amortization of principal payments in future periods. See Liquidity and Capital Resources Debt Financing for additional information.

Results of Operations

Quarter Ended September 30, 2008 Compared to Quarter Ended September 30, 2007

Revenues

Product sales revenues increased by $13.7 million, or 33%, to $55.5 million for the three months ended September 30, 2008 from $41.8 million for the three months ended September 30, 2007. This increase in product sales revenues was primarily due to a 34% increase in the average sales price per dose for BioThrax. In 2007, we provided a discounted price to HHS due to the limited remaining shelf life of doses delivered in September 2007. Product sales revenues for the three months ended September 30, 2008 and 2007 consisted of BioThrax sales to HHS of $55.5 million and $41.8 million, respectively.

Contracts and grants revenues decreased by $737,000, or 40%, to $1.1 million for the three months ended September 30, 2008 from $1.9 million for the three months ended September 30, 2007. Contracts and grants revenues for the three months ended September 30, 2008 consisted of $467,000 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 $654,000 from NIAID and other governmental agencies. Contracts and grants revenues for the three months ended September 30, 2007 consisted of $538,000 in revenue from the Sanofi Pasteur collaboration, grant revenue from NIAID of $893,000 and grant revenue from the Wellcome Trust of $427,000.

Cost of Product Sales

Cost of product sales decreased by $888,000, or 8%, to $10.5 million for the three months ended September 30, 2008 from $11.4 million for the three months ended September 30, 2007. This decrease was primarily attributable to decreased costs resulting from improved production yield.

Research and Development Expense

Research and development expenses increased by $3.9 million, or 30%, to $16.6 million for the three months ended September 30, 2008 from $12.8 million for the three months ended September 30, 2007. This increase reflects higher contract service costs and asset and technology acquisition costs, and includes increased expenses of $2.1 million on product candidates that are categorized in the biodefense segment, $1.1 million on product candidates categorized in the commercial segment and $601,000 in other research and development expenses, which are in support of technology platforms and central research and development activities.

The increase in spending on biodefense product candidates, detailed in the table below, was attributable to spending on product candidates that we acquired during the year, as well as to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials. The increase in spending for 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 includes a $1 million milestone payment and other development costs related to this product candidate, which was purchased from VaxGen, Inc., or VaxGen, in May 2008. The decrease in spending for the next generation anthrax vaccines program resulted from lower costs related to feasibility studies and formulation development. The increase in spending in our anthrax immune globulin therapeutic was primarily due to the timing of costs related to plasma collection. The increase in spending for our anthrax monoclonal

therapeutic is driven by spending for pre-IND filing preparation. The decrease in spending for the botulinum vaccine candidates resulted from advancing this program to the process development stage and the manufacture of clinical trial material in 2007.

The increase in spending on commercial product candidates, detailed in the table below, primarily reflects additional personnel and contracted services. The increase in spending for our typhoid vaccine candidate resulted from conducting a Phase IIb study 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 for our ongoing Phase II clinical trial in the United Kingdom and Serbia as a result of recruiting difficulties. The decrease in spending for our group B streptococcus vaccine candidate resulted from a decision not to proceed with Phase I clinical trials for two of the protein components of the vaccine candidate. As a result, we expect that spending for our group B streptococcus vaccine candidate will be even further reduced in the future. The spending for our tuberculosis vaccine candidate is related to the formation of our joint venture with the University of Oxford in July 2008. Our chlamydia and meningitis B vaccine candidates are in preclinical development.

The increase in other research and development expenses was primarily attributable to spending associated 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 other non-governmental and philanthropic organizations in providing funding for further development or procurement.

Our principal research and development expenses for the three months ended September 30, 2008 and 2007 are shown in the following table:

(in thousands)	Three Months Ended September 30, 2008	2007
Biodefense:		
BioThrax enhancements	$ 1,799	$ 995
Recombinant protective antigen anthrax vaccine	2,211	-
Next generation anthrax vaccines	348	702
Anthrax immune globulin therapeutic	1,230	891
Anthrax monoclonal therapeutic	281	-
Botulinum vaccines	659	1,806
Total biodefense	6,528	4,394
Commercial:		
Typhoid vaccine	5,181	3,099
Hepatitis B therapeutic vaccine	810	1,520
Group B streptococcus vaccine	1,537	1,969
Tuberculosis vaccine	873	-
Chlamydia vaccine	264	910
Meningitis B vaccine	309	361
Total commercial	8,974	7,859
Other	1,125	524
Total	$ 16,627	$ 12,777

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $923,000, or 6%, to $14.1 million for the three months ended September 30, 2008 from $15.0 million for the three months ended September 30, 2007. The decrease in selling, general and administrative expenses was driven by lower costs in our headquarters and staff organization and primarily reflects a decrease of approximately $1.0 million resulting from decreased professional services for our headquarters organization, partially offset by an increase of $93,000 in sales and marketing expenses related to the growth of our staff and an increase in our sales and marketing activities. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses decreased by $725,000, or 6%, to $10.8 million for the three months ended September 30, 2008 from $11.5 million for the three months ended September 30, 2007. Selling, general and administrative expenses related to our commercial segment decreased by $197,000, or 6%, to $3.3 million for the three months ended September 30, 2008 from $3.5 million for the three months ended September 30, 2007.

Total Other Income (Expense)

Total other income (expense) increased by $26,000, or 6%, to $477,000 for the three months ended September 30, 2008 from $451,000 for the three months ended September 30, 2007. This increase resulted primarily from a increase in other income (expense) of $13,000, a decrease in interest expense of $9,000, and a increase in interest income of $4,000.

Minority Interest in Subsidiary

In July 2008, we formed a joint venture with the University of Oxford related to our tuberculosis vaccine candidate. The minority interest in subsidiary represents the portion of the net loss realized by our joint venture that is attributable to our partners.

Income Taxes

Provision for income taxes increased by $3.8 million, or 189%, to $5.9 million for the three months ended September 30, 2008 from $2.0 million for the three months ended September 30, 2007. The provision for income taxes for the three months ended September 30, 2008 resulted primarily from our income before provision for income taxes of $16.2 million and an effective tax rate of approximately 36%. The provision for income taxes for the three months ended September 30, 2007 resulted primarily from our income before provision from income taxes of $4.9 million and an effective tax rate of approximately 42%. The decrease in the effective tax rate is due to utilization of foreign operating expenses to reduce tax liabilities. The benefit from income taxes for the three months ended September 30, 2007 also reflects research and development tax credits of $120,000.

Results of Operations

Nine Months Ended September 30, 2008 Compared to Nine Months Ended September 30, 2007

Revenues

Product sales revenues increased by $49.6 million, or 55%, to $139.3 million for the nine months ended September 30, 2008 from $89.8 million for the nine months ended September 30, 2007. This increase in product sales revenues was primarily due to a 36% increase in the number of doses of BioThrax delivered and a 14% increase in the average sales price per dose. Product sales revenues for the nine months ended September 30, 2008 consisted of BioThrax sales to HHS of $138.5 million and aggregate international and other sales of $781,000. Product sales revenues for the nine months ended September 30, 2007 consisted of BioThrax sales to HHS of $63.5 million and sales to the DoD of $26.2 million.

Contracts and grants revenues decreased by $32,000, or 1%, to $3.5 million for the nine months ended September 30, 2008 from $3.5 million for the nine months ended September 30, 2007. Contracts and grants revenues for the nine months ended September 30, 2008 consisted of $2.0 million from the Sanofi Pasteur collaboration, related to recognition of deferred revenue associated with the upfront payment received in 2006 as well as development service revenue, and $1.5 million from NIAID and other governmental agencies. Contracts and grants revenues for the nine months ended September 30, 2007 consisted of $2.2 million in revenue from the Sanofi Pasteur collaboration, grant revenue from NIAID of

$893,000 and grant revenue from the Wellcome Trust of $427,000.

Cost of Product Sales

Cost of product sales increased by $4.4 million, or 20%, to $27.2 million for the nine months ended September 30, 2008 from $22.8 million for the nine months ended September 30, 2007. This increase was attributable to a 36% increase in the number of doses of BioThrax delivered, partially offset by decreased costs resulting from improved production yield.

Research and Development Expense

Research and development expenses increased by $3.6 million, or 9%, to $45.3 million for the nine months ended September 30, 2008 from $41.7 million for the nine months ended September 30, 2007. This increase reflects higher contract service costs, and includes increased expenses of $3.4 million on product candidates categorized in the commercial segment and $1.3 million in other research and development expenses, which are in support of technology platforms and central research and development activities, partially offset by decreased expenses of $1.1 million on product candidates that are categorized in the biodefense segment.

The decrease 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, partially offset by increased spending on product candidates that we acquired during the year. 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 the purchase of this vaccine candidate from VaxGen in May 2008. The increase in spending in our next generation anthrax vaccines program resulted from feasibility studies and formulation development of product candidates. The decrease in spending in our anthrax immune globulin therapeutic candidate was primarily due to the timing of costs related to plasma collection. The spending for the anthrax monoclonal therapeutic candidate was primarily due to the purchase of this vaccine candidate and related technology in March 2008. The decrease in spending for the botulinum vaccine candidates resulted from advancing this program to the process development stage and the manufacture of clinical trial material in 2007.

The increase in spending on commercial product candidates, detailed in the table below, primarily reflects additional personnel and contracted services. The increase in spending for our typhoid vaccine candidate resulted from the manufacture of clinical material and initiating and conducting a Phase IIb study 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 recruiting difficulties. The increase in spending for our group B streptococcus vaccine candidate resulted from preparing for Phase I clinical trials for two of the protein components of the vaccine candidate. We have decided not to proceed with these trials and, as a result, we expect that spending for our group B streptococcus vaccine candidate will be significantly reduced in the future. The spending for our tuberculosis vaccine candidate related to the formation of our joint venture with the University of Oxford in July 2008. Our chlamydia and meningitis B vaccine candidates are in preclinical development.

The increase in other research and development expenses was primarily attributable to spending associated with 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 other non-governmental and philanthropic organizations in providing funding for further development or procurement.

Our principal research and development expenses for the nine months ended September 30, 2008 and 2007 are shown in the following table:

(in thousands)	Nine Months Ended September 30, 2008	2007
Biodefense:		
BioThrax enhancements	$ 4,883	$ 4,196
Recombinant protective antigen anthrax vaccine	4,847	-
Next generation anthrax vaccine	3,156	1,848
Anthrax immune globulin therapeutic	3,591	6,692
Anthrax monoclonal therapeutic	531	-
Botulinum vaccine	2,609	7,980
Total biodefense	19,617	20,716
Commercial:		
Typhoid vaccine	11,658	7,622
Hepatitis B therapeutic vaccine	2,625	3,988
Group B streptococcus vaccine	5,498	4,549
Tuberculosis vaccine	873	-
Chlamydia vaccine	1,019	2,304
Meningitis B vaccine	1,122	948
Total commercial	22,795	19,411
Other	2,896	1,562
Total	$ 45,308	$ 41,689

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $2.3 million, or 6%, to $41.2 million for the nine months ended September 30, 2008 from $38.9 million for the nine months ended September 30, 2007. The increase in selling, general and administrative expenses was driven by an increase in our headquarters and staff organization to support the overall growth of our business, and primarily reflects an increase of approximately $1.8 million resulting from the addition of personnel and increased legal and other professional services for our headquarters organization and an increase of $494,000 in sales and marketing expenses related to the growth of our staff and an increase in our sales and marketing activities. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses increased by $1.6 million, or 5%, to $31.7 million for the nine months ended September 30, 2008 from $30.1 million for the nine months ended September 30, 2007. Selling, general and administrative expenses related to our commercial segment increased by $734,000, or 8%, to $9.5 million for the nine months ended September 30, 2008 from $8.8 million for the nine months ended September 30, 2007.

Total Other Income (Expense)

Total other income decreased by $278,000, or 14%, to $1.8 million for the nine months ended September 30, 2008 from $2.1 million for the nine months ended September 30, 2007. This decrease resulted primarily from a decrease in interest income of $347,000 as a result of lower investment returns related to decreases in interest rates, partially offset by a decrease in interest expense of $50,000.

Minority Interest in Subsidiary

In July 2008, we formed a joint venture with the University of Oxford related to our tuberculosis vaccine candidate. The minority interest in subsidiary represents the portion of the net loss realized by our joint venture that is attributable to our partners.

Income Taxes

Provision for (benefit from) income taxes increased by $15.3 million to a provision for income taxes of $12.1 million for the nine months ended September 30, 2008 from a benefit from income taxes of $3.2 million for the nine months ended September 30, 2007. The provision for income taxes for the nine months ended September 30, 2008 resulted primarily from our income before provision for income taxes of $31.3 million and an effective tax rate of approximately 39%. The benefit from income taxes for the nine months ended September 30, 2007 resulted primarily from our loss before benefit from income taxes of $8.0 million and an effective tax rate of approximately 40%. The benefit from income taxes for the nine months ended September 30, 2007 also reflects research and development tax credits of $635,000.

Liquidity and Capital Resources

Sources of Liquidity

We require cash to meet our operating expenses and for capital expenditures, acquisitions and principal and interest payments on our debt. We have funded our cash requirements from inception through September 30, 2008 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases, 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 five year period ended December 31, 2007 and the nine months ended September 30, 2008.

As of September 30, 2008, we had cash and cash equivalents of $104.7 million.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2008 and 2007:

	Nine Months Ended September 30,	
(in thousands)	**2008**	**2007**
Net cash provided by (used in):		
Operating activities(1)	$ 19,346	$ (24,339)
Investing activities	(26,464)	(36,197)
Financing activities	6,076	8,384
Total net cash used	$ (1,042)	$ (52,152)

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

Net cash provided by operating activities of $19.3 million for the nine months ended September 30, 2008 resulted principally from net income of $19.2 million and a decrease in billed but uncollected accounts receivable of $4.7 million for the nine month period, partially offset by a decrease in income taxes payable of $4.8 million primarily due to the timing of payment of our 2007 income tax liability.

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

Net cash used in investing activities for the nine months ended September 30, 2008 and 2007 resulted principally from the purchase of property, plant and equipment and, in 2008, the issuance of a note receivable in the amount of $10.0 million. Capital expenditures of $16.5 million and $36.2 million for the nine months ended September 30, 2008 and 2007, respectively, relate primarily to construction, qualification and validation activities for our new manufacturing facility in Lansing.

Net cash provided by financing activities of $6.1 million for the nine months ended September 30, 2008 resulted primarily from the release of $5.0 million of restricted cash related to our continuing compliance with the debt covenants specified in our HSBC term loan and $620,000 from the exercise of stock options.

Net cash provided by financing activities of $8.4 million for the nine months ended September 30, 2007 resulted primarily from the additional proceeds from a term loan with HSBC of $15.3 million, $2.5 million in proceeds from the exercise of stock options and $6.7 million related to excess tax benefits from the exercise of stock options, partially offset by $11.1 million of principal payments on long-term indebtedness, including the repayment of $8.9 million from our revolving line of credit with Fifth Third Bank, and a $5.0 million restricted cash deposit in accordance with our HSBC term loan.

Debt Financing

As of September 30, 2008, we had $58.4 million principal amount of debt outstanding, comprised primarily of the following:

- $2.5 million outstanding under a forgivable loan from the Department of Business and Economic Development of the State of Maryland used to finance eligible costs incurred to purchase the first facility in Frederick, Maryland;
- $7.9 million outstanding under a mortgage loan from PNC Bank used to finance the remaining portion of the purchase price for the first Frederick facility;
- $6.5 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance the purchase price for the second facility on the Frederick site;
- $26.5 million outstanding under a term loan from HSBC Realty Credit Corporation used to finance a portion of the costs of our facility expansion in Lansing, Michigan; and
- $15.0 million outstanding under a $15.0 million revolving line of credit with Fifth Third Bank.

Tax Benefits

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

Funding Requirements

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

We may seek to raise additional external debt or equity financing to provide additional financial flexibility and we may from time to time file shelf registration statements to facilitate such financing. Our committed external sources of funds consist of credit that may be available from time to time under our revolving line of credit with Fifth Third Bank and grant and development funding of our anthrax immune globulin therapeutic candidate, anthrax monoclonal antibody therapeutic candidate, next generation anthrax vaccine candidate and recombinant

botulinum vaccine candidate. Our ability to borrow additional amounts under our loan agreements is subject to our satisfaction of specified conditions.

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

- the level and timing of BioThrax product sales and cost of product sales;
- the timing of, and the costs involved in 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 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 May 2008, FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles,* or SFAS No. 162. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the U.S. SFAS No. 162 is effective 60 days following the Securities and Exchange Commission approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles.* We anticipate that the adoption of this statement will not have a material impact on our financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an Amendment of FASB Statement No. 133,* or SFAS No. 161. SFAS No. 161 states that entities are required to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations and how derivative instruments and related hedged items affect an entity s financial position, financial performance, and cash flows. The provisions of SFAS No. 161 are effective for fiscal years beginning on or after November 15, 2008, with early adoption encouraged.

We anticipate that the adoption of this statement will not have a material impact on our financial statements.

In February 2008, the FASB issued a one-year deferral for non-financial assets and liabilities to comply with SFAS No. 157, *Fair Value Measurements,* or SFAS No. 157. We adopted SFAS No. 157 for financial assets and liabilities effective January 1, 2008. There was no material effect upon adoption of this accounting pronouncement on our consolidated results of operations or financial position. We do not expect the adoption of SFAS No. 157 as it pertains to non-financial assets and liabilities to have a material impact on our financial statements.

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

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

In November 2007, the EITF issued EITF No. 07-1, *Accounting for Collaborative Arrangements,* or EITF No. 07-1. EITF No. 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The provisions of EITF No. 07-1 are effective for fiscal years beginning on or after December 15, 2008 and interim periods within those fiscal years. EITF No. 07-1 shall be applied to all periods presented for all collaborative arrangements existing as of the effective date. We are currently evaluating the impact of the adoption of this statement on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is currently confined to our cash and cash equivalents and restricted cash that have maturities of less than three months. We currently do not hedge interest rate exposure or foreign currency exchange exposure. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments, but would likely increase the interest expense associated with our debt.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2008. The term disclosure controls and procedures, as defined in Rules 13 a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal

financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2008, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the quarter ended September 30, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Litigation against Protein Sciences Corporation. On July 9, 2008, we filed suit against Protein Sciences Corporation, or 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 raising claims in connection with the letter of intent, asset purchase agreement and related loan agreement entered into by us and PSC. On September 12, 2008, a stipulation of discontinuance was filed with the court regarding the claims against Mr. Adams and Ms. Cox. Also on September 12, 2008, we filed a first amended complaint against PSC. As amended, the complaint alleges fraud, breach of the asset purchase agreement, loan agreement and related letter of intent, breach of the duty of good faith and fair dealing, unjust enrichment, and unfair business practices. We are seeking monetary damages of no less than $13 million, punitive damages, declaratory judgment that we have no further funding obligations to PSC, injunctive relief associated with PSC's misappropriation of funds provided by us, injunctive relief to protect the collateral for our loan, a declaratory judgment that the asset purchase agreement remains in effect and injunctive relief barring PSC s breach of the no-shop provision, and other appropriate relief. On October 3, 2008, we filed a separate suit against Mr. Adams and Ms. Cox in the Federal District Court for the District of Connecticut, alleging fraud and unfair trade practices and seeking compensatory and punitive damages.

On July 29, 2008, PSC announced that it has terminated the asset purchase agreement for alleged breach of the obligation to continue to provide funding and to preserve confidentiality. PSC has since reiterated its position that the asset purchase agreement is terminated in a September 2008 letter to shareholders. Additionally, PSC asserted in an earlier communication to us that we are liable for a break-up fee of $1.5 million, that this liability reduces the balance of the loan due to us from $10 million to $8.5 million, and that PSC does not believe that the note is due until December 31, 2008. We dispute PSC's position and contend that PSC has defaulted on the loan, breached the contract, has no right to terminate the asset purchase agreement and is required to repay the $10 million loan immediately.

PSC has moved to dismiss the first amended complaint in the New York action and a hearing on that motion is currently scheduled for November 2008. PSC has not yet asserted any counterclaims, but it has notified us in writing that it will assert counterclaims for among other things, breach of contract, intentional misrepresentations, tortious interference with business relations and unfair trade practices. In the Connecticut action, Adams and Cox have yet to respond to the complaint.

BioThrax product liability litigation. Between 2001 and 2003, over 100 individual plaintiffs filed a series of lawsuits in which they claimed damages resulting from personal injuries allegedly caused by vaccination with BioThrax by the DoD. In April 2006, the U.S. District Court for the Western District of Michigan entered summary judgment in our favor in four consolidated lawsuits brought by approximately 120 claimants. The District Court s ruling in these consolidated cases was based on two grounds. First, the District Court found that we were entitled to protection under a Michigan state statute that provides immunity for drug manufacturers if the drug was approved by the FDA and its labeling is in compliance with FDA approval, unless the plaintiffs establish that the manufacturer intentionally withheld or misrepresented information to the FDA and the drug would not have been approved, or the FDA would have withdrawn approval, if the information had been accurately submitted. Second, the District Court found that we were entitled to the immunity afforded by the government contractor defense, which, under specified circumstances, extends the sovereign immunity of the U.S. to government contractors who manufacture a product for the government. Specifically, the government contractor defense applies when the government approves reasonably precise specifications, the product conforms to those specifications and the supplier warns the government about known dangers arising from the use of the product. The District Court found that we established each of those factors.

In 2005 and 2006, we were named as a defendant in three federal lawsuits, each filed on behalf of a single plaintiff claiming different injuries caused by DoD s immunization with BioThrax. Each plaintiff sought a different amount of damages. Each of these lawsuits has been dismissed with prejudice and no BioThrax product liability cases remain pending. We believe that we are entitled to indemnification under our prior contract with the DoD for legal fees associated with the BioThrax product liability cases brought by military