Emergent BioSolutions Inc.
Form 10-Q
November 05, 2010

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

Form 10-Q

(Mark One)

þ	QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the quarterly period ended September 30, 2010
	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 (State or Other Jurisdiction of Incorporation or Organization)	14-1902018 (I.R.S. Employer Identification No.)
2273 Research Boulevard, Suite 400 Rockville, Maryland (Address of Principal Executive Offices)	20850 (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. þ Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). o 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 þ 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 þ No

As of October 29, 2010, the registrant had 34,720,191 shares of common stock outstanding.

Emergent BioSolutions Inc.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our ability to perform under our contract with the U.S. government for sales of BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, including the timing of deliveries;
- our ability to perform under our contract with the U.S. government to develop and obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55, our large-scale vaccine manufacturing facility in Lansing, Michigan;
- our ability to perform under our contract with the U.S. government to develop our recombinant protective antigen anthrax vaccine product candidate;
- our plans for future sales of BioThrax, including our ability to obtain new procurement and development contracts from the U.S. government;
- our efforts to pursue label expansions and improvements for BioThrax;
- our efforts to expand our manufacturing facilities and capabilities;
- the rate and degree of market acceptance and clinical utility of our products and product candidates;
- our ongoing and planned product 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;
- our ability to successfully integrate the operations, products, product candidates and personnel of any businesses that we may acquire, including Trubion Pharmaceuticals, Inc., which we acquired in October 2010;
- the potential benefits of our existing or planned collaborations;
- 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;
- our ability to sell two buildings classified on our balance sheet as assets held for sale; 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 or filed as exhibits hereto, completely and with the understanding that our actual future results may be materially different from what we expect. We disclaim 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, 2010	December 31, 2009
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 151,229	$ 102,924
Restricted cash	215	215
Accounts receivable	7,937	54,872
Inventories	17,320	13,521
Note receivable	10,000	10,000
Deferred tax assets, net	2,239	1,870
Income tax receivable, net	13,206	2,574
Prepaid expenses and other current assets	8,690	7,838
Total current assets	210,836	193,814
Property, plant and equipment, net	141,257	131,834
Assets held for sale	12,930	13,960
Deferred tax assets, net	86	3,894
Other assets	1,128	1,187
Total assets	$ 366,237	$ 344,689
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 22,518	$ 17,159
Accrued expenses and other current liabilities	1,300	1,570
Accrued compensation	13,749	14,926
Indebtedness under line of credit	-	15,000
Long-term indebtedness, current portion	12,038	5,791
Deferred revenue	253	255
Total current liabilities	49,858	54,701
Long-term indebtedness, net of current portion	36,225	44,927
Other liabilities	1,160	1,246
Total liabilities	87,243	100,874
Commitments and contingencies	-	-
Stockholders’ equity:		
	-	-

Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively		
Common stock, $0.001 par value; 100,000,000 shares authorized, 31,350,209 and 30,831,360 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	31	31
Additional paid-in capital	130,832	120,492
Accumulated other comprehensive loss	(2,173)	(1,476)
Retained earnings	147,602	122,152
Total Emergent BioSolutions Inc. stockholders' equity	276,292	241,199
Noncontrolling interest in subsidiary	2,702	2,616
Total stockholders' equity	278,994	243,815
Total liabilities and stockholders' equity	$366,237	$344,689

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, 2010	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2010	Nine Months Ended September 30, 2009
	(Unaudited)		(Unaudited)	
Revenues:				
Product sales	$67,266	$39,004	$161,991	$170,012
Contracts and grants	6,720	4,268	20,933	10,970
Total revenues	73,986	43,272	182,924	180,982
Operating expenses:				
Cost of product sales	11,532	8,684	30,116	34,480
Research and development	21,156	18,772	59,680	55,362
Selling, general and administrative	20,693	19,767	54,534	55,115
Income (loss) from operations	20,605	(3,951)	38,594	36,025
Other income (expense):				
Interest income	38	426	802	1,031
Interest expense	-	(4)	-	(14)
Other income (expense), net	(1,003)	6	(1,012)	(28)
Total other income (expense)	(965)	428	(210)	989
Income (loss) before provision for (benefit from) income taxes	19,640	(3,523)	38,384	37,014
Provision for (benefit from) income taxes	7,696	(2,984)	15,088	14,130
Net income (loss)	11,944	(539)	23,296	22,884
Net loss attributable to noncontrolling interest	1,176	1,488	2,155	4,026
Net income attributable to Emergent BioSolutions Inc.	$13,120	$949	$25,451	$26,910
Earnings per share - basic	$0.42	$0.03	$0.82	$0.89
Earnings per share - diluted	$0.41	$0.03	$0.80	$0.86
Weighted-average number of shares - basic	31,301,796	30,506,661	31,094,616	30,321,873
Weighted-average number of shares - diluted	32,113,313	31,534,831	31,816,900	31,314,147

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, 2010	Nine Months Ended September 30, 2009
	(Unaudited)	
Cash flows from operating activities:		
Net income	$23,296	$22,884
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	5,206	3,645
Depreciation and amortization	4,020	3,677
Deferred income taxes	4,516	7,236
Non-cash development expenses from joint venture	2,241	6,026
(Gain) loss on disposal of property, plant and equipment	(31)	32
Provision for impairment of long-lived assets	1,029	3,818
Excess tax benefits from stock-based compensation	(1,077)	(1,555)
Changes in operating assets and liabilities:		
Accounts receivable	46,935	(858)
Inventories	(3,799)	5,156
Income taxes	(10,632)	(2,461)
Prepaid expenses and other assets	(794)	(1,031)
Accounts payable	5,990	4,372
Accrued compensation	(1,177)	2,783
Accrued expenses and other liabilities	(356)	51
Deferred revenue	(2)	23
Net cash provided by operating activities	75,365	53,798
Cash flows from investing activities:		
Purchases of property, plant and equipment	(14,042)	(14,376)
Net cash used in investing activities	(14,042)	(14,376)
Cash flows from financing activities:		
Proceeds from borrowings on line of credit	15,000	30,000
Principal payments on long-term indebtedness and line of credit	(32,454)	(47,596)
Issuance of common stock subject to exercise of stock options	4,056	4,193
Excess tax benefits from stock-based compensation	1,077	1,555
Net cash used in financing activities	(12,321)	(11,848)
Effect of exchange rate changes on cash and cash equivalents	(697)	(270)
Net increase in cash and cash equivalents	48,305	27,304
Cash and cash equivalents at beginning of period	102,924	91,473
Cash and cash equivalents at end of period	$151,229	$118,777

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 ("GAAP") 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 ("SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC.

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, 2010, results of operations for the three and nine month periods ended September 30, 2010 and 2009, and cash flows for the nine month periods ended September 30, 2010 and 2009. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Earnings per share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except share and per share data)	2010	2009	2010	2009
Numerator:				
Net income attributable to Emergent BioSolutions Inc.	$13,120	$949	$25,451	$26,910
Denominator:				
Weighted-average number of shares - basic	31,301,796	30,506,661	31,094,616	30,321,873
Dilutive securities - stock options	811,517	1,028,170	722,284	992,274
Weighted-average number of shares - diluted	32,113,313	31,534,831	31,816,900	31,314,147
Earnings per share - basic	$0.42	$0.03	$0.82	$0.89
Earnings per share - diluted	$0.41	$0.03	$0.80	$0.86

Stock options with exercise prices in excess of the average per share closing price during the period are not considered in the calculation of fully diluted earnings per share. For the three month and nine month periods ended September 30, 2010, options to purchase approximately 1.3 million and 1.8 million shares of common stock, respectively, were excluded from this calculation. For the three and nine month periods ended September 30, 2009, options to purchase approximately 1.4 million and 1.3 million shares of common stock, respectively, were excluded from this calculation.

Accounting for stock-based compensation

As of September 30, 2010, the Company has two stock-based employee compensation plans, the Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan") and the Emergent BioSolutions Employee Stock Option Plan (the "2004 Plan" and together with the 2006 Plan, the "Emergent Plans"). The Company has granted options to purchase shares of common stock under each of the Emergent Plans, and has granted restricted stock units under the 2006 Plan.

The Company determines the fair value of restricted stock units using the closing market price of the Company's common stock on the day prior to the date of grant. The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. The fair value of each option is estimated on the date of grant. Set forth below are the 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,	
	2010	2009	2010	2009
Expected dividend yield	0 %	0 %	0 %	0 %
Expected volatility	55 %	55 %	55 %	55 %
Risk-free interest rate	0.82 %	1.72 %	0.82%-1.46%	1.32%-1.72%
Expected average life of options	3.29 years	3.0 years	3.41 years	3.35 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 — a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company analyzed the volatility of similar companies at a similar stage of development to estimate expected volatility. The volatility of these similar companies ranged from 38% to 77%, with an average estimated volatility of 55%. The Company used a rate of 55% for grants made in 2010, approximately the mid-point of this range.
- Risk-free interest rate — 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 is granted.
- Expected average life of options — the period of time that options granted are expected to remain outstanding, based primarily on the Company's expectation of optionee exercise behavior subsequent to vesting of options.

Fair value of financial instruments

The carrying amounts of the Company's short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair values due to their short maturities. The fair value of the Company's long-term indebtedness is estimated based on the current interest rates. The carrying value and fair value of long-term indebtedness at September 30, 2010 was $48.3 million and $48.1 million, respectively, and at September 30, 2009 was $39.6 million and $38.9 million, respectively.

Comprehensive income

Comprehensive income is comprised of net income and other changes in equity that are excluded from net income. The Company includes gains and losses on intercompany transactions with foreign subsidiaries that are considered to be long-term investments and translation gains and losses incurred when converting its subsidiaries' financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income. Comprehensive income for the three and nine months ended September 30, 2010 was $12.6 million and $24.8 million, respectively. Comprehensive income for the three and nine months ended September 30, 2009 was $1.0 million and $26.6 million, respectively.

Reclassifications

Certain amounts classified as inventory in the consolidated balance sheet as of September 30, 2009, and in the consolidated statement of cash flows for the nine months then ended have been reclassified as other current assets to conform with the current period presentation.

2. Inventories

Inventories consist of the following:

(in thousands)	September 30, 2010	December 31, 2009
Raw materials and supplies	$1,970	$1,565
Work-in-process	9,568	9,870
Finished goods	5,782	2,086
Total inventories	$17,320	$13,521

3. Note receivable

In 2008, the Company entered into a loan and security agreement with Protein Sciences Corporation ("PSC") to loan PSC 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 PSC's intellectual property. Under this loan agreement and a related promissory note, $10.0 million of principal is outstanding as of September 30, 2010, and the Company has recorded this as a note receivable. By its original terms, the note accrued interest at an annual rate of 8% and was due and payable no later than December 31, 2008. Thereafter, the note accrued interest at a default rate of 11%. In early 2009, the Company entered into a forbearance agreement with PSC, pursuant to which the note continued to accrue interest at an annual rate of 11%, and became due and payable on May 31, 2009. The Company also agreed not to foreclose on the collateral for the loan prior to May 31, 2009. Since the expiration of the forbearance agreement, the note has accrued interest at a default rate of 14%. As of September 30, 2010, the Company has recorded accrued interest on the note receivable of $1.5 million, included in prepaid expenses and other current assets.

On November 2, 2010, the Company and PSC executed a settlement agreement, whereby PSC paid the Company $11.5 million, consisting of full repayment of the original $10 million of principal plus $1.5 million in interest. In accordance with the terms of this agreement, all claims arising from the loan and security agreement and related promissory note, and from the original agreement to acquire the assets of PSC, were resolved (see Note 5, Litigation). In connection with this settlement, the Company recorded a charge of approximately $1.0 million in September 2010 to reduce the accrued interest due from PSC. This charge is reflected in the other income (expense) line in the Company's statements of operations.

4. Stock options and restricted stock units

As of September 30, 2010, the Company has two stock-based employee compensation plans, the 2006 Plan and the 2004 Plan. The Company has granted options to purchase shares of common stock under the Emergent Plans and has granted restricted stock units under each of the 2006 Plan. The Emergent Plans have both incentive and non-qualified stock option features. The Company no longer grants equity awards under the 2004 Plan.

As of September 30, 2010, an aggregate of 8,678,826 shares of common stock are authorized for issuance under the 2006 Plan, of which a total of 3,335,476 shares of common stock remain available for future awards to be made to plan participants. Awards of restricted stock units are counted against the maximum aggregate number of shares of common stock available for issuance under the 2006 Plan as one and one-half (1.5) shares of common stock for every restricted stock unit granted. The maximum number of shares subject to awards that may be granted per year under the 2006 Plan to a single participant is 287,700. The exercise price of each option must be not less than 100% of the fair market value of the shares underlying such option on the date of grant. Awards granted under the 2006 Plan have a contractual life of no more than 10 years. The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Emergent Plans are determined by the Company’s compensation committee, which administers the Emergent Plans. Each equity award granted under the Emergent Plans vests as specified in the relevant agreement and no option can be exercised after ten years from the date of grant.

The following is a summary of option award activity under the Emergent Plans:

	2006 Plan		2004 Plan		
	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2009	3,485,499	$ 12.72	130,082	$ 7.52	
Granted	804,053	15.86	-	-	
Exercised	(478,849)	8.23	(40,000)	3.50	
Forfeited	(133,732)	14.18	-	-	
Outstanding at September 30, 2010	3,676,971	$ 14.00	90,082	$ 9.30	$14,918,379
Exercisable at September 30, 2010	1,458,805	$ 12.05	90,082	$ 9.30	$9,026,708

The following is a summary of restricted stock unit award activity under the 2006 Plan:

	Number of Shares	Weighted-Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding at December 31, 2009	-	$ -	$-
Granted	394,995	16.05	
Vested	-	-	
Forfeited	(7,990)	15.91	
Outstanding at September 30, 2010	387,005	$ 16.05	$6,679,706

5. Litigation

Litigation against Protein Sciences Corporation. Until reaching settlement with PSC on November 2, 2010, the Company had been pursuing several legal actions against PSC and its senior management arising out of a letter of intent, a loan and security agreement and related promissory note, and an asset purchase agreement between the Company and PSC that were entered into in 2008. On June 8, 2009, the Company initiated legal proceedings in the Superior Court of the State of Connecticut, Judicial District of New Haven, to acquire possession through disclosure of PSC's physical assets that secured the loan. On July 9, 2008, the Company initiated legal proceedings against PSC in the Supreme Court of the State of New York among other claims, claims for fraud, breach of contract, breach of the duty of good faith and fair dealing, unjust enrichment and unfair business practices. On October 3, 2008, the Company initiated legal proceedings in the United States District Court for the District of Connecticut against PSC's executive management team of Daniel D. Adams, PSC's Executive Chairman, and Manon M.J. Cox, PSC's President and Chief Executive Officer, alleging, among other things, that these individuals engaged in fraudulent conduct in connection with their efforts to obtain $10 million in bridge financing from the Company. On July 19, 2010, the Company filed a motion for summary judgment in lieu of complaint in the Supreme Court of the State of New York seeking repayment of its loan and interest.

On November 2, 2010, the Company and PSC entered into a settlement and mutual release of claims with respect to the letter of intent, the loan and security agreement and related promissory note and forbearance agreement, the asset purchase agreement and all other claims related thereto. Under the terms of the settlement, PSC paid the Company $11.5 million, consisting of full repayment of the original $10 million of principal plus $1.5 million in interest. At the time of this filing, the parties are in the process of filing stipulations with the relevant courts to dismiss all litigation with prejudice.

Patent Oppositions. The Company’s live attenuated modified vaccinia Ankara virus ("MVA") platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based in part on rights to certain MVA-related materials and technology that the Company acquired from the Bavarian State Ministry of the Environment and Public Health. From 2006 to 2008, the Company filed patent oppositions in the European Patent Office against four of Bavarian Nordic’s patents covering certain aspects of MVA technology. In each of the four pending opposition proceedings, the subject patents have also been opposed by one or more additional parties, including Sanofi Pasteur, Transgene, Baxter, Virbac, and Innogenetics. The Company and the other opponents have alleged that the opposed patents should be revoked for failure to fulfill one or more of the patentability requirements of the European Patent Convention, such as the requirements for novelty and inventive step. In each opposition, the Company expects that a single hearing will be held before the Opposition Division of the European Patent Office, in which each opponent will present oral argument and Bavarian Nordic will present rebuttal arguments. The first of these hearings, which occurred in June 2010, resulted in the Bavarian Nordic patent under consideration being maintained but narrowed in scope. A time period has been set for all parties to file appeals, and the Company anticipates that all appeals will be filed by the due date of November 27, 2010. Hearings in two of the other pending oppositions occurred in October 2010. Bavarian Nordic introduced amended patent claims into the record, which claims were upheld strictly and expressly conditioned on such claims being interpreted within a narrowly-defined scope. The Opposition Division scheduled a hearing on the fourth pending opposition for January 2011. The Company routinely monitors the grant of further Bavarian Nordic European patents to determine whether any additional oppositions should be filed.

Class-action litigation related to Trubion Pharmaceuticals acquisition. On August 17, 2010, two class action lawsuits were filed in the Superior Court of Washington, King County (the “State Court”), against Trubion Pharmaceuticals, Inc. (“Trubion”), its board of directors, and the Company (collectively, the “Defendants”), alleging in summary that, in connection with the proposed merger of Trubion with a subsidiary of the Company (the “Acquisition”), the members of the Trubion board of directors breached their fiduciary duties by conducting an unfair sale process and agreeing to an unfair price. Both complaints also claim that Trubion and the Company aided and abetted the Trubion board of directors in its breach of fiduciary duties. On September 9, 2010, the actions were consolidated (the “State Action”). On October 1, 2010, the plaintiffs in the State Action served on the Defendants a consolidated amended class action complaint (the “Amended Complaint”). The Amended Complaint alleges, among other things and in addition to the matters alleged in the initial complaints, that the Defendants omitted material information from the Proxy Statement/Prospectus.

On October 4, 2010, a class action lawsuit was filed in the U.S. District Court for the Western District of Washington against the Defendants (the “Federal Action” and, collectively with the State Action, the “Actions”), which makes allegations related to the Acquisition that are substantially similar to those matters alleged in the Amended Complaint, includes additional allegations regarding purported violations of the federal securities laws and seeks substantially similar relief.

On October 8, 2010, the Defendants reached agreement in principle with the plaintiffs in the Actions regarding the settlement of the Actions. In connection with the settlement contemplated by that agreement in principle, the Actions will be stayed pending approval of the settlement of the State Action by the State Court. Thereafter, the State Action and all claims asserted therein will be dismissed with prejudice and counsel for the plaintiff in the Federal Action will take all necessary steps to dismiss the Federal Action and all claims asserted therein with prejudice. The terms of the settlement contemplated by that agreement in principle require that Trubion and the Company make certain additional disclosures related to the Acquisition, as set forth in the Company’s Current Report on Form 8-K filed on October 8, 2010. The parties also agreed that the plaintiffs in the Actions may seek attorneys’ fees and costs in an aggregate amount up to $475,000, to be paid by Trubion if such fees and costs are approved by the State Court. There will be no other payment by Trubion, any of the members of the Trubion board of directors or the Company to the plaintiffs or their respective counsels in connection with the settlement and dismissal of the Actions. The agreement in principle further contemplates that the parties will enter into a stipulation of settlement, which will be subject to customary conditions, including State Court approval following notice to Trubion's shareholders. In the event that the parties enter into a stipulation of settlement, a hearing will be scheduled at which the State Court will consider the fairness, reasonableness and adequacy of the settlement. There can be no assurance that the parties will ultimately enter into a stipulation of settlement, that the State Court will approve any proposed settlement, or that any eventual settlement will be under the same terms as those contemplated by the agreement in principle.

Other. From time to time, the Company is involved in product liability claims and other litigation considered normal in the nature of its business. The Company does not believe that any such proceedings would have a material adverse effect on the results of its operations.

6. Segment information

For financial reporting purposes, the Company reports financial information for two business segments: biodefense and commercial. In the biodefense segment, the Company develops, manufactures and commercializes vaccines and antibody therapies for use against biological agents that are potential weapons of bioterrorism or biowarfare. Revenues in this segment relate primarily to the Company's FDA-licensed product, BioThrax. In the commercial segment, the Company develops vaccines and antibody therapies for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. 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.

	Reportable Segments			
(in thousands)	Biodefense	Commercial	All Other	Total
Nine Months Ended September 30, 2010				
External revenue	$182,924	$-	$-	$182,924
Net income (loss) to Emergent BioSolutions Inc.	65,303	(32,378)	(7,474)	25,451
Assets	178,883	23,000	164,354	366,237
Nine Months Ended September 30, 2009				
External revenue	$180,770	$212	$-	$180,982
Net income (loss) to Emergent BioSolutions Inc.	69,301	(32,506)	(9,885)	26,910
Assets	172,737	21,780	122,285	316,802

7. Related party transactions

The Company entered into an agreement in February 2009 with an entity controlled by family members of the Company's Chief Executive Officer to market and sell BioThrax. The agreement was effective as of November 2008 and requires payment based on a percentage of net sales of biodefense products of 17.5% in Saudi Arabia and 15% in Qatar and United Arab Emirates, and reimbursement of certain expenses. No payments under this agreement have been triggered for the nine months ended September 30, 2010 and 2009.

The Company entered into a severance agreement in April 2010 with the Company's former Senior Vice President, Legal Affairs and General Counsel, whose employment with the Company terminated in March 2010. Severance payments and other benefits under the agreement are substantially identical to those provided under the provisions of the Company's Severance Plan and Termination Protection Program. One-half of the amounts payable under the severance agreement was paid in September 2010, with the remaining amounts being paid in six equal monthly installments beginning in October 2010.

The Company entered into a consulting agreement in April 2010 with the Company's former Senior Vice President, Legal Affairs and General Counsel. The agreement, which was terminated in July 2010, provided for consulting and support services in connection with the Company's pending litigation with PSC. During the nine months ended September 30, 2010, the Company paid approximately $12,000 for services rendered under this agreement, of which no balance remained unpaid in accounts payable at September 30, 2010.

The Company entered into a consulting agreement in September 2010 with an entity controlled by the Company's former Senior Vice President, Corporate Affairs, who is also a family member of the Company's Chief Executive Officer. The agreement provides for consulting services in connection with special projects as assigned by the Company's President. During the nine months ended September 30, 2010, the Company paid approximately $5,000 for services rendered under this agreement, which is included in accounts payable at September 30, 2010.

The Company has entered into a transportation arrangement with an entity owned by the Company's Chief Executive Officer. For the nine months ended September 30, 2010 and 2009, the Company paid approximately $25,000 and $24,000, respectively, under this arrangement for transportation and logistical support, of which $4,000 remained in accounts payable at September 30, 2010.

The Company has entered into a consulting agreement with a member of the Company's Board of Directors. During each of the nine months ended September 30, 2010 and 2009, the Company paid approximately $135,000 under this agreement for strategic consultation and project support for the Company's marketing and communications group, of which no balance remained unpaid in accounts payable at September 30, 2010.

8. Oxford collaboration

In July 2008, the Company entered into a collaboration with the University of Oxford ("Oxford") and certain University of Oxford researchers to conduct clinical trials in the advancement of a vaccine product candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium ("OETC"). The Company has a 51% equity interest in OETC and controls the OETC Board of Directors. In addition, the Company has certain funding and services obligations of up to $20.3 million related to its investment. The Company has evaluated its variable interests in OETC and has determined that it is the primary beneficiary as it has the ability to direct the activities of OETC and will absorb the majority of expected losses. Accordingly, the Company consolidates the entity. As of September 30, 2010, assets of $229,000 and liabilities of $389,000 related to this entity are included within the Company's consolidated balance sheet. During the three and nine months ended September 30, 2010, the entity incurred net losses of $2.4 million and $4.4 million, respectively, of which $1.2 million and $2.2 million, respectively, is included in the Company's consolidated statement of operations.

In conjunction with the establishment of OETC, the Company granted a put option to Oxford and the Oxford researchers whereby the Company may be required to acquire all of the OETC shares held by Oxford and the Oxford researchers at fair market value of the underlying shares. This put option is contingent upon the satisfaction of a number of conditions that must exist or occur subsequent to the granting by the European Commission of marketing authorization for the OETC-sponsored vaccine product candidate for tuberculosis. The Company accounts for the put option in accordance with the accounting provisions related to derivatives and distinguishing liabilities from equity. In accordance with these provisions, the Company has determined that the put option has a de minimis fair value as of September 30, 2010.

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

(in thousands)	Emergent BioSolutions Inc.	Noncontrolling Interest	Total
Stockholders' equity at December 31, 2009	$ 241,199	$ 2,616	$ 243,815
Non-cash development expenses from joint venture	-	2,241	2,241
Net income (loss)	25,451	(2,155)	23,296
Other	9,642	-	9,642
Stockholders' equity at September 30, 2010	$ 276,292	$ 2,702	$ 278,994

9. Assets held for sale

The Company currently owns two buildings in Frederick, Maryland that it determined in 2009 would not be placed into service. Accordingly, the Company committed to a plan to sell the buildings, along with associated improvements. These buildings are classified on the Company's balance sheets as assets held for sale are recorded at the lower of the carrying amount or fair market value less costs to sell, and are no longer depreciated once classified as held for sale. The Company recorded the assets held for sale at fair market value, based on factors that include recent purchase offers less estimated selling costs, and recorded an impairment charge of $1.0 million for the nine months ended September 30, 2010. The charge is classified in the Company's statement of operations as selling, general and administrative expense within the Company's commercial segment. The Company continues to actively seek to sell these buildings.

10. Subsequent Events

On October 28, 2010, the Company completed its acquisition of Trubion. As consideration for the acquisition, Emergent (i) paid an aggregate of $27.9 million in cash and issued an aggregate of 3,351,817 shares of the Company's common stock and 20,425,554 contingent value rights ("CVRs") to the holders of common stock of Trubion, and (ii) issued 1,677,827 CVRs to the holders of outstanding options to purchase Trubion common stock, which holders also received cash of approximately $3.9 million. Holders of CVRs are entitled to receive a pro rata portion of certain contingent payments following the achievement of future development milestones under collaboration agreements with Pfizer Inc. and a wholly-owned subsidiary of Abbott Laboratories. The Company has incurred transaction costs related to the acquisition of approximately $1.3 million as of September 30, 2010, recorded in selling, general and administrative expenses in the Company's commercial segment. As of the date of this filing, the valuation of acquired intangible assets and other fair value adjustments are not complete, and as such the purchase price allocation for the transaction has not been completed.

The Company has evaluated subsequent events through the time of filing these financial statements.

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, include forward-looking statements that involve risks and uncertainties. You should review the "Special Note Regarding Forward-Looking Statements" and the "Risk Factors" sections of this quarterly report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Product Portfolio

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

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

Our commercial segment focuses on vaccines and antibody therapies 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 tuberculosis vaccine, a typhoid vaccine and an influenza vaccine. Additionally, through our recent acquisition of Trubion Pharmaceuticals, Inc., or Trubion, which we completed on October 28, 2010, we acquired certain clinical-stage product candidates focused on the targeted disease areas of oncology and autoimmunity and novel platform technologies for developing additional innovative therapeutic candidates. Specifically, the oncology product candidates include targeted treatments for chronic lymphocytic leukemia and non-Hodgkin's lymphoma, and the autoimmunity product candidates include targeted treatments for rheumatoid arthritis and systemic lupus erythematosus.

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

Product Sales

We have derived substantially all of our product sales revenues from BioThrax sales to the U.S. Department of Health and Human Services, or HHS, and the 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 our sales of BioThrax to the U.S. government. Our total revenues from BioThrax sales were $162.0 million and $170.0 million for the nine months ended September 30, 2010 and 2009, respectively. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers domestically and internationally and pursuing label expansions and improvements for BioThrax.

Contracts and Grants

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

- BioThrax post-exposure prophylaxis
- Next generation anthrax vaccine
- Large-scale manufacturing for BioThrax
- Recombinant protective antigen anthrax vaccine
- Anthrax immune globulin therapeutic
- Anthrax monoclonal antibody therapeutic
- Advanced double mutant recombinant protective antigen anthrax vaccine
- Recombinant botulinum vaccine
- Typhella™ (typhoid vaccine live oral ZH9)

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

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

Manufacturing Infrastructure

We conduct our primary vaccine manufacturing operations at a multi-building campus on approximately 12.5 acres in Lansing, Michigan. To augment our existing manufacturing capabilities, we have constructed Building 55, a 50,000 square foot large-scale manufacturing facility on our Lansing campus. In July 2010, we entered into an agreement with the Biomedical Advanced Research and Development Authority, or BARDA, to finalize development of and obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55. This agreement provides for funding from BARDA of up to approximately $107 million over a five-year contract term, including a two-year base period of performance valued at approximately $55 million. Prior to the award, we incurred costs of approximately $83 million for the building and associated capital equipment, as well as for validation and qualification activities required for regulatory approval and initiation of commercial manufacture of BioThrax.

In November 2009, we purchased a building in Baltimore, Maryland for product development and manufacturing purposes, and have begun renovation and improvement of this facility. Our specific plans for this facility will be contingent on the progress of our existing development programs and the outcome of our efforts to acquire new product candidates. As we proceed with this project, we expect the costs to be substantial and will likely seek external sources of funds to finance the project.

We also own two buildings in Frederick, Maryland that we currently expect to sell. Accordingly, we have classified these buildings as assets held for sale in our consolidated balance sheets. We recorded the assets held for sale at fair market value, based on factors that include recent purchase offers, less estimated selling costs, and recorded an impairment charge of approximately $1.0 million for the nine months ended September 30, 2010. We continue to actively seek to sell these buildings.

Critical Accounting Policies and Estimates

There have been no significant changes to our Critical Accounting Policies and Estimates during the nine months ended September 30, 2010. Refer to the Critical Accounting Policies and Estimates section in our Annual Report on Form 10-K for the year ended December 31, 2009 filed with the Securities and Exchange Commission, or SEC.

Financial Operations Overview

Revenues

On September 30, 2008, we entered into an agreement with HHS to supply up to 14.5 million doses of BioThrax for placement into the Strategic National Stockpile, or SNS. This agreement was amended in July 2010 to, among other things, allow us to accelerate the delivery of BioThrax doses into the SNS by approximately three months. The term of the agreement is from September 30, 2008 through September 30, 2011. Delivery of doses under the agreement commenced in September 2009 and will continue through June 2011. Funds for the procurement of these doses of BioThrax have been fully committed. The total purchase price for the 14.5 million doses will be up to approximately $400 million. Through September 30, 2010, we have delivered approximately 8.5 million doses under this 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 invoice under the agreement upon acceptance of each delivery of BioThrax doses to the SNS.

We have received contract and grant funding from National Institute of Allergy and Infectious Diseases, or NIAID, and BARDA for the following development programs:

Product Candidate/Manufacturing	Funding Source	Award Date	Amount (Up to)	Performance Period
Anthrax immune globulin therapeutic	NIAID	9/2007	$9.5 million	9/2007 — 12/2011
Recombinant botulinum vaccine	NIAID	6/2008	$1.8 million	6/2008 — 5/2011
Next generation anthrax vaccine	NIAID	7/2008	$2.8 million	7/2008 — 6/2013
Anthrax monoclonal antibody therapeutic	NIAID/BARDA	9/2008	$24.3 million	9/2008 — 8/2012
Next generation anthrax vaccine	NIAID/BARDA	9/2008	$24.4 million	9/2008 — 9/2011
Advanced double mutant recombinant protective antigen anthrax vaccine	NIAID	9/2009	$4.9 million	9/2009 — 8/2011
Large-scale manufacturing for BioThrax	BARDA	7/2010	$107.0 million	7/2010 — 9/2014
Next generation anthrax vaccine	NIAID	8/2010	$28.7 million	8/2010 — 8/2014
Recombinant protective antigen anthrax vaccine	BARDA	9/2010	$186.6 million	9/2010 — 9/2015

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 facilities, utilities and salaries and personnel-related expenses for indirect manufacturing support staff. Variable manufacturing costs for BioThrax consist primarily of costs for materials, direct labor and contract filling operations.

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

Research and Development Expenses

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

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, sales and marketing, business development, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales or research and development expense and professional fees for legal and accounting services. We currently market and sell BioThrax directly to the U.S. government with a small, targeted marketing and sales group. As we seek to broaden the market for BioThrax and if we receive marketing approval for additional products, we expect that we will increase our spending for marketing and sales activities.

Total Other Income (Expense)

Total other income (expense) consists primarily of interest income and interest expense, and in 2010, a charge to reduce previously accrued interest income related to a settlement agreement with Protein Sciences Corporation, or PSC. We earn interest income on our cash, cash equivalents and a note receivable, and we incur interest expense on our indebtedness. We capitalize interest expense based on the cost of major ongoing projects which have not yet been placed in service, such as new manufacturing facilities. 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, 2010 Compared to Quarter Ended September 30, 2009

Revenues

Product sales revenues increased by $28.3 million, or 72%, to $67.3 million for the three months ended September 30, 2010 from $39.0 million for the three months ended September 30, 2009. This increase in product sales revenues was primarily due to a 46% increase in the number of doses of BioThrax delivered coupled with an 18% increase in the sales price per dose. Product sales revenues for the three months ended September 30, 2010 consisted of BioThrax sales to HHS of $67.2 million and aggregate other sales of $39,000. Product sales revenues for the three months ended September 30, 2009 consisted of BioThrax sales to HHS of $38.9 million and aggregate international and other sales of $117,000.

Contracts and grants revenues increased by $2.5 million, or 57%, to $6.7 million for the three months ended September 30, 2010 from $4.3 million for the three months ended September 30, 2009. The increase in contracts and grants revenue was primarily due to revenues from our recently awarded contract for development of large-scale manufacturing of BioThrax, along with increases in revenue from our advanced double mutant recombinant protective antigen anthrax vaccine and next generation anthrax vaccine development contracts. These increases were partially offset by a decrease in in revenues from our anthrax monoclonal antibody therapeutic development contract. All contracts and grants revenues for the three months ended September 30, 2010 and 2009 were from NIAID and BARDA.

Cost of Product Sales

Cost of product sales increased by $2.8 million, or 33%, to $11.5 million for the three months ended September 30, 2010 from $8.7 million for the three months ended September 30, 2009. This increase was primarily attributable to the 46% increase in the number of BioThrax doses sold, partially offset by a decrease in cost per dose sold associated with increased production yield in the period during which the doses sold were produced.

Research and Development Expense

Research and development expenses increased by $2.4 million, or 13%, to $21.2 million for the three months ended September 30, 2010 from $18.8 million for the three months ended September 30, 2009. This increase reflects higher contract service costs, and includes increased expenses of $509,000 on product candidates that are categorized in the biodefense segment and increased expenses of $2.0 million in other research and development, which are in support of technology platform development activities and central research and development activities. These increases were partially offset by decreased expenses of $105,000 on product candidates categorized in the commercial segment.

The increase in spending on biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials. The increase in spending for our next generation anthrax vaccine program was due to the preparation for and conduct of clinical and non-clinical studies. The increase in spending for our large-scale manufacturing for Biothrax program was primarily due to facility qualification and validation activities. The spending for BioThrax related programs was related to clinical and non-clinical studies to support applications for marketing approval of these programs. The decrease in spending for the rPA anthrax vaccine product candidate was primarily due to reduced spending while awaiting a development contract award from BARDA, which we received in September 2010. The increase in spending for our advanced double mutant recombinant protective antigen anthrax vaccine product candidate resulted from spending for process, formulation and assay development. The spending for our anthrax immune globulin therapeutic product candidate was primarily for clinical studies and model development. The decrease in spending for the anthrax monoclonal therapeutic product candidate was primarily due to the timing of process and formulation development. The 2009 spending for our botulinum vaccine product candidates resulted from conducting non-clinical studies. We expect that spending for our botulinum vaccine candidates will remain minimal in the future, due primarily to reduced interest from and funding by the U.S. government for these product candidates.

The decrease in spending on commercial product candidates, detailed in the table below, was primarily attributable to the timing of development efforts and to the termination or scaling back of certain programs. The spending for our tuberculosis vaccine product candidate is related to the costs incurred for the conduct of a Phase IIb clinical trial, which commenced in April 2009. The spending for Typhella was primarily due to stability and clinical studies. The increase in spending for our influenza vaccine product candidate is related to process and analytical development. The decrease in spending for our hepatitis B therapeutic vaccine product candidate was related to the cessation of the Phase II clinical trial in the United Kingdom and Serbia. We have significantly reduced ongoing spending with regard to this product candidate while we investigate options to sell or outlicense the related technology, and expect that future spending will be reduced. We expect spending for other commercial vaccine product candidates, including group B streptococcus, chlamydia and meningitis B, will continue to be minimal in the future. In October 2010, we acquired Trubion Pharmaceuticals, Inc. and its development programs for product candidates to treat certain autoimmune diseases and cancer, including rheumatoid arthritis, systemic lupus erythematosus, chronic lymphocytic leukemia and non-Hodgkin's lymphoma. We are currently evaluating the development requirements for these programs.

The increase in other research and development expenses was primarily attributable to spending associated with technology platform development activities and central research and development activities.

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

Our principal research and development expenses for the three months ended September 30, 2010 and 2009 are shown in the following table:

	Three Months Ended September 30,	
(in thousands)	2010	2009
Biodefense:		
Next generation anthrax vaccine	$2,423	$1,553
Large-scale manufacturing for BioThrax	2,607	290
BioThrax related programs	1,760	1,947
Recombinant protective antigen anthrax vaccine	840	2,359
Advanced double mutant recombinant protective antigen vaccine	1,378	72
Anthrax immune globulin therapeutic	1,104	860
Anthrax monoclonal antibody therapeutic	1,295	2,775
Botulinum vaccines	4	1,046
Total biodefense	11,411	10,902
Commercial:		
Tuberculosis vaccine	3,836	3,697
Typhella™	1,194	898
Influenza vaccine	999	599
Hepatitis B therapeutic vaccine	14	805
Other commercial vaccines	5	154
Total commercial	6,048	6,153
Other	3,697	1,717
Total	$21,156	$18,772

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $926,000, or 5%, to $20.7 million for the three months ended September 30, 2010 from $19.8 million for the three months ended September 30, 2009. This increase is primarily due to increased personnel and professional services to support the business, partially offset by lower legal service costs. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses increased by $1.0 million, or 8%, to $13.5 million for the three months ended September 30, 2010 from $12.5 million for the three months ended September 30, 2009. Selling, general and administrative expenses related to our commercial segment decreased by $81,000, or 1%, to $7.2 million for the three months ended September 30, 2010 from $7.3 million for the three months ended September 30, 2009.

Total Other Income (Expense)

Total other income (expense) decreased by $1.3 million to an expense of $965,000 for the three months ended September 30, 2010 from income of $428,000 for the three months ended September 30, 2009. The decrease was due primarily to a charge of approximately $1.0 million to reduce previously accrued interest income related to the settlement with PSC.

Income Taxes

Provision for (benefit from) income taxes increased by $10.7 million to a provision for income taxes of $7.7 million for the three months ended September 30, 2010 from a benefit from income taxes of $3.0 million for the three months ended September 30, 2009. The increase in income tax expense is due to a $22.9 million increase in income (loss) before provision for (benefit from) income taxes plus the loss attributable to noncontrolling interest, partially offset by the impact of utilization of foreign entity and research and development deductions during the third quarter of 2009.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest decreased by $312,000, or 21%, to $1.2 million for the three months ended September 30, 2010 from $1.5 million for the three months ended September 30, 2009. The decrease resulted from the timing of clinical and development activities and related expenses incurred by our joint venture with the University of Oxford. These amounts represent the portion of the loss incurred by the joint venture for the three months ended September 30, 2010 and 2009, respectively, that is attributable to the University of Oxford.

Nine Months Ended September 30, 2010 Compared to Nine Months Ended September 30, 2009

Revenues

Product sales revenues decreased by $8.0 million, or 5%, to $162.0 million for the nine months ended September 30, 2010 from $170.0 million for the nine months ended September 30, 2009. This decrease in product sales revenues was due to a 2% decrease in the number of doses of BioThrax delivered, along with 2009 payments from HHS of approximately $34.0 million related to the approval of four-year expiry dating for BioThrax. These deceases were partially offset by a 22% increase in the sales price per dose. Product sales revenues for the nine months ended September 30, 2010 consisted of BioThrax sales to HHS of $159.6 million and aggregate international and other sales of $2.4 million. Product sales revenues for the nine months ended September 30, 2009 consisted of BioThrax sales to HHS of $169.6 million, including approximately $34.0 million related to the approval of four-year expiry dating for BioThrax, and aggregate international and other sales of $458,000.

Contracts and grants revenues increased by $10.0 million, or 91%, to $20.9 million for the nine months ended September 30, 2010 from $11.0 million for the nine months ended September 30, 2009. The increase in contracts and grants revenue was primarily due to increased revenues from development contracts for our next generation anthrax vaccine, our double mutant recombinant protective antigen anthrax vaccine, our anthrax monoclonal antibody therapeutic, and from our recently awarded contract for development of large-scale manufacturing of BioThrax. Contracts and grants revenues for the nine months ended September 30, 2010 consisted of $20.2 million in development contract and grant revenue from NIAID and BARDA and $750,000 from a milestone payment related to the 2008 sale of technology rights and related materials and documentation pertaining to our Pertussis technology. Contracts and grants revenues for the nine months ended September 30, 2009 consisted primarily of development contract and grant revenue from NIAID and BARDA.

Cost of Product Sales

Cost of product sales decreased by $4.4 million, or 13%, to $30.1 million for the nine months ended September 30, 2010 from $34.5 million for the nine months ended September 30, 2009. This decrease was primarily attributable to a decrease in the cost per dose sold associated with increased production yield in the period in which the doses were produced.

Research and Development Expense

Research and development expenses increased by $4.3 million, or 8%, to $59.7 million for the nine months ended September 30, 2010 from $55.4 million for the nine months ended September 30, 2009. This increase reflects higher contract service costs, and includes increased expenses of $6.3 million on product candidates that are categorized in the biodefense segment and increased expenses of $3.6 million in other research and development, which are in support of technology platform development activities and central research and development activities. These increases were partially offset by decreased expenses of $5.6 million on product candidates categorized in the commercial segment.

The increase in spending on biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials. The increase in spending for our next generation anthrax vaccine program was due to the preparation for and conduct of clinical and non-clinical studies. The increase in spending for our large-scale manufacturing of BioThrax program was primarily due to facility qualification and validation. The decrease in spending for BioThrax related programs was due to the timing of clinical and non-clinical studies to support applications for marketing approval of these programs. The decrease in spending for the rPA anthrax vaccine product candidate was primarily due to reduced spending while awaiting a development contract award from BARDA, which we received in September 2010. The increase in spending for our advanced double mutant recombinant protective antigen vaccine product candidate resulted from spending for process, formulation and assay development. The decrease in spending for our anthrax immune globulin therapeutic product candidate was primarily due to the timing of clinical and tolerability studies along with model development. The increase in spending for the anthrax monoclonal therapeutic product candidate was primarily due to the timing of process and assay development, stability studies and the conduct of non-clinical studies. The spending for our botulinum vaccine product candidates resulted from conducting non-clinical studies.

The decrease in spending on commercial product candidates was primarily attributable to the timing of development efforts and to the termination or scaling back of certain programs. The decrease in spending for our tuberculosis vaccine product candidate is related to the timing of costs incurred for the preparation, initiation, and conduct of a Phase IIb clinical trial, which commenced in April 2009. The decrease in spending for Typhella primarily resulted from the manufacture of clinical material and conduct of a Phase IIb clinical trial in the United States, both of which were substantially completed during 2009. The increase in spending for our influenza vaccine product candidate is related to process and analytical development. The decrease in spending for our hepatitis B therapeutic vaccine product candidate was related to the cessation of the Phase II clinical trial in the United Kingdom and Serbia.

The increase in other research and development expenses was primarily attributable to spending associated with technology platform development activities and central research and development activities.

Our principal research and development expenses for the nine months ended September 30, 2010 and 2009 are shown in the following table:

(in thousands)	Nine Months Ended September 30, 2010	Nine Months Ended September 30, 2009
Biodefense:		
Next generation anthrax vaccine	$6,975	$3,260
Large-scale manufacturing for BioThrax	6,022	1,505
BioThrax related programs	5,112	6,378
Recombinant protective antigen anthrax vaccine	2,290	6,173
Advanced double mutant recombinant protective antigen vaccine	4,470	292
Anthrax immune globulin therapeutic	4,994	5,407
Anthrax monoclonal antibody therapeutic	7,118	4,743
Botulinum vaccines	595	3,554
Total biodefense	37,576	31,312
Commercial:		
Tuberculosis vaccine	8,158	9,483
Typhella™	2,432	4,449
Influenza vaccine	2,588	1,731
Hepatitis B therapeutic vaccine	245	2,650

Other commercial vaccines	163	829
Total commercial	13,586	19,142
Other	8,518	4,908
Total	$59,680	$55,362

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $581,000, or 1%, to $54.5 million for the nine months ended September 30, 2010 from $55.1 million for the nine months ended September 30, 2009. This decrease is primarily due to a decrease of $2.8 million in the impairment charges associated with our Frederick, Maryland facilities and decrease in legal service costs, partially offset by increased personnel and professional services to support the business. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses increased by $2.4 million, or 7%, to $38.3 million for the nine months ended September 30, 2010 from $35.9 million for the nine months ended September 30, 2009. Selling, general and administrative expenses related to our commercial segment decreased by $3.0 million, or 16%, to $16.2 million for the nine months ended September 30, 2010 from $19.2 million for the nine months ended September 30, 2009.

Total Other Income (Expense)

Total other income (expense) decreased by $1.2 million to an expense of $210,000 for the nine months ended September 30, 2010 from income of $989,000 for the nine months ended September 30, 2009. This decrease resulted primarily from a charge of approximately $1.0 million to reduce previously accrued interest income related to the settlement with PSC.

Income Taxes

Provision for income taxes increased by $958,000, or 7%, to $15.1 million for the nine months ended September 30, 2010 from $14.1 million for the nine months ended September 30, 2009. The estimated effective tax rate for the nine month periods ended September 30, 2010 and 2009 was 37% and 34%, respectively. The increase in the provision for income taxes was primarily due to the impact of the utilization of foreign entity and research and development deductions on our tax liability for the nine months ended September 30, 2009, partially offset by increased deductions for domestic manufacturing activities.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest decreased by $1.9 million, or 46%, to $2.2 million for the nine months ended September 30, 2010 from $4.0 million for the nine months ended September 30, 2009. The decrease resulted from the timing of clinical and development activities and related expenses incurred by our joint venture with the University of Oxford. These amounts represent the portion of the loss incurred by the joint venture for the nine months ended September 30, 2010 and 2009, respectively, that is attributable to the University of Oxford.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our cash requirements from inception through September 30, 2010 principally with a combination of revenues from BioThrax product sales, debt financings and facilities leases, development funding from government entities and non-government and philanthropic organizations, the net proceeds from our initial public offering and from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the five years ended December 31, 2009 and for the nine months ended September 30, 2010.

As of September 30, 2010, we had cash and cash equivalents of $151.2 million. Additionally, at September 30, 2010 our accounts receivable balance was $7.9 million.

The acquisition of Trubion in October 2010 resulted in a payment of approximately $27.9 million by us to Trubion stockholders. As a result of the acquisition, we acquired approximately $20 million of cash, cash equivalents, and investments held by Trubion at the time of the acquisition.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2010 and 2009:

(in thousands)	Nine Months Ended September 30, 2010	Nine Months Ended September 30, 2009
Net cash provided by (used in):		
Operating activities(1)	$74,668	$53,528
Investing activities	(14,042)	(14,376)
Financing activities	(12,321)	(11,848)
Total net cash provided by (used in)	$48,305	$27,304

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

Net cash provided by operating activities of $74.7 million for the nine months ended September 30, 2010 was due principally to net income attributable to Emergent BioSolutions Inc. of $25.5 million, a decrease in accounts receivable of $46.9 million due to the collection of amounts billed primarily to HHS, and non-cash charges of $5.2 million for stock-based compensation, $4.0 million for depreciation and amortization and $2.2 million for development expenses from our joint venture, partially offset by a decrease in income taxes of $10.6 million due to estimated federal and state tax payments.

Net cash provided by operating activities of $53.5 million for the nine months ended September 30, 2009 was due principally to our net income attributable to Emergent BioSolutions Inc. of $26.9 million, a decrease in inventories of $3.9 million reflecting the value of BioThrax lots delivered, an increase in accounts payable of $4.4 million related to the timing of payment of invoices, and a net increase in income taxes related to timing differences of $4.8 million, coupled with non-cash charges of $6.0 million for development expenses from our joint venture, $3.8 million related to the impairment of our Frederick facilities, $3.7 million for depreciation and amortization and $3.6 million for stock-based compensation.

Net cash used in investing activities for the nine months ended September 30, 2010 and 2009 of $14.0 million and $14.4 million, respectively, resulted principally from the construction and related costs for Building 55, our large-scale manufacturing facility in Lansing, Michigan, and infrastructure investments and other equipment.

Net cash used in financing activities of $12.3 million for the nine months ended September 30, 2010 resulted primarily from $32.5 million in principal payments on indebtedness, including $30.0 million in payments on our revolving line of credit with Fifth Third Bank, partially offset by $15.0 million in proceeds from borrowings under our revolving line of credit with Fifth Third Bank, $4.1 million in proceeds from stock option exercises and $1.1 million related to excess tax benefits from the exercise of stock options.

Net cash provided by financing activities of $11.8 million for the nine months ended September 30, 2009 resulted primarily from $30.0 million in proceeds from borrowings under our revolving line of credit with Fifth Third Bank, $4.2 million in proceeds from stock option exercises and $1.6 million related to excess tax benefits from the exercise of stock options, partially offset by $47.6 million in principal payments on indebtedness, including $45.0 million in payments on our revolving line of credit with Fifth Third Bank

Debt Financing

As of September 30, 2010, we had $48.3 million principal amount of debt outstanding, comprised primarily of the following:

- $2.5 million outstanding under a loan from the Department of Business and Economic Development of the State of Maryland used to finance eligible costs incurred to purchase our first facility in Frederick, Maryland;
- $5.8 million outstanding under a mortgage loan from PNC Bank used to finance the remaining portion of the purchase price for our first Frederick facility;
    - $6.8 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance a portion of the purchase price for our second facility on the Frederick site;

- $21.7 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;
- $6.6 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance a portion of the purchase price of our facility in Baltimore, Maryland; and
- $4.9 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance a portion of the purchase price of our facility in Gaithersburg, Maryland.

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, development contract and grant funding, and our existing line of credit. There are numerous risks and uncertainties associated with BioThrax product sales and with the development and commercialization of our product candidates. We may seek additional external debt financing to provide additional financial flexibility. Our future capital requirements will depend on many factors, including:

- the level and timing of BioThrax product sales and cost of product sales;
- our ability to obtain funding from government entities and non-government and philanthropic organizations for our development programs;
- the acquisition of new facilities, and capital improvements to new or existing facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to Building 55, our large-scale manufacturing facility in Lansing, Michigan, the build out of our new facility in Baltimore, Maryland, and any other new facilities;
- our ability to sell two buildings classified on our balance sheet as assets held for sale;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the level of participation of our collaborative partners in our development programs, including those recently acquired in the acquisition of Trubion;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, other product candidates that we may pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the extent to which we lend money to, and are able to obtain repayment from, third parties;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- the extent to which we acquire or invest in companies, businesses, products and technologies;
- the extent to which we become obligated to make cash payments related to the contingent value rights issued to former holders of Trubion common stock in connection with our acquisition of Trubion that are not offset by corresponding cash inflows from our collaborative partners; 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. Current economic conditions may make it difficult to obtain financing on attractive terms or at all. Lenders may be able to impose covenants on us that could be difficult to satisfy, which could put us at increased risk of defaulting on debt. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

Our ability to borrow additional amounts under our revolving line of credit agreement is subject to our satisfaction of specified conditions. Additional equity or debt financing, grants, or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

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, and our long-term indebtedness. We currently do not hedge interest rate exposure or foreign currency exchange exposure, and the movement of interest rates and foreign currency exchange rates could have an adverse or positive impact on our results of operations. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments, but would likely increase the interest cost 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, 2010. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2010, 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, 2010 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. Until reaching settlement with Protein Sciences Corporation, or PSC, on November 2, 2010, we had been pursuing several legal actions against PSC and its senior management arising out of a letter of intent, a loan and security agreement and related promissory note, and an asset purchase agreement between us and PSC that were entered into in 2008. On June 8, 2009, we initiated legal proceedings in the Superior Court of the State of Connecticut, Judicial District of New Haven, to acquire possession through foreclosure of PSC’s physical assets that secure the loan. On July 9, 2008, we initiated legal proceedings against PSC in the Supreme Court of the State of New York including, among other claims, claims for fraud, breach of contract, breach of the duty of good faith and fair dealing, unjust enrichment and unfair business practices. On October 3, 2008, we initiated legal proceedings in the United States District Court for the District of Connecticut against PSC’s executive management team of Daniel D. Adams, PSC's Executive Chairman, and Manon M.J. Cox, PSC's President and Chief Executive Officer alleging, among other things, that these individuals engaged in fraudulent conduct in connection with their efforts to obtain $10 million in bridge financing from us. On July 19, 2010, the Company filed a motion for summary judgment in lieu of complaint in the Supreme Court of the State of New York seeking repayment of its loan and interest.

On November 2, 2010, weand PSC entered into a settlement and mutual release of claims with respect to the letter of intent, the loan and security agreement and related promissory note and forbearance agreement, the asset purchase agreement and all other claims related thereto. Under the terms of the settlement, PSC paid us $11.5 million, consisting of full repayment of the original $10 million of principal plus $1.5 million in interest. At the time of this filing, the parties are in the process of filing stipulations with the relevant courts to dismiss all litigation with prejudice.

Class-action Litigation Related to Trubion Pharmaceuticals Acquisition. On August 17, 2010, two class action lawsuits were filed in the Superior Court of Washington, King County, or State Court, against Trubion Pharmaceuticals, Inc., or Trubion, its board of directors, and us, or collectively, the Defendants, alleging in summary that, in connection with the proposed merger of Trubion with a subsidiary of ours, or the Acquisition, the members of the Trubion board of directors breached their fiduciary duties by conducting an unfair sale process and agreeing to an unfair price. Both complaints also claim that Trubion and we aided and abetted the Trubion board of directors in its breach of fiduciary duties. On September 9, 2010, the actions were consolidated into a single action, or State Action. On October 1, 2010, the plaintiffs in the State Action served on the Defendants a consolidated amended class action complaint, or Amended Complaint, alleging, among other things and in addition to the matters alleged in the initial complaints, that the Defendants omitted material information from the Proxy Statement/Prospectus.

On October 4, 2010, a class action lawsuit was filed in the U.S. District Court for the Western District of Washington against the Defendants, or Federal Action and, collectively with the State Action, the Actions, which makes allegations related to the Acquisition that are substantially similar to those matters alleged in the Amended Complaint, includes additional allegations regarding purported violations of the federal securities laws and seeks substantially similar relief.

On October 8, 2010, the Defendants reached agreement in principle with the plaintiffs in the Actions regarding the settlement of the Actions. In connection with the settlement contemplated by that agreement in principle, the Actions will be stayed pending approval of the settlement of the State Action by the State Court. Thereafter, the State Action and all claims asserted therein will be dismissed with prejudice and counsel for the plaintiff in the Federal Action will take all necessary steps to dismiss the Federal Action and all claims asserted therein with prejudice. The terms of the settlement contemplated by that agreement in principle require that Trubion and we make certain additional disclosures related to the Acquisition, as set forth in our Current Report on Form 8-K filed on October 8, 2010. The parties also agreed that the plaintiffs in the Actions may seek attorneys' fees and costs in an aggregate amount up to $475,000, to be paid by Trubion if such fees and costs are approved by the State Court. There will be no other payment by Trubion, any of the members of the Trubion board of directors or us to the plaintiffs or their respective counsels in connection with the settlement and dismissal of the Actions. The agreement in principle further contemplates that the parties will enter into a stipulation of settlement, which will be subject to customary conditions, including State Court approval following notice to Trubion's shareholders. In the event that the parties enter into a stipulation of settlement, a hearing will be scheduled at which the State Court will consider the fairness, reasonableness and adequacy of the settlement. There can be no assurance that the parties will ultimately enter into a stipulation of settlement, that the State Court will approve any proposed settlement, or that any eventual settlement will be under the same terms as those contemplated by the agreement in principle.

Patent Oppositions. Our live attenuated modified vaccinia Ankara virus, or MVA, platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based in part on rights to certain MVA-related materials and technology that we acquired from the Bavarian State Ministry of the Environment and Public Health. From 2006 to 2008, we filed patent oppositions in the European Patent Office against four of Bavarian Nordic's patents covering certain aspects of MVA technology. In each of the four pending opposition proceedings, the subject patents have also been opposed by one or more additional parties, including Sanofi Pasteur, Transgene, Baxter, Virbac, and Innogenetics. We and the other opponents have alleged that the opposed patents should be revoked for failure to fulfill one or more of the patentability requirements of the European Patent Convention, such as the requirements for novelty and inventive step. In each opposition, we expect that a single hearing will be held before the Opposition Division of the European Patent Office, in which each opponent will present oral argument and Bavarian Nordic will present rebuttal arguments. The first of these hearings, which occurred in June 2010, resulted in the Bavarian Nordic patent under consideration being maintained but narrowed in scope. A time period has been set for all parties to file appeals, and we anticipate that all appeals will be filed by the due date of November 27, 2010. Hearings in two of the other pending oppositions occurred in October 2010. Bavarian Nordic introduced amended patent claims into the record, which claims were upheld strictly and expressly conditioned on such claims being interpreted within a narrowly-defined scope. The Opposition Division scheduled a hearing on the fourth pending opposition for January 2011. We routinely monitor the grant of further Bavarian Nordic European patents to determine whether any additional oppositions should be filed.

Other. We are, and may in the future become, subject to other legal proceedings, claims and litigation arising in the ordinary course of our business in connection with the manufacture, distribution and use of our products and product candidates. For example, Emergent BioDefense Operations Lansing Inc., or EBOL, was a defendant, along with many other vaccine manufacturers, in a series of lawsuits that have been filed in various state and federal courts in the United States alleging that thimerosal, a mercury-containing preservative allegedly used by the defendants in the manufacture of some vaccines, caused personal injuries, including brain damage, central nervous system damage and autism. The last of the lawsuits in which EBOL was named a defendant, which were pending in California, were dismissed without prejudice in July 2010.

ITEM 1A. RISK FACTORS

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

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

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

Our existing and prior contracts with HHS and the DoD do not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government. The success of our business and our operating results for the foreseeable future are substantially dependent on the terms of our BioThrax sales to the U.S. government, including price per dose, the number of doses and the timing of deliveries.

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

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

- the commitment of substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
  - the possibility that we may be ineligible to respond to a request for proposal issued by the government;
    - the submission by third parties of protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- if our competitors protest or challenge contract awards made to us pursuant to competitive bidding, the potential that we may incur or could suffer expenses or delays, and that any such protest or challenge would result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract.

The U.S. government may choose not to award us future contracts for the development and supply of anthrax vaccines and other biodefense product candidates that we are developing, or may instead award such contracts to our competitors. If we are unable to win particular contracts, we may not be able to operate in the market for products that are provided under those contracts for a number of years. For example, in December 2009, the Biomedical Advanced Research and Development Authority, or BARDA, cancelled a previously issued request for proposal for development and procurement of a recombinant protective antigen, or rPA, anthrax vaccine for the SNS for which we had submitted a proposal. BARDA subsequently issued a Broad Agency Announcement, or BAA, solely for the development of an rPA anthrax vaccine under which we were awarded a development contract in September 2010. Additionally, if we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition and operating results could be materially adversely affected.

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

Our principal customer for BioThrax is the U.S. government. We anticipate that the U.S. government will also be the principal customer for any other biodefense products that we successfully develop. Over its lifetime, a U.S. government program may be implemented through the award of many different individual contracts and subcontracts. The funding of some government programs is subject to Congressional appropriations, generally made on a fiscal year basis even though a program may continue for several years. Our government customers are subject to stringent budgetary constraints and political considerations. For example, the sale of most of the doses of BioThrax supplied under our most recent procurement contract with HHS was subject to the annual appropriations process. Additionally, our government-funded development contracts typically consist of a base period of performance followed by successive option periods for performance of certain future activities. The value of these optional services, which options are in the sole discretion of the government, may constitute the majority of the total value of the underlying contract. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, our business, revenues and operating results may suffer.

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

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

- procurement integrity;
- export control;
- government security;
- employment practices;
- protection of the environment;
- accuracy of records and the recording of costs; and
- foreign corrupt practices.

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

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

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

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

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

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including equitable price adjustments;
- cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- decline to exercise an option to renew a contract;
- exercise an option to purchase only the minimum amount, if any, specified in a contract;
- decline to exercise an option to purchase the maximum amount, if any, specified in a contract;
- claim rights to products, including intellectual property, developed under the contract;
- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- suspend or debar the contractor from doing business with the government or a specific government agency;
- pursue criminal or civil remedies under the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

Generally, government contracts, including our HHS contracts for BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the government's convenience. Under general principles of government contracting law, if the government terminates a contract for convenience, the other party to that contract may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination.

If the government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source.

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

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

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

BioThrax. On September 29, 2009, the United States Court of Appeals for the District of Columbia Circuit issued its opinion in Rempfer v. Torti, affirming the February 29, 2008 finding of the District Court that the FDA did not violate the Administrative Procedure Act in connection with its December 19, 2005 Final Order classifying BioThrax as safe and effective. The plaintiffs' petition for writ of certiorari in the United States Supreme Court was denied on March 1, 2010.

Although we are not a party to any lawsuits challenging the DoD's mandatory use of BioThrax, if a court were to again enjoin the DoD's use of BioThrax on a mandatory basis, the amount of future purchases of BioThrax by the U.S. government could be affected. Furthermore, contractual indemnification provisions and statutory liability protections may not fully protect us from all related liabilities, and statutory liability protections could be revoked or amended to reduce the scope of liability protection. For example, we have invoiced the DoD for reimbursement of our costs incurred with respect to the lawsuits filed against us by current and former members of the U.S. military claiming damages as the result of personal injuries allegedly suffered from vaccination with BioThrax, and we are continuing our efforts to negotiate with the DoD for a satisfactory resolution of that claim. In addition, lawsuits brought directly against us by third parties, even if not successful, would require us to spend time and money defending the related litigation that may not be reimbursed by insurance carriers or covered by indemnification under existing contracts.

Risks Related to Our Financial Position and Need for Additional Financing

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

Although we have been profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. Our profitability is substantially dependent on revenues from BioThrax product sales. Revenues from BioThrax product sales have fluctuated significantly in recent quarters, and we expect that they will continue to fluctuate significantly from quarter to quarter based on several factors, including the timing of our fulfilling orders from the U.S. government. Additionally, our profitability may be adversely affected as we progress through various stages of ongoing or planned clinical trials for our product candidates. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

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

As of September 30, 2010, we had $48.3 million principal amount of debt outstanding. We may seek to raise substantial external debt financing to provide additional financial flexibility. The assumption of debt could have significant adverse consequences, including:

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

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

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

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

As of September 30, 2010, we had $151.2 million of cash and cash equivalents. Our future capital requirements will depend on many factors, including:

- the level and timing of BioThrax product sales and cost of product sales;
- our ability to obtain funding from government entities and non-government and philanthropic organizations for our development programs;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to Building 55, our large-scale manufacturing facility in Lansing, Michigan, the build out of our new facility in Baltimore, Maryland, and any other new facilities;
- the level of participation of our collaborative partners in our development programs, including those recently acquired in the acquisition of Trubion;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, other product candidates that we may pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the extent to which we lend money to, and are able to obtain repayment from, third parties;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- the extent to which we acquire or invest in companies, businesses, products and technologies;
- the extent to which we become obligated to make cash payments related to the contingent value rights issued to former holders of Trubion Pharmaceuticals, Inc., or Trubion, common stock in connection with our acquisition of Trubion that are not offset by corresponding cash inflows from our collaborative partners; 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. Current economic conditions may make it difficult to obtain financing on attractive terms or at all. Lenders may be able to impose covenants on us that could be difficult to satisfy, which could put us at increased risk of defaulting on debt. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

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

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

Risks Related to Manufacturing and Manufacturing Facilities

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

We continually evaluate alternatives for the manufacture of BioThrax and our various product candidates. We may seek to acquire one or more additional facilities or sign agreements with contract manufacturing organizations. We have constructed Building 55, a large-scale manufacturing facility on our Lansing, Michigan campus for which we received an award from BARDA in July 2010 for scale-up, qualification and validation to manufacture BioThrax. Additionally, in 2009, we acquired a facility in Baltimore, Maryland that we expect to utilize for certain product development or manufacturing projects. In order to do so, we anticipate that we will be required to make certain capital expenditures to upgrade and maintain this facility.

Constructing, preparing and maintaining a facility for manufacturing purposes is a significant project. For example, the process for qualifying and validating Building 55 for FDA licensure will be costly and time consuming, may result in unanticipated delays and may cost more than expected due to a number of factors, including regulatory requirements. The costs and time required to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements for sales of our products outside the U.S. may be significant. If our qualification and validation activities are delayed, we may not be able to meet our obligations to our customers, which may limit our opportunities for growth. Costs associated with constructing, qualifying and validating manufacturing facilities could require us to raise additional funds from external sources, and we may not be able to do so on favorable terms or at all.

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

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

We also depend on certain single-source suppliers for materials and services necessary for the manufacture of BioThrax and our product candidates. A disruption in the availability of such materials or services from these suppliers could require us to qualify and validate alternative suppliers. If we are unable to locate or establish alternative suppliers, our ability to manufacture our products could be adversely affected and also could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

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

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

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

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

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

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

In addition, providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. For example, the U.S. government has designated our Lansing facility as a facility requiring additional security to protect against potential terrorist threats to the facility. Any disruption that impedes our ability to manufacture and ship BioThrax in a timely manner could reduce our revenues and materially harm our business, financial condition and operating results.

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

We have outsourced the operation for filling BioThrax into vials to a single company. Our contract with this company expires on December 31, 2010, and we are negotiating a new filling agreement with this Company that we expect to execute in the fourth quarter of 2010. We have not established internal redundancy for our filling functions; however, we have identified and contracted with an additional provider that we believe can handle our filling needs. Before this additional provider can perform filling services for us, it must be qualified and licensed by the FDA. Such qualification and licensure may require use of a significant number of doses of BioThrax for consistency lots and stability testing that we may not be able to sell in the future once testing is complete. If our existing BioThrax filler is unable to perform filling services for us, we would need to obtain FDA approval of our potential substitute filler, engage, qualify and license an alternative filling company or develop our own filling capabilities. Any new contract filling company or filling capabilities that we acquire or develop will need to be approved by the FDA. Identifying and engaging a new contract filling company or developing our own filling capabilities and obtaining FDA approval could involve significant time and cost. As a result, we might not be able to deliver BioThrax orders on a timely basis and our revenues could decrease.

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

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

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

We currently rely, or plan to rely, on third parties to manufacture the supplies of some or all of our vaccine and therapeutic product candidates that we require for preclinical and clinical development, including the product candidates from our recently-completed acquisition of Trubion. For example, through a prior agreement between Trubion and Pfizer, Inc., or Pfizer, we now depend on Pfizer for the supply of SBI-087, a next generation CD20-directed product candidate targeted for treatment of rheumatoid arthritis, or RA. Any significant delay in obtaining adequate supplies of our product candidates could adversely affect our ability to develop or commercialize these product candidates. For example, in 2008 the initial manufacturer of our anthrax monoclonal antibody therapeutic product candidate informed us it was discontinuing contract manufacturing operations and we were forced to secure alternative manufacturing resources to continue development of this product candidate.

In addition, we expect that we will rely on third parties for a portion of the manufacturing process for commercial supplies of product candidates that we successfully develop, including fermentation for some of our vaccine product candidates, plasma fractionation and purification and contract fill and finish operations, and we rely on those manufacturers to comply with a wide variety of rules and regulations. If our contract manufacturers are unable to scale-up production to generate enough materials for commercial launch, if manufacturing is of insufficient quality, or if the costs of manufacturing are prohibitively high, the success of those products may be jeopardized. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our ability to develop product candidates and commercialize any products that receive regulatory approval on a timely and competitive basis.

We operate under short-term supply agreements with a number of third party manufacturers that are not obligated to accept any purchase orders we may submit. If any third party terminates its agreement with us, or otherwise fails to fulfill our purchase orders, we would need to rely on alternative sources or develop our own manufacturing capabilities to satisfy our requirements.

If alternative suppliers are not available or are delayed in fulfilling our requirements, or if we are unsuccessful in developing our own manufacturing capabilities, we may not be able to obtain adequate supplies of our product candidates on a timely basis. A change of manufacturers would require review and approval by the FDA and the applicable foreign regulatory agencies. This review and approval may be costly and time consuming. There are a limited number of manufacturers that operate under cGMP requirements and that are both capable of manufacturing for us and willing to do so.

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

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

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

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

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

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

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

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

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

We hold a number of insurance policies in an effort to protect ourselves against extraordinary or unanticipated costs. Our general liability and excess insurance policies provide for coverage up to annual aggregate limits of $12 million, with coverage of $1 million per occurrence and $2 million in the aggregate for general liability and $10 million per occurrence and in the aggregate for excess liability. Both policies exclude coverage for liabilities relating to the release of pollutants. We do not currently hold insurance policies expressly providing for coverage relating to our use of hazardous materials other than storage tank liability insurance for our Lansing facility with coverage of $1 million per occurrence and $2 million annual aggregate limit and a $25,000 per claim deductible. We hold product liability and clinical trial liability insurance policies for our commercial products and each clinical trial we are conducting in amounts we deem appropriate.

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

Risks Related to Our Acquisition of Trubion Pharmaceuticals

We will be subject to continued risks of product development, regulatory approvals and commercialization with respect to the product candidates we acquired as a result of our acquisition of Trubion.

Our recently-acquired Trubion product candidates are subject to the same risks that affected our product candidates prior to the Trubion acquisition. For example, TRU-016, a CD37-targeted therapy for the treatment of B-cell malignancies, is being developed with a wholly owned subsidiary of Abbott Laboratories, or Abbott, for patients with chronic lymphocytic leukemia, or CLL. A Phase I clinical trial of TRU-016 in this indication is underway. We and Abbott will be responsible for completing the clinical development of, seeking regulatory approval for and commercializing this product candidate. The results of the ongoing clinical trial for TRU-016 may not be sufficient to support an application for marketing approval. If the efficacy of this product candidate cannot be confirmed in pivotal clinical trials, we may be forced to delay or cease development efforts. Our product development costs will increase if we experience delays in clinical trials or in seeking marketing approval. Significant delays could impair our ability to commercialize TRU-016 or any of the other product candidates we acquired through the Trubion acquisition. If we are unable to complete the development of, obtain regulatory approvals for and commercialize these product candidates, we will not realize the anticipated benefits of our acquisition of Trubion.

Our commercial success depends in significant part on the success of the partnered clinical product candidates we recently acquired from Trubion. We cannot be certain that the collaborative partners for those product candidates will continue development, or that those product candidates will be safe or effective, complete clinical trials, receive regulatory approval or be successfully commercialized.

In June 2010, Pfizer decided to discontinue development of TRU-015, an investigational drug in Phase II evaluation for the treatment of RA that was developed under Trubion's CD20 collaboration with Pfizer. Accordingly, the lead commercial product candidate that we acquired through our acquisition of Trubion is SBI-087, a second generation anti-CD20 product candidate. SBI-087 is earlier in development than TRU-015 and is currently the subject of an ongoing Phase II trial. Patient dosing in the Phase II SBI-087 RA trial commenced in December 2009 and final data is not anticipated until the end of 2011. Because SBI-087 is at an earlier stage in clinical development, the decision by Pfizer to develop SBI-087 instead of TRU-015 is likely to delay the potential commercialization of any product candidate under our collaboration with Pfizer, which could adversely affect our business.

Initial clinical testing of TRU-016 and SBI-087 commenced in 2008. Even if we and our collaborative partners for those product candidates determine to proceed with further clinical testing, a number of additional clinical trials will be required before a Biologics License Application, or BLA, can be submitted to the FDA for product approval. Clinical trials required for FDA approval of SBI-087 for RA or systemic lupus erythematosus, or SLE, and TRU-016 for CLL and non-Hodgkin’s lymphoma, or NHL, may not be successfully completed. If required clinical trials are not completed or their results do not meet safety and efficacy thresholds required by the FDA, these product candidates will likely not receive regulatory approval. The regulatory approval process can take many years and require the expenditure of substantial resources. Even if any of these product candidates receive regulatory approval, the approved product candidate may never be successfully commercialized. If these product candidates do not receive regulatory approval or are not successfully commercialized, we may not realize the anticipated benefits of our acquisition of Trubion.

We depend on our collaborative relationships with Pfizer and Abbott to develop, manufacture, and commercialize certain of our recently acquired product candidates.

As a result of our acquisition of Trubion, we are party to collaboration agreements with each of Pfizer pursuant to which Pfizer is responsible for regulatory approval of and any subsequent commercialization of SBI-087, and Abbott pursuant to which we and Abbott must jointly agree to all development and commercialization plans and timelines for TRU-016. If either of our collaborative partners opts-out of or terminates its agreement with us or fails to fulfill its obligations, we would need to obtain the capital necessary to fully fund the development and commercialization of the related product candidates or enter into alternative arrangements with a third party. We could also become involved in disputes with either of these collaborative partners, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration. If either Abbott or Pfizer terminates or breaches its agreement with us, or otherwise fails to complete its obligations in a timely manner, our collaboration product development programs would be substantially delayed and the chances of successfully developing or commercializing our collaboration product candidates would be materially and adversely affected.

In June 2010 Pfizer decided to discontinue development of TRU-015. We cannot predict how or whether Pfizer will proceed with the collaboration or the development of any of the remaining collaboration product candidates, including SBI-087 and other therapeutics directed to CD20, as well as certain other product candidates directed to a small number of targets other than CD20 that have been established pursuant to the agreement. Our ability to receive any significant revenue from our product candidates covered by the collaboration agreement depends on the efforts of Pfizer and on our ability to collaborate effectively. Any future payments, including royalties to us, will depend on the extent to which we and Pfizer advance product candidates through development and commercialization. Pfizer may terminate the collaboration relationship, in whole or in part, without cause, by giving 90 days' written notice to us. Pfizer also has the right to terminate the agreement, on a target-by-target basis, upon 60 days' written notice, if any safety or regulatory issue arises that would have a material adverse effect on Pfizer's ability to develop, manufacture, or commercialize one or more product candidates.

With respect to control over decisions and responsibilities, the collaboration agreement provides for a research committee and a CD20-directed therapy development committee consisting of representatives of Pfizer and us. Ultimate decision-making authority as to most matters within the collaboration, including development plans and timelines, however, is vested in Pfizer.

In August 2009, Trubion entered into a collaboration agreement with Facet Biotech, or Facet, for the joint worldwide development and commercialization of TRU-016, a product candidate in Phase I clinical development for CLL and other CD37-directed protein therapeutics. Facet became a wholly-owned subsidiary of Abbott on April 21, 2010. Under the terms of the collaboration agreement, neither we nor Abbott have the right to develop or commercialize protein therapeutics directed to CD37 outside of the collaboration. Our ability to receive funding for TRU-016 under the collaboration depends on our ability to collaborate effectively with Abbott. Any future payments, including milestones payable to us, will depend on the extent to which we and Abbott advance TRU-016 through development and commercialization. Abbott may terminate the collaboration agreement without cause, and would not be obligated to pay us a termination fee if such a termination were to occur after February 27, 2011. Abbott also has the right upon 90 days' written notice to terminate the agreement for any uncured material breach by us, and has the right to opt out of the collaboration during the six-month period following a change in control of Trubion, which includes the right to opt out of the collaboration as a result of our acquisition until April 28, 2011. With respect to control over decisions and responsibilities, the collaboration agreement provides for a joint steering committee that must make decisions by consensus. Failure to reach consensus on material aspects of the development or commercialization of TRU-016 would lead to dispute resolution by our respective designated officers, and potentially arbitration, any of which may delay the development of TRU-016, which may harm our business.

Under certain circumstances, the parties have the right to opt-out of the collaboration or may be deemed to have opted-out of the collaboration. If Abbott opts-out of the collaboration with respect to a product, then we would become responsible for all development and commercialization costs for that product and be obligated to pay Abbott certain royalty payments upon the sale of that product. We are currently the lead manufacturing party for TRU-016 and if we opt-out of the collaboration as allowed under the collaboration agreement, and are the lead TRU-016 manufacturing party at that time, we would be obligated to continue to supply TRU-016 to Abbott for up to 18 months.

Risks Related to Product Development

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

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

- successful development, formulation and cGMP scale-up of biological manufacturing that meets FDA requirements;
- successful development of animal models;
- successful completion of non-clinical development, including studies in approved animal models;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- successful completion of clinical trials;
- receipt of marketing approvals from the FDA and equivalent foreign regulatory authorities;
- procurement of our biodefense product candidates prior to FDA approval;
- establishing commercial manufacturing processes of our own or arrangements with contract manufacturers;
- manufacturing stable commercial supplies of product candidates, including materials based on recombinant technology;
- launching commercial sales of the product candidate, whether alone or in collaboration with others; and
- acceptance of the product candidate by potential government customers, physicians, patients, healthcare payors and others in the medical community.

If, as a result of the foregoing factors or otherwise, we are prevented from developing and commercializing a product candidate in an economically acceptable manner, that product program may be adversely affected and the commercial success of the product candidate may be harmed. For example, we recently agreed with one of our contract manufacturers to extend the commencement date of the commercial term for manufacture of our anthrax immune globulin therapeutic product candidate. We are currently in negotiations with that contract manufacturer for a longer-term resolution regarding commercial production; however, in the event that we are not able to negotiate a satisfactory resolution we may be required to explore other options for our anthrax immune globulin program that could result in less favorable commercial success for this product candidate, or no commercial success at all.

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

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive preclinical studies and clinical trials to establish proof of concept, safety and efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete, and the outcome of such trials is uncertain. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. For example, in December 2008, we and Sanofi Pasteur determined that the joint efforts of our collaboration related to our meningitis B product development program had not identified a viable product candidate, which effectively ended most development activities under this collaboration.

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

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

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;
- regulators may determine that service providers we use in the conduct of a clinical trial are precluded from providing such services;
- the cost of our clinical trials could escalate and become cost prohibitive;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

In addition, because some of our current and future vaccine product candidates contain live attenuated viruses, our testing of these vaccine product candidates is subject to additional risk. For example, there have been reports of serious adverse events following administration of live vaccine products in clinical trials conducted by other vaccine developers. Also, for some of our current and future vaccine product candidates, we expect to conduct clinical trials in chronic carriers of the disease that our product candidate seeks to prevent. There have been reports of disease flares in chronic carriers following administration of live vaccine products.

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

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

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

Under the Project BioShield Act, the Secretary of HHS can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA. However, our biodefense product candidates might not be selected by the Secretary under this authority. Moreover, this authority could result in increased competition for our products and product candidates.

Risks Related to Commercialization

If we fail to achieve significant sales of BioThrax to customers in addition to the U.S. government, our opportunities for growth could be harmed.

An element of our business strategy is to establish a market for sales of BioThrax to customers in addition to the U.S. government. These potential customers include foreign governments and state and local governments, which we expect will be interested in BioThrax to protect emergency responders such as police, fire and emergency medical personnel, multinational companies, non-governmental organizations and hospitals.

The market for sales of BioThrax to customers other than the U.S. government is undeveloped, and we may not be successful in generating meaningful sales of BioThrax to these potential customers. To date, we have supplied only small amounts of BioThrax directly to several foreign governments and our sales of BioThrax to customers other than the U.S. government has represented a small portion of our revenue. If we fail to significantly increase our sales of BioThrax to these customers, our business and opportunities for growth could be materially harmed.

Government regulations may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, many foreign governments require licensure of BioThrax in their jurisdiction before they will consider procuring doses. Additionally, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of BioThrax and related technology, the U.S. government may decide, particularly in the current environment of elevated concerns about global terrorism, to increase the scope of export prohibitions. These prohibitions could limit our sales of BioThrax to foreign governments and other foreign customers. In addition, U.S. government demand for an anthrax vaccine may limit supplies of BioThrax available for sale to non-U.S. government customers. For example, our efforts to develop domestic commercial and international sales may be impeded by the DoD's right under the Defense Production Act to require us to deliver more doses than we currently anticipate. Furthermore, the DoD's sale of BioThrax to foreign governments under the Foreign Military Sales program has had and may continue to have an adverse effect on our ability to sell BioThrax internationally.

Our ability to meet any potential increased demand that develops for sales of BioThrax to customers other than the U.S. government depends on our available production capacity. We use substantially all of our current production capacity at our FDA-approved manufacturing facility in Lansing, Michigan to manufacture BioThrax for current sales to U.S. government customers. Additionally, we have constructed Building 55, a large-scale manufacturing facility at our Lansing campus that is available for large-scale production of BioThrax, subject to final qualification and validation activities. To prepare for the event that we obtain significant orders for BioThrax from customers other than the U.S. government that cannot be accommodated by our existing facilities, we may explore additional manufacturing alternatives that would enable us to increase our manufacturing capacity and, as a result, allow us to increase sales of BioThrax to customers other than the U.S. government. If we are successful in this effort, it could be several years until a facility is qualified and validated and able to produce saleable vaccine. If we are unsuccessful in this effort, our opportunities for growth could be limited.

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

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

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

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

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

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

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

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

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

The use of vaccines carries a risk of adverse health effects. The adverse reactions that have been associated with the administration of BioThrax include local reactions, such as redness, swelling and temporary limitation of motion in the inoculated arm, and systemic reactions, such as headache, fever, chills, nausea and general body aches. In addition, some serious adverse events have been reported to the vaccine adverse event reporting system database maintained by the CDC and the FDA with respect to BioThrax, including diabetes, heart attacks, autoimmune diseases, including Guillian Barre syndrome, lupus, multiple sclerosis, lymphoma and death. None of these events have been causally linked to the administration of BioThrax. The report of any adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event.

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

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

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

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

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Furthermore, lawsuits brought against us by third parties or activists, even if not successful, require us to spend time and money defending the related litigation. The need to address political and social issues may divert our management's time and attention from other business concerns. For example, between 2001 and 2006, members of the military and various activist groups who oppose mandatory inoculation with BioThrax petitioned the FDA and the federal courts to revoke the license for BioThrax and to terminate the DoD program for the mandatory administration of BioThrax to military personnel. Although the DoD has prevailed in those challenges to date, the actions of these groups have created negative publicity about BioThrax.

Additional lawsuits, publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of, and thereby limit the demand for, BioThrax and our biodefense product candidates. In such event, our ability to market and sell such products may be hindered and the commercial success of BioThrax and other products we develop will be harmed, thereby reducing our revenues.

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

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

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

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

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

Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. We believe that our most significant competitors in the area of vaccine and therapeutics are a number of pharmaceutical companies that have vaccine programs, including Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Pfizer, and Novartis, as well as smaller more focused companies engaged in vaccine and therapeutic development, such as Aeras, Crucell, Cangene, Human Genome Sciences, Soligenix, Dynport Vaccine Company, Elusys, Bavarian Nordic and PharmAthene.

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

Although BioThrax is the only anthrax vaccine approved by the FDA for the prevention of anthrax infection, the government is funding the development of new products that could compete with BioThrax, and could eventually procure those new products in addition to, or instead of, BioThrax, potentially reducing our BioThrax revenues. We also face competition for our biodefense product candidates. For example, HHS has awarded a development and SNS procurement contract to a competitor for an anthrax immune globulin therapeutic and is assisting this company in its production efforts by providing it with BioThrax doses that we delivered for placement into the SNS so that the competitor can immunize donors and obtain plasma for the competitor's anthrax immune globulin therapeutic product candidate. HHS has awarded another development and SNS procurement contract to another competitor for an anthrax monoclonal antibody as a post-exposure therapeutic for anthrax infection.

Numerous companies have vaccine product candidates in development that would compete with any of our commercial product candidates for which we are seeking to obtain marketing approval. One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the U.S. and Europe. The Aeras Global Tuberculosis Vaccine Foundation is developing or supporting the development of five tuberculosis vaccine product candidates in addition to ours, any of which could present competitive risks. If approved for the treatment of RA, we anticipate that some of our commercial product candidates would compete with other marketed protein therapeutics for the treatment of RA, including: Enbrel ® (Amgen, Pfizer and Takeda), Remicade ® (Centocor Ortho Biotech, Merck and Mitsubishi Tanabe), Humira ® (Abbott and Eisai), Orencia ® (BMS), Cimzia ® (UCB and Otsuka), Simponi ® (Centocor Ortho Biotech and Merck), Actemra ® (Roche and Chugai) and Rituxan ® (Genentech, Roche and Biogen Idec). If approved for the treatment of SLE, our product candidates will compete with other therapies. If approved for the treatment of CLL, NHL, or other B-cell malignancies, we anticipate that our product candidates would compete with other B-cell depleting therapies. While we are not aware of any CD37- directed therapeutics in development or on the market, other biologic therapies are marketed for the treatment of NHL or CLL or both, such as Rituxan/Mabthera ® (Genentech, Roche and Biogen Idec), Zevalin ® (Spectrum Pharmaceuticals, Inc. and Bayer Schering AG), Bexxar ® (GSK), Campath ® (Genzyme and Bayer Schering AG), Treanda ® (Cephalon Oncology) and Arzerra ® (GSK and Genmab).

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early stage companies may also prove to be significant competitors, particularly through competing for government funding and through collaborative arrangements with large and established companies. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring products, product candidates and technologies complementary to, or necessary for, our programs or advantageous to our business.

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

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

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

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

In addition, although our prior contracts with the DoD and HHS provided that the U.S. government would indemnify us for any damages resulting from product liability claims, our current contracts with HHS do not contain such indemnification, and we may not be able to negotiate similar indemnification provisions in future contracts.

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

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

BioThrax is currently identified as a covered countermeasure under a PREP Act declaration issued in October 2008, which provides us with immunity with respect to the manufacture, administration or use of BioThrax. Under our prior BioThrax contracts with the DoD and HHS, the U.S. government agreed to indemnify us against claims by third parties for death, personal injury and other damages related to BioThrax, including reasonable litigation and settlement costs, to the extent that the claim or loss results from specified risks not covered by insurance or caused by our grossly negligent or criminal behavior. As required under our prior BioThrax contracts, we have notified the DoD of personal injury claims that have been filed against us as a result of the vaccination of U.S. military personnel with BioThrax and are seeking reimbursement from the DoD for uninsured costs incurred in defending these claims. The collection process can be lengthy and complicated, and there is no guarantee that we will be able to recover these amounts from the U.S. government.

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

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

- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently have product liability insurance for coverage up to a $15 million annual aggregate limit with a deductible of $75,000 per claim up to $375,000 in aggregate. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Product liability insurance is difficult to obtain and increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. For example, from 2002 through February 2006, we were unable to obtain product liability insurance for sales of BioThrax on commercially reasonable terms. We do not believe that the amount of insurance we have been able to obtain for BioThrax is sufficient to manage the risk associated with the potential large scale deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on statutory protections in addition to insurance to mitigate our liability exposure for BioThrax.

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

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

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

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

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

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

Medicare Part B reimburses for physician-administered drugs and biologics based on the product's "average sales price." This reimbursement methodology went into effect in 2005 and has generally led to lower Medicare reimbursement levels than under the reimbursement methodology in effect prior to that time. The Medicare Part D outpatient prescription drug benefit went into effect in January 2006. Coverage under Medicare Part D is provided primarily through private entities, which act as plan sponsors and negotiate price concessions from pharmaceutical manufacturers.

In March 2010, Congress enacted sweeping legislation to reform the U.S. health care system. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, generally is intended to expand health care coverage to currently uninsured Americans and to limit the rate of increase in health care spending. The legislation contains a number of cost-containment measures that could adversely affect our operating results and our overall financial condition. For example, the legislation imposes an annual fee on branded prescription drug manufacturers, including biologics manufacturers, which will be allocated based on market share in the aggregate for certain government programs. In addition, the legislation creates a licensure pathway for biological products shown to be biosimilar to previously licensed biological reference products, and will permit litigation of patent infringement cases between patent owners and biosimilar manufacturers prior to biosimilar market entry. The legislation also establishes a program to phase out the coverage gap under Medicare Part D by 2020 through a combination of manufacturer discounts and federal subsidies, and creates an Independent Payment Advisory Board to recommend changes in Medicare payment rates.

We expect the reforms imposed by the new law to have a significant impact on our business and the entire life sciences industry. Until many of the provisions are implemented, however, the full impact of the legislation cannot be known.

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

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

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

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

Proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could force us to lower the prices at which we sell any approved products and impair our ability to derive revenue from these products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have the right to use certain property and equipment that is owned by the U.S. government, referred to as government furnished equipment, or GFE, at our Lansing, Michigan site in the manufacture of BioThrax. We have the option to purchase all or part of the existing GFE from the U.S. government on terms to be negotiated with the U.S. government. If the U.S. government modifies the terms under which we use the GFE in a manner that is unfavorable to us, including substantially increasing the usage fee, or we are unable to reach an agreement with the U.S. government concerning the terms of the purchase of that part of the GFE necessary for our business, our business could be harmed. If the U.S. government were to terminate or fail to extend all BioThrax supply contracts with us, we potentially could be required to rent or purchase that part of the GFE necessary for the continued production of BioThrax in our current manufacturing facility.

Risks Related to Regulatory Approvals

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

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

In the United States, BioThrax and our product candidates are regulated by the FDA as biologics. To obtain approval from the FDA to market our product candidates, we will be required to submit to the FDA a BLA. Ordinarily, the FDA requires a sponsor to support a BLA with substantial evidence of the product's safety and effectiveness in treating the targeted indication based on data derived from adequate and well controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted. However, our biodefense product candidates require slightly different treatment. Specifically, because humans are rarely exposed to anthrax toxins under natural conditions, and cannot be intentionally exposed, statistically significant effectiveness of our biodefense product candidates cannot be demonstrated in humans, but instead must be demonstrated, in part, by utilizing animal models before they can be approved for marketing. This is known as the FDA's "animal rule".

We intend to use the animal rule in pursuit of FDA approval for BioThrax as a post-exposure prophylaxis, our anthrax immune globulin therapeutic, our rPA anthrax vaccine, our anthrax monoclonal antibody therapeutic, our next generation anthrax vaccine, and our double mutant rPA vaccine. We cannot guarantee that the FDA will permit us to proceed with licensure of any of our BioThrax related programs or our other product candidates under the animal rule. Even if we are able to proceed pursuant to the animal rule, the FDA may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products.

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

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

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

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

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

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

After approving the renovated Lansing facilities in December 2001, the FDA conducted routine, biannual inspections of the Lansing facilities in September 2002, May 2004, May 2006, March 2008 and December 2009. Following each of these inspections, the FDA issued inspectional observations on Form FDA 483, some of which were significant. We responded to the FDA regarding the inspectional observations relating to each inspection and, where necessary, implemented corrective action. All observations from each of those inspections were successfully closed out. In December 2005, the FDA stated in its final order on BioThrax that at that time we were in substantial compliance with all regulatory requirements related to the manufacture of BioThrax and that the FDA would continue to evaluate the production of BioThrax to assure compliance with federal standards and regulations. If in connection with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, or if the FDA is not satisfied with the corrective actions we take in connection with any such inspection, the FDA may undertake enforcement action against us.

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

- restrictions on the marketing or manufacturing of a product;
- warning letters;
- withdrawal of the product from the market;
- refusal to approve pending applications or supplements to approved applications;
- voluntary or mandatory product recall;
- fines or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals, including license revocation;
- shut down, or substantial limitations of the operations in, manufacturing facilities;
- refusal to permit the import or export of products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

If our competitors are able to obtain orphan drug exclusivity for their products that are the same as our products, we may be precluded from selling or obtaining approval of our competing products by the applicable regulatory authorities for a significant period of time.

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

Any collaboration that we enter into may not be successful. For example, based on preclinical studies performed under a license agreement that we entered into with Sanofi Pasteur, both parties determined that the joint efforts had not identified a promising meningitis B vaccine product candidate and we mutually terminated the collaboration.

Additionally, the success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. It is likely that our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations.

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

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

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

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

We do not have the ability to independently conduct the clinical or non-clinical trials required to obtain regulatory approval for our products. We depend on independent clinical investigators, contract research organizations and other third party service providers to conduct the clinical and non-clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical and non-clinical trials, but do not exercise day-to-day control over their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates. In addition, we encourage government entities and non-government organizations to conduct studies of, and pursue other development efforts for, our product candidates.

We expect to rely on data from clinical trials conducted by third parties seeking marketing approval for our product candidates. For example, our BLA supplement for a label expansion of BioThrax for a regimen of fewer doses is based on the results of a clinical trial conducted by the CDC. These government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. In addition, government entities depend on annual Congressional appropriations to fund these development efforts.

Risks Related to Our Intellectual Property

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

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

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

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

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not do so, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties.

For example, we licensed an oligonucleotide adjuvant, CpG 7909, for use in our double mutant rPA product candidate and our next generation anthrax vaccine product candidate from Coley Pharmaceutical Group, Inc., or Coley. Coley which was subsequently acquired by Pfizer Inc., is responsible for prosecuting, maintaining and defending these licensed patent rights. Coley notified us that a patent interference had been declared in the U.S. Patent and Trademark Office between our licensed patent and a third party patent application, which could result in revocation of the patent we have licensed. We may not know the outcome for a considerable period of time.

If we are unable to in-license any intellectual property necessary to develop, manufacture or sell any of our product candidates, we will not be successful in developing or commercializing such product candidate.

We expect that we may need to in-license various components or technologies, including, for example, adjuvants and novel delivery systems, for some of our current or future product candidates. We may be unable to obtain the necessary licenses on acceptable terms, or at all. If we are unable to obtain such licenses, we could be prevented or delayed from continuing further development or from commercially launching the applicable product candidate.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. For example, we consider our license from the Oxford-Emergent Tuberculosis Consortium for our tuberculosis vaccine product candidate to be material to our business. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

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

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for BioThrax or the label expansions and improvements that we are pursuing for BioThrax, our only intellectual property protection for BioThrax, other than the BioThrax trademark, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and biological starting materials. However, these types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, with agreements with our employees, consultants and third parties.

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

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

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

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

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology and pharmaceutical industries. For example, Bavarian Nordic sued Acambis for patent infringement and other claims arising out of Acambis' importation of an MVA-based smallpox vaccine for biodefense use by the U.S. government. Bavarian Nordic claimed that its patents broadly covered the manufacture of MVA-based biological products and that Bavarian Nordic had rights in the biological materials used by Acambis. The Acambis strain has a distinct lineage from the strains used by us. That litigation was terminated in July 2007 by a settlement and consent order. Bavarian Nordic subsequently sued Oxford BioMedica PLC, Oxford BioMedica Ltd. and Biomedica Inc., collectively Oxford BioMedica, alleging that Oxford BioMedica has infringed certain Bavarian Nordic U.S. patents by making, using and importing, and inducing others to use Oxford BioMedica's experimental drug TroVax®, which is an MVA-based therapeutic cancer vaccine. The Oxford BioMedica strain also has a distinct lineage from the strain used by us. The lawsuit was settled in January 2010 by agreement between the parties. While the terms of the settlement have not been published, the parties have announced that Oxford BioMedica received a license for TroVax under Bavarian Nordic's MVA patents, and in return Bavarian Nordic received a license under Oxford BioMedica's patents on heterologous prime boost technology and a sublicense under certain patents licensed by Sanofi to Oxford BioMedica. Typically, patent infringement settlements are structured to specifically cover the alleged infringing product, and the settlement has no direct impact on other products in the field. We have licensed from StMUG rights to materials and technology related to MVA. Our MVA platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based in part on these rights.

Our MVA platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based in part on rights to certain MVA-related materials and technology that we acquired from the Bavarian State Ministry of the Environment and Public Health. From 2006 to 2008, we filed patent oppositions in the European Patent Office against four of Bavarian Nordic's patents covering certain aspects of MVA technology. In each of the four pending opposition proceedings, the subject patents have also been opposed by one or more additional parties, including Sanofi Pasteur, Transgene, Baxter, Virbac, and Innogenetics. We and the other opponents have alleged that the opposed patents should be revoked for failure to fulfill one or more of the patentability requirements of the European Patent Convention, such as the requirements for novelty and inventive step. In each opposition, we expect that a single hearing will be held before the Opposition Division of the European Patent Office, in which each opponent will present oral argument and Bavarian Nordic will present rebuttal arguments. The first of these hearings, which occurred in June 2010, resulted in the Bavarian Nordic patent under consideration being maintained but narrowed in scope. A time period has been set for all parties to file appeals, and we anticipate all appeals to be filed by the due date of November 27, 2010. Hearings in two of the other pending oppositions occurred in October 2010. Bavarian Nordic introduced amended patent claims into the record, which claims were upheld strictly and expressly conditioned on such claims being interpreted within a narrowly-defined scope. The Opposition Division scheduled a hearing on the fourth pending opposition for January 2011. We routinely monitor the grant of further Bavarian Nordic European patents to determine whether any additional oppositions should be filed.

Risks Related to Our Acquisition Strategy

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

Since our inception we have pursued a strategy of growing our business through licensing and acquisition. We commenced operations in September 1998 through an acquisition of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how, all from the Michigan Biologic Products Institute. We acquired a portion of our pipeline of vaccine and therapeutic product candidates through our acquisition of Microscience Limited in a share exchange in 2005 and our acquisitions of substantially all of the assets, for cash, of Antex Biologics, Inc. in 2003 and of ViVacs GmbH in 2006. More recently, we acquired additional pipeline product candidates as a result of our acquisition of Trubion, which we completed in October 2010.

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

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

In addition, we expect competition for acquisition candidates in the vaccine and therapeutic field to increase, which may result in fewer suitable acquisition opportunities for us as well as higher acquisition prices. If we are unable to successfully obtain rights to suitable products and product candidates, including through the acquisition of Trubion, our business, financial condition and prospects for growth could suffer.

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

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

- use of cash resources;
- higher than anticipated acquisition costs and expenses;
- potentially dilutive issuances of equity securities;
- the incurrence of debt and contingent liabilities, impairment losses or restructuring charges;
- large write-offs and difficulties in assessing the relative percentages of in-process research and development expense that can be immediately written off as compared to the amount that must be amortized over the appropriate life of the asset; and
- amortization expenses related to other intangible assets.

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

- challenges associated with managing an increasingly diversified business;
- prioritizing product portfolios;
- disruption of our ongoing business;
- difficulty and expense in assimilating and integrating the operations, products, technology, information systems or personnel of the acquired company;
- diversion of management's time and attention from other business concerns;
- inability to maintain uniform standards, controls, procedures and policies;
- the assumption of known and unknown liabilities of the acquired company, including intellectual property claims;
- challenges and costs associated with reductions in work force; and
- subsequent loss of key personnel.

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

Risks Related to Our Common Stock

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

Mr. El-Hibri has the ability to control the election of the members of our Board of Directors through his ownership interests among our significant stockholders. As of October 29, 2010, Mr. El-Hibri was the beneficial owner of approximately 32% of our outstanding common stock. Because Mr. El-Hibri has significant influence over the election of the members of our board, and because of his substantial control of our capital stock, Mr. El-Hibri will likely have the ability to delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

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

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

These provisions include:

- the classification of our directors;
- limitations on changing the number of directors then in office;
- limitations on the removal of directors;
- limitations on filling vacancies on the board;
- limitations on the removal and appointment of the chairman of our Board of Directors;
- advance notice requirements for stockholder nominations for election of directors and other proposals;

- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval.

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

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

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

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

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

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

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through October 29, 2010, our common stock has traded as high as $27.00 per share and as low as $4.40 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

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

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. For example, we have filed a registration statement that would permit us to issue up to $100 million in common stock. Moreover, holders of an aggregate of approximately 10.0 million shares of our common stock outstanding as of October 29, 2010 have the right to require us to register these shares of common stock under specified circumstances.

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

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

Not applicable.

Purchases of Equity Securities

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. REMOVED AND RESERVED

ITEM 5. OTHER INFORMATION

On November 3, 2010, we and the contract manufacturer of our anthrax immune globulin therapeutic product candidate, Talecris Biotherapeutics, Inc., or Talecris, agreed to extend the commencement date of the commercial manufacturing term for that product candidate to July 31, 2011. In the event that we request Talecris to produce any quantities of the product candidate before or after commencement of the commercial term, the parties are required to negotiate in good faith as to the timing, price, quantity and support, among other terms, of such production, subject to Talecris' right to delay or refuse such specific request.

ITEM 6.

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

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

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

Date: November 4, 2010

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

Date: November 4, 2010

EXHIBIT INDEX

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated August 12, 2010, among the Registrant, Trubion Pharmaceuticals, Inc., 35406 LLC, and 30333 Inc. (Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on August 13, 2010)
2.2	Amendment No. 1 to Agreement and Plan of Merger, dated September 29, 2010, among the Registrant, Trubion Pharmaceuticals, Inc., 35406 LLC, and 30333 Inc. (Incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on September 30, 2010)
10.1	Contingent Value Rights Agreement, dated August 12, 2010, among the Registrant, Trubion Pharmaceuticals, Inc. and Mellon Investor Services LLC, as rights agent (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on August 13, 2010)
10.2	Form of Support Agreement, dated August 12, 2010, between the Registrant and certain former holders of common stock of Trubion Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on August 13, 2010)
10.3	Form of Lock-up Agreement, dated August 12, 2010, between the Registrant and certain former holders of common stock of Trubion Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on August 13, 2010)
10.4 #†	Contract No. HHSO100201000034C, dated July 13, 2010, between Emergent BioDefense Operations Lansing Inc. and the Department of Health and Human Services
10.5 #†	Modification No. 9 to Contract No. 200-2009-30162, dated July 16, 2010, between Emergent BioDefense Operations Lansing Inc. and the Centers for Disease Control and Prevention
10.6 #†	Contract No. HHSO100201000059C, dated September 17, 2010, between Emergent Product Development Gaithersburg Inc. and the Department of Health and Human Services
10.7 #	Modification No. 7 to Contract No. HHSO100200700037C, dated September 22, 2010, between Emergent BioDefense Operations Lansing Inc. and the Department of Health and Human Services
10.8 #	Amendment No. 5 to Product Supply Agreement, dated November 3, 2010, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics, Inc.
31.1	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Filed herewith

† Confidential treatment requested. Confidential materials omitted and filed separately with the Securities and Exchange Commission.