Emergent BioSolutions Inc.
Form 10-Q
May 06, 2011

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 March 31, 2011

OR

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

For the transition period from to

Commission file number: 001-33137

EMERGENT BIOSOLUTIONS INC.
(Exact Name of Registrant as Specified in Its Charter)

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

(301) 795-1800
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. 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 April 29, 2011, the registrant had 35,507,560 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 contracts with the U.S. government related to BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, including the timing of deliveries;
- our plans for future sales of BioThrax, including our ability to obtain new contracts or modifications to existing contracts with the U.S. government;
- our plans to pursue label expansions and other improvements for BioThrax;
- our ability to perform under our development contract with the U.S. government for our product candidate PreviThraxTM (Recombinant Protective Antigen Anthrax Vaccine, Purified);
- 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 plans to expand our manufacturing facilities and capabilities;
- the rate and degree of market acceptance of our products and product candidates;
- the success of preclinical studies and clinical trials of our product candidates and post-approval clinical utility of our products;
- our ongoing and planned development programs, preclinical studies and clinical trials;
- our ability to identify and acquire or in-license products and product candidates that satisfy our selection criteria;
- our ability to successfully integrate and develop the products or product candidates, programs, operations and personnel of any entities or businesses that we acquire, including those of Trubion Pharmaceuticals, Inc., which we acquired in October 2010;
- the potential benefits of our existing collaborations and our ability to selectively enter into additional collaborative arrangements;
- the timing of and our ability to obtain and maintain regulatory approvals for our products and product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property portfolio; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

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

You should read this quarterly report, including the documents that we have incorporated by reference herein 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)

	March 31, 2011	December 31, 2010
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	$136,925	$169,019
Investments	6,338	2,029
Accounts receivable	11,976	39,326
Inventories	22,163	12,722
Deferred tax assets, net	6,743	2,638
Income tax receivable, net	23,966	8,728
Restricted cash	217	217
Prepaid expenses and other current assets	7,875	8,814
Total current assets	216,203	243,493
Property, plant and equipment, net	157,963	152,701
In-process research and development	51,400	51,400
Goodwill	5,029	5,029
Assets held for sale	12,741	12,741
Deferred tax assets, net	26,812	33,757
Other assets	1,129	1,198
Total assets	$471,277	$500,319
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$24,034	$25,409
Accrued expenses and other current liabilities	1,257	1,309
Accrued compensation	13,687	23,975
Contingent value rights, current portion	9,113	-
Long-term indebtedness, current portion	16,927	17,187
Deferred revenue, current portion	5,916	7,839
Total current liabilities	70,934	75,719
Contingent value rights, net of current portion	6,000	14,532
Long-term indebtedness, net of current portion	29,657	30,239
Deferred revenue, net of current portion	3,823	4,386
Other liabilities	1,940	1,882
Total liabilities	112,354	126,758
Commitments and contingencies	-	-

Stockholders’ equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 35,424,190 and 35,011,423 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively	35	35
Additional paid-in capital	204,367	197,689
Accumulated other comprehensive loss	(2,803)	(2,110)
Retained earnings	152,453	173,850
Total Emergent BioSolutions Inc. stockholders' equity	354,052	369,464
Noncontrolling interest in subsidiaries	4,871	4,097
Total stockholders’ equity	358,923	373,561
Total liabilities and stockholders’ equity	$471,277	$500,319

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

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

	Three Months Ended March 31,	
	2011	2010
	(Unaudited)	
Revenues:		
Product sales	$5,597	$38,853
Contracts and grants	12,936	7,947
Total revenues	18,533	46,800
Operating expenses:		
Cost of product sales	1,068	7,508
Research and development	34,759	19,922
Selling, general and administrative	18,212	16,192
Income (loss) from operations	(35,506)	3,178
Other income (expense):		
Interest income	35	388
Interest expense	-	(5)
Other income (expense), net	(1)	(8)
Total other income (expense)	34	375
Income (loss) before provision for (benefit from) income taxes	(35,472)	3,553
Provision for (benefit from) income taxes	(12,299)	1,635
Net income (loss)	(23,173)	1,918
Net loss attributable to noncontrolling interests	1,776	605
Net income (loss) attributable to Emergent BioSolutions Inc.	$(21,397)	$2,523
Earnings per share - basic	$(0.61)	$0.08
Earnings per share - diluted	$(0.61)	$0.08
Weighted-average number of shares - basic	35,179,317	30,879,970
Weighted-average number of shares - diluted	35,179,317	31,432,751

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

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

	Three Months Ended March 31,	
	2011	2010
	(Unaudited)	
Cash flows from operating activities:		
Net income (loss)	$(23,173)	$1,918
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	2,441	1,522
Depreciation and amortization	2,235	1,296
Deferred income taxes	2,879	819
Non-cash development expenses from joint ventures	2,550	17
Loss (gain) on disposal of property and equipment	13	(34)
Provision for impairment of long-lived assets	-	548
Provision for fair value of contingent value rights	581	-
Excess tax benefits from stock-based compensation	(39)	(376)
Changes in operating assets and liabilities:		
Accounts receivable	27,350	21,467
Inventories	(9,441)	(3,560)
Income taxes	(15,238)	(2,459)
Prepaid expenses and other assets	1,008	576
Accounts payable	(453)	1,115
Accrued expenses and other liabilities	6	146
Accrued compensation	(10,288)	(5,580)
Deferred revenue	(2,486)	(14)
Net cash provided by (used in) operating activities	(22,055)	17,401
Cash flows from investing activities:		
Purchases of property, plant and equipment	(8,432)	(5,030)
Purchase of investments	(4,309)	-
Net cash used in investing activities	(12,741)	(5,030)
Cash flows from financing activities:		
Proceeds from borrowing on line of credit	-	15,000
Issuance of common stock subject to exercise of stock options	4,198	1,253
Principal payments on long-term indebtedness and line of credit	(842)	(15,755)
Excess tax benefits from stock-based compensation	39	376
Net cash provided by financing activities	3,395	874
Effect of exchange rate changes on cash and cash equivalents	(693)	215
Net increase (decrease) in cash and cash equivalents	(32,094)	13,460
Cash and cash equivalents at beginning of period	169,019	102,924
Cash and cash equivalents at end of period	$136,925	$116,384

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

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EMERGENT BIOSOLUTIONS INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Summary of significant accounting policies

Basis of presentation and consolidation

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

The unaudited consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2010, as filed with the Securities and Exchange Commission.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of March 31, 2011 and the results of operations and cash flows for the three month periods ended March 31, 2011 and 2010. 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 (loss) per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income (loss) by the weighted average number of shares outstanding for the period. Diluted net income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock.

The following table presents the calculation of basic and diluted net income (loss) per share:

	Three Months Ended March 31,	
(in thousands, except share and per share data)	2011	2010
Numerator:		
Net income (loss)	$(21,397)	$2,523
Denominator:		
Weighted-average number of shares—basic	35,179,317	30,879,970
Dilutive securities—equity awards	-	552,781
Weighted-average number of shares—diluted	35,179,317	31,432,751
Earnings per share-basic	$(0.61)	$0.08
Earnings per share-diluted	$(0.61)	$0.08

For the three month period ended March 31, 2011, no equity awards were included in the calculation of diluted earnings per share because the net loss attributable to Emergent BioSolutions Inc. would make these equity awards antidilutive. For the three month period ended March 31, 2010, outstanding stock options to purchase approximately 2.1 million shares of common stock are not considered in the diluted earnings per share calculation because the exercise price of these options is greater than the average per share closing price during the year.

Accounting for stock-based compensation

As of March 31, 2011, 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 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 March 31,	
	2011	2010
Expected dividend yield	0 %	0 %
Expected volatility	60 %	55 %
Risk-free interest rate	1.04 %	1.50 %
Expected average life of options	3.4 years	3.4 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 (implied volatility) during a period. The Company analyzed its own historical volatility to estimate expected volatility over the same period as the expected average life of the options.
- Risk-free interest rate — the 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.

Comprehensive income (loss)

Comprehensive income (loss) is comprised of net income (loss) and other changes in equity that are excluded from net income (loss). The Company includes gains and losses on intercompany transactions with foreign subsidiaries that are considered to be long-term investments and translation gains and losses incurred when converting its subsidiaries' financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income (loss). Comprehensive loss for the three months ended March 31, 2011 was $22.1 million. Comprehensive income for the three months ended March 31, 2010 was $2.7 million.

2. Inventories

Inventories consist of the following:

(in thousands)	March 31, 2011	December 31, 2010
Raw materials and supplies	$2,264	$2,311
Work-in-process	12,339	7,917
Finished goods	7,560	2,494
Total inventories	$22,163	$12,722

3. Fair value measurements

The Company measures and records cash equivalents and investment securities considered available-for-sale at fair value in the accompanying financial statements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value include:

Level 1 — Observable inputs for identical assets or liabilities such as quoted prices in active markets;
Level 2 — Inputs other than quoted prices in active markets that are either directly or indirectly observable; and
Level 3 — Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

The following table represents the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2011:

(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				

Investment in money market funds (1)	$78,381	$-	$-	$78,381
U.S. Treasury securities (2)	-	6,338	-	6,338
Total assets	$78,381	$6,338	$-	$84,719
Liabilities:				
Contingent value rights	$-	$-	$15,113	$15,113
Total liabilities	$-	$-	$15,113	$15,113

(1) Included in cash and cash equivalents in accompanying consolidated balance sheets.
(2) Included in investments in accompanying consolidated balance sheets.

For the three months ended March 31, 2010, the Company had no assets or liabilities that were measured at fair value on a recurring basis.

The fair value of the Contingent Value Right (“CVR”) obligations are based on management’s assessment of certain development and collaboration milestones, which are inputs that have no observable market (Level 3). The obligation is measured using a discounted cash flow model.

The following table is a reconciliation of the beginning and ending balance of the liabilities measured at fair value using significant unobservable inputs (Level 3) for the three months ended March 31, 2011.

(in thousands)	
Balance at January 1, 2011	$14,532
Expense (income) included in earnings	581
Purchases, sales, issuances and settlements	-
Transfers in/(out) of Level 3	-
Balance at March 31, 2011	$15,113

For the three months ended March 31, 2011, the changes in the fair value of the CVR obligations resulted from an adjustment to the discount rates and a update to the estimated timing of achievement for certain development milestones. For the three months ended March 31, 2011, the Company recorded a charge to adjust the CVRs to fair value of $581,000. This charge is classified in the Company's statement of operations as research and development within the Company's biosciences segment.

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. As of March 31, 2011 and 2010, the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis.

The carrying amounts of the Company's short-term financial instruments, which include cash, 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 quoted prices for the same or similar issues or on the current rates offered to the Company for debt of the same remaining maturities. Both the carrying value and fair value of long-term indebtedness at March 31, 2011 was $46.6 million. The carrying value and fair value of long-term indebtedness was $50.0 million and $49.7 million, respectively, at March 31, 2010.

4. Investments

The Company invests in a variety of highly liquid investment-grade securities. The following is a summary of the Company's available for sale securities at March 31, 2011:

(in thousands)	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Market Value
Money market funds	$78,381	$-	$-	$78,381
U.S. Treasury securities	6,338	-	-	6,338
Total	84,719	-	-	84,719
Less: cash equivalents	(78,381)	-	-	(78,381)
Amounts classified as investments	$6,338	$-	$-	$6,338

5. Stock options and restricted stock units

As of March 31, 2011, 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 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 March 31, 2011, an aggregate of 8,678,826 shares of common stock are authorized for issuance under the 2006 Plan, of which a total of 2,129,771 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 one 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, 2010	3,397,915	$ 14.31	67,541	$ 9.80	$32,023,466
Granted	732,727	24.15	-	-	
Exercised	(340,027)	12.35	-	-	
Forfeited	(72,751)	17.69	-	-	
Outstanding at March 31, 2011	3,717,864	$ 16.36	67,541	$ 9.80	$29,969,023
Exercisable at March 31, 2011	1,838,779	$ 13.24	67,541	$ 9.80	$21,043,025

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, 2010	395,555	$ 16.09	$9,279,720
Granted	366,373	24.15	
Vested	(109,577)	15.91	
Forfeited	(16,304)	18.25	
Outstanding at March 31, 2011	636,047	$ 20.71	$15,366,896

6. Litigation

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, a single hearing was held before the Opposition Division of the European Patent Office, in which each opponent presented oral argument and Bavarian Nordic presented 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. The Opposition Division set a date of November 27, 2010 for all parties to file appeals, and the Company timely filed its appeal. 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 set due dates of January 29, 2011 and February 7, 2011 for Notices of Appeal to be filed for these Oppositions, and the Company timely filed its Notices of Appeal. The Company's Appeal Briefs were also timely filed. The Opposition Division held its hearing for the fourth pending opposition in January 2011. As for the previous Oppositions, Bavarian Nordic introduced amended patent claims into the record, and the Opposition Division upheld the amended claims, which are narrower in scope than the originally granted claims. A due date has not yet been set for the parties to file their appeals. 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 made allegations related to the Acquisition that are substantially similar to those matters alleged in the Amended Complaint and includes additional allegations regarding purported violations of the federal securities laws and sought 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. 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. The Actions were stayed pending approval of the settlement of the State Action by the State Court, after which 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. On April 26, 2011, the State Court entered an order granting preliminary approval of the settlement and requiring that notice of the settlement and preliminary approval be mailed to class members by May 17, 2011. The order also provides that all class members who wish to be excluded from the settlement of the Actions give notice by June 21, 2011. The State Court's hearing to determine whether the settlement is fair, reasonable and adequate to the class members and should be approved is scheduled to occur on July 29, 2011. 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.

7. Segment information

For financial reporting purposes, the Company reports financial information for two business segments: biodefense and biosciences. 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® (Anthrax Vaccine Absorbed). In the biosciences segment, the Company develops vaccines, antibody therapies and technology platforms for use against infectious diseases, oncology, autoimmune and inflammatory disorders 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 biosciences. The assets in this segment consist primarily of cash. For the period ended March 31, 2010, the Company reclassified its business segments to conform with the current period presentation.

	Reportable Segments			
(in thousands)	Biodefense	Biosciences	All Other	Total
Three Months Ended March 31, 2011				
External revenue	$15,500	$3,033	$-	$18,533
Net loss attributable to Emergent BioSolutions Inc.	(6,092)	(15,125)	(180)	(21,397)
Assets	179,732	107,927	183,618	471,277
Three Months Ended March 31, 2010				
External revenue	$46,800	$-	$-	$46,800
Net income (loss) attributable to Emergent BioSolutions Inc.	13,385	(9,606)	(1,256)	2,523
Assets	193,175	41,270	108,346	342,791

8. 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 three months ended March 31, 2011.

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 paid in six equal monthly installments concluding in March 2011.

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 three months ended March 31, 2011, the Company paid approximately $15,000 for services rendered under this agreement, of which $15,000 remained in accounts payable at March 31, 2011.

The Company entered into a transportation arrangement with an entity owned by the Company's Chief Executive Officer. This agreement was terminated in February 2011 with an effective termination date of December 31, 2010.

The Company has entered into a consulting agreement with a member of the Company's Board of Directors. For each of the three month periods ended March 31, 2011 and 2010, the Company paid approximately $45,000 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 March 31, 2011.

9. Variable interest entities

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 service 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 March 31, 2011 and 2010, respectively, assets of $413,000 and $79,000 and liabilities of $513,000 and $66,000 related to OETC are included within the Company's consolidated balance sheet. During the three months ended March 31, 2011 and 2010, respectively, the OETC incurred net losses of $3.6 million and $1.2 million of which $1.8 million and $630,000 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 March 31, 2011.

In July 2010, the Company entered into a collaboration with Temasek Life Sciences Ventures Pte Limited to advance the development of monoclonal products for worldwide prophylaxis or treatment of infection caused by existing pandemic influenza strains or anticipated future pandemic influenza strains via a hemagglutinin-based medical countermeasure, resulting in the formation of EPIC Bio Pte Limited ("EPIC"). The Company has a 60% equity interest in EPIC and controls the EPIC Board of Directors. The Company has evaluated its variable interests in EPIC and has determined that it is the primary beneficiary as it has the ability to direct the activities of EPIC and will absorb the majority of expected losses. Accordingly, the Company consolidates the entity. As of March 31, 2011, assets of $1.9 million and liabilities of $423,000 related to EPIC are included within the Company's consolidated balance sheet. During the three months ended March 31, 2011, EPIC incurred net losses of $24,000 of which $14,000 is included in the Company's consolidated statement of operations.

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, 2010	$ 369,464	$ 4,097	$373,561
Non-cash development expenses from joint ventures	-	2,550	2,550
Net income (loss)	(21,397)	(1,776)	(23,173)
Other	5,985	-	5,985
Stockholders' equity at March 31, 2011	$ 354,052	$ 4,871	$358,923

10. Restructuring

In November 2010, the Company adopted a plan to restructure and reprioritize the operations of Emergent Product Development UK Limited ("EPDU"). The Company has made estimates and judgments regarding the amount and timing of this restructuring expense and liability, including current and future period termination benefits and other exit costs to be incurred when related actions take place. The Company has also assessed the recoverability of certain long-lived assets employed in the business and in certain instances shortened the expected useful life of the assets based on changes in their expected use. When the Company determines that the useful lives of assets are shorter than it had originally estimated, the Company records additional depreciation to reflect the assets' new shorter useful lives. Severance and other related costs and asset-related charges are reflected within the Company's consolidated statement of income as a component of selling, general and administrative expense within the Company's biosciences segment. Actual results may differ from these estimates.

The Company expects to complete this restructuring in the first half of 2011, and estimates that the total cost of the restructuring will be approximately $6.3 million. These estimated costs are detailed below:

(in thousands)	Incurred in 2011	Inception to Date Cost Incurred	Total Expected to be Incurred
Termination benefits	$466	$2,884	$3,000
Contract termination costs	-	650	2,800
Other costs	-	260	500
Total	$466	$3,794	$6,300

The following is a summary of the activity for the liabilities related to the EPDU restructuring:

(in thousands)	Termination Benefits	Lease Termination Costs	Total
Balance at December 31, 2010	$ 2,418	$ 650	$ 3,068
Expenses incurred	466	-	466
Amount paid	(1,808)	-	(1,808)
Other adjustments	-	-	-
Balance at March 31, 2011	$ 1,076	$ 650	$ 1,726

11. 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. 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. No impairment charge was recorded for the three months ended March 31, 2011. The Company recorded an impairment charge of $548,000 for the three months ended March 31, 2010. This charge was classified in the Company's statement of operations as selling, general and administrative expense within the Company's biosciences segment. The Company continues to actively seek to sell these buildings.

12. Subsequent events

In April 2011, the Company entered into a modification of its current procurement contract with the U.S. government to supply an additional 3.4 million doses of BioThrax at a value of up to $101 million.

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 protecting and enhancing life by developing and manufacturing vaccines and antibody therapeutics that are supplied to healthcare providers and purchasers for use in preventing and treating disease. For financial reporting purposes, we operate in two business segments, biodefense and biosciences.

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 PreviThraxTM (Recombinant Protective Antigen Anthrax Vaccine, Purified), Anthrivig TM (Human Anthrax Immunoglobulin), Thravixa TM (Fully Human Anthrax Monoclonal Antibody), NuThrax TM (Anthrax Vaccine Absorbed with CPG 7909 Adjuvant) and a double mutant recombinant protective antigen anthrax vaccine. Operations in this segment include biologics manufacturing, regulatory and quality affairs, marketing and sales in support of BioThrax and a product development infrastructure in support of our investigational product candidates.

Our biosciences segment is directed to commercial opportunities. Our programs in this segment target oncology, including B-cell malignancies of chronic lymphocytic leukemia, or CLL, and non-Hodgkin’s lymphoma, or NHL; autoimmune and inflammatory disorders, or AIID, including rheumatoid arthritis, or RA, and systemic lupus erythematosus, or SLE; and other infectious diseases such as tuberculosis, influenza and typhoid. Our programs in this segment include clinical and preclinical stage investigational product candidates. Operations in this segment include product development in support of our investigational product candidates, and manufacturing and related infrastructure initiatives in support of our technology platforms.

Our biodefense segment has generated net income for each of the last five fiscal years. Over this timeframe, our biosciences segment has generated revenue through development contracts and grant funding, but none of our biosciences product candidates has received marketing approval and, therefore, our biosciences segment has not generated any product sales revenues. As a result, our biosciences 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 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 $5.6 million and $38.9 million for the three months ended March 31, 2011 and 2010, 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 funding for the following development programs:

- BioThrax post-exposure prophylaxis;
- NuThrax;
- Large-scale manufacturing for BioThrax;
- PreviThrax;
- Anthrivig;
- Thravixa;
- Double mutant recombinant protective antigen anthrax vaccine;
- Recombinant botulinum vaccine; and
- Typhella

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. Our TRU-016 product candidate is being funded via our collaboration with Abbott Laboratories, or Abbott, in which we and Abbott share all funding responsibilities equally. Our SBI-087 product candidate is substantially funded by Pfizer Inc., or Pfizer.

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.

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.

Critical Accounting Policies and Estimates

There have been no significant changes to our Critical Accounting Policies and Estimates during the three months ended March 31, 2011. Refer to the Critical Accounting Policies and Estimates section in our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the Securities and Exchange Commission.

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. In April 2011, we entered into a modification to this contract to supply an additional 3.4 million doses at a value of up to $101 million. The term of the agreement is from September 30, 2008 through September 30, 2011. Funds for the procurement of these doses of BioThrax have been fully committed. The total purchase price of the modified contract for 17.9 million doses is approximately $500 million. Through March 31, 2011, we have delivered approximately 11.8 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 $2.3 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 the 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
Anthrivig	NIAID	9/2007	$9.5 million	9/2007 — 12/2011
Recombinant botulinum vaccine	NIAID	6/2008	$1.8 million	6/2008 — 5/2011
NuThrax	NIAID	7/2008	$2.8 million	7/2008 — 6/2013
Thravixa	NIAID/BARDA	9/2008	$24.3 million	9/2008 — 8/2012
NuThrax	NIAID/BARDA	9/2008	$24.4 million	9/2008 — 9/2011
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
NuThrax	NIAID	7/2010	$28.7 million	8/2010 — 8/2014
PreviThrax	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 cost, which consist of primarily fixed costs. These fixed manufacturing costs consist of facilities, utilities 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:

§ personnel-related expenses;
§ 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 Pharmaceuticals, Inc., or 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 our third-party collaborators, 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.

Results of Operations

Quarter Ended March 31, 2011 Compared to Quarter Ended March 31, 2010

Revenues

Product sales revenues decreased by $33.3 million, or 86%, to $5.6 million for the three months ended March 31, 2011 from $38.9 million for the three months ended March 31, 2010. This decrease in product sales revenues was primarily due to an 88% decrease in the number of doses of BioThrax delivered. This decrease in doses delivered was due primarily to the annual shutdown of our manufacturing facility in late 2010, the use of production lots in the qualification of a second fill-finish contract manufacturer, as part of our risk mitigation strategy, and the redeployment of our potency testing capacity from BioThrax release testing to qualification of replacement reference standards and other development testing during the first quarter of 2011. Product sales revenues for the three months ended March 31, 2011 consisted of BioThrax sales to HHS of $5.0 million and aggregate international and other sales of $565,000. Product sales revenues for the three months ended March 31, 2010 consisted of BioThrax sales to HHS of $38.8 million and aggregate international and other sales of $37,000.

Contracts and grants revenues increased by $5.0 million, or 63%, to $12.9 million for the three months ended March 31, 2011 from $7.9 million for the three months ended March 31, 2010. The increase in contracts and grants revenue was primarily due to revenues from our recently awarded contract from BARDA for large-scale manufacturing for BioThrax and our collaborations with Abbott and Pfizer, along with increased activity and associated revenue from our development contracts with NIAID and BARDA for NuThrax, PreviThrax, and our double mutant recombinant protective antigen anthrax vaccine. Contracts and grants revenues for the three months ended March 31, 2011 consisted of $9.9 million in development contract and grant revenue from NIAID and BARDA and $3.0 million from

Abbott and Pfizer. Contracts and grants revenues for the three months ended March 31, 2010 consisted of $7.2 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.

Cost of Product Sales

Cost of product sales decreased by $6.4 million, or 86%, to $1.1 million for the three months ended March 31, 2011 from $7.5 million for the three months ended March 31, 2010. This decrease was primarily attributable to the 88% decrease in the number of BioThrax doses sold.

Research and Development Expense

Research and development expenses increased by $14.8 million, or 74%, to $34.8 million for the three months ended March 31, 2011 from $19.9 million for the three months ended March 31, 2010. This increase primarily reflects higher contract service and personnel-related costs, and includes increased expenses of $896,000 for product candidates that are categorized in the biodefense segment, increased expenses of $13.9 million for product candidates and technology platform development activities categorized in the biosciences segment, and increased expenses of $41,000 in other research and development, which are in support of central research and development activities. For the three months ended March 31, 2011 and 2010, we incurred research and development expenses net of development contract and grant reimbursements along with the net loss attributable to noncontrolling interests of $20.0 million and $12.1 million, respectively.

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 NuThrax program was due to the conduct of stability studies, assay development and manufacturing. The increase in spending for our large-scale manufacturing for Biothrax program was primarily due to characterization assay development and manufacturing that increased subsequent to the associated development contract award in July 2010. The spending for BioThrax related programs was related to clinical and non-clinical studies to support applications for marketing approval of these programs. The increase in spending for our PreviThrax product candidate was primarily due to formulation stability studies and potency assay qualification. The decrease in spending for our double mutant recombinant protective antigen anthrax vaccine product candidate resulted from the timing of manufacturing and assay development. The decrease in spending for our Anthrivig product candidate was primarily due to the timing of clinical studies, model development and regulatory activities. The decrease in spending for our Thravixa product candidate was primarily due to the timing of manufacturing development and stability testing. The spending for our botulinum vaccine product candidates resulted from the conduct and completion of non-clinical studies.

The increase in spending on biosciences product candidates, detailed in the table below, was primarily attributable to the timing of development efforts partially offset by the termination or scaling back of certain programs. The increase in spending for our tuberculosis vaccine product candidate is related to the costs incurred for the continued conduct of a Phase IIb clinical trial, which commenced in April 2009. The spending for Typhella was primarily due to manufacturing and clinical studies. The spending for our influenza vaccine product candidate is related to process and analytical development. The increase in spending for our TRU-016 and DRACO product candidates, primarily for clinical studies and manufacturing costs, is related to our October 2010 acquisition of Trubion and its development programs for product candidates to treat certain autoimmune diseases and oncology, including RA, SLE, CLL and NHL. The increase in spending for our other biosciences activities was primarily due to increased spending associated with development of platform technologies along with preclinical product candidates that we acquired in our acquisition of Trubion.

The spending for other research and development activities was primarily attributable to central research and development activities.

Our principal research and development expenses for the three months ended March 31, 2011 and 2010 are shown in the following table:

	Three Months Ended March 31,	
(in thousands)	2011	2010
Biodefense:		
NuThrax	$3,639	$2,200
Large-scale manufacturing for BioThrax	3,246	1,535
BioThrax related programs	2,143	2,102
PreviThrax	2,881	850
Double mutant recombinant protective antigen vaccine	846	1,507
Anthrivig	619	1,596
Thravixa	1,278	3,484
Botulinum vaccines	95	577
Total biodefense	14,747	13,851
Biosciences:		
Tuberculosis vaccine	5,904	2,254
Typhella	840	599
Influenza vaccine	770	763
TRU-016	5,025	-
DRACO	1,961	-
Other biosciences	4,254	1,238
Total biosciences	18,754	4,854
Other	1,258	1,217
Total	$34,759	$19,922

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $2.0 million, or 12%, to $18.2 million for the three months ended March 31, 2011 from $16.2 million for the three months ended March 31, 2010. This increase is primarily due to increased personnel-related expenses 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 $1.8 million, or 15%, to $14.0 million for the three months ended March 31, 2011 from $12.2 million for the three months ended March 31, 2010. Selling, general and administrative expenses related to our biosciences segment increased by

$161,000, or 4%, to $4.2 million for the three months ended March 31, 2011 from $4.0 million for the three months ended March 31, 2010.

Total Other Income (Expense)

Total other income decreased by $341,000, or 91%, to $34,000 for the three months ended March 31, 2011 from $375,000 for the three months ended March 31, 2010. The decrease was due primarily to 2010 interest income related to the note receivable from Protein Sciences Corporation.

Income Taxes

Provision for (benefit from) income taxes decreased by $13.9 million to a benefit from income taxes of $12.3 million for the three months ended March 31, 2011 from a provision for income taxes of $1.6 million for the three months ended March 31, 2010. The estimated annual effective tax rate for the three months ended March 31, 2011 and 2010 was 37% and 39%¸ respectively. The decrease in income taxes is primarily due to a $37.9 million decrease in our income before provision for income taxes and the loss attributable to noncontrolling interests.

Net Loss Attributable to Noncontrolling Interests

Net loss attributable to noncontrolling interests increased by $1.2 million, or 194%, to $1.8 million for the three months ended March 31, 2011 from $605,000 for the three months ended March 31, 2010. The loss was primarily a result of clinical and development activities and related expenses incurred by our joint venture with the University of Oxford. These amounts primarily represent the portion of the loss incurred by the joint venture for the three months ended March 31, 2011 and 2010, 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 March 31, 2011 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases, development funding from government entities and non-government and philanthropic organizations, the net proceeds from our initial public offering and 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, 2010.

As of March 31, 2011, we had cash, cash equivalents and investments of $143.3 million. Additionally, at March 31, 2011 our accounts receivable balance was $12.0 million.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2011 and 2010:

	Three Months Ended March 31,	
(in thousands)	2011	2010
Net cash provided by (used in):		
Operating activities(1)	$(22,748)	$17,616
Investing activities	(12,741)	(5,030)
Financing activities	3,395	874
Total net cash provided by (used in)	$(32,094)	$13,460

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

Net cash used in operating activities of $22.7 million for the three months ended March 31, 2011 was principally due to our net loss attributable to Emergent BioSolutions Inc. of $21.4 million, a $9.4 million increase in inventory related to the timing of BioThrax shipments, a net decrease in income taxes of $12.4 million related to timing differences, a decrease in accrued compensation of $10.3 million primarily due to the payment of the 2010 bonuses, partially offset by a decrease in accounts receivable of $27.4 million due to the timing of collection of amounts billed primarily to HHS, and non-cash charges of $2.4 million for stock-based compensation, $2.2 million for depreciation and amortization, and $2.6 million for development expenses primarily from our joint venture with the University of Oxford.

Net cash provided by operating activities of $17.6 million for the three months ended March 31, 2010 was due principally to a decrease in accounts receivable of $21.5 million due to amounts billed to and collected from HHS as of March 31, 2010, partially offset by a decrease in accrued compensation of $5.6 million primarily due to the payment of 2009 annual bonuses.

Net cash used in investing activities for the three months ended March 31, 2011 was $12.7 million, primarily due to capital expenditures of $8.4 million related to the construction and related costs for our facility in Baltimore, Maryland, and infrastructure investments and other equipment, along with the purchase of U.S. Treasury securities of $4.3 million.

Net cash used in investing activities for the three months ended March 31, 2010 of $5.0 million resulted principally from the construction and related costs for our manufacturing facility in Lansing, Michigan and infrastructure investments and other equipment.

Net cash provided by financing activities of $3.4 million for the three months ended March 31, 2011 resulted primarily from $4.2 million in proceeds from stock option exercises and $39,000 related to excess tax benefits from the exercise of stock options, partially offset by $842,000 in principal payments on indebtedness.

Net cash provided by financing activities of $874,000 for the three months ended March 31, 2010 resulted primarily from $15.0 million in proceeds from borrowings under our revolving line of credit with Fifth Third Bank, $1.3 million in proceeds from stock option exercises and $376,000 related to excess tax benefits from the exercise of stock options, partially offset by $15.8 million in principal payments on indebtedness, including $15.0 million in payments on our revolving line of credit with Fifth Third Bank.

Debt Financing

As of March 31, 2011, we had $46.6 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;
- $5.6 million outstanding under a mortgage loan from PNC Bank used to finance the remaining portion of the purchase price for our first Frederick facility;
- $6.5 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, the balance of which we repaid in April 2011;
- $20.9 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;
- $6.4 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
- $4.7 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, collaboration funding, 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 level of participation of collaborative partners in our development programs, including those recently acquired in our acquisition of Trubion;
- 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 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 market acceptance and sales growth of any of our products and product candidates upon regulatory approval;
- the extent to which growth generates increased administrative costs;
- 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 effect of competing technological and market developments; and
- 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.

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, our investments, and our long-term indebtedness. We currently do not hedge interest rate exposure or interest on foreign currency exchange exposure, and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents and the small amount of our non-cash investments of $6.3 million as of March 31, 2011, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments, but would likely increase the interest expense associated with our debt.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2011. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2011, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the quarter ended March 31, 2011 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

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 us 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. 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, 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. 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. The Actions were stayed pending approval of the settlement of the State Action by the State Court, after which 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. On April 26, 2011, the State Court entered an order granting preliminary approval of the settlement and requiring that notice of the settlement and preliminary approval be mailed to class members by May 17, 2011. The order also provides that all class members who wish to be excluded from the settlement of the Actions give notice by June 21, 2011. The State Court's hearing to determine whether the settlement is fair, reasonable and adequate to the class members and should be approved is scheduled to occur on July 29, 2011. 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, a single hearing was held before the Opposition Division of the European Patent Office, in which each opponent presented oral argument and Bavarian Nordic presented 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. The Opposition Division set a date of November 27, 2010 for all parties to file appeals, and we timely filed our appeal. 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 set due dates of January 29, 2011 and February 7, 2011 for Notices of Appeal to be filed for these oppositions, and we timely filed our Notices of Appeal. Our Appeal Briefs were also timely filed. The Opposition Division held its hearing for the fourth pending opposition in January 2011. As for the previous oppositions, Bavarian Nordic introduced amended patent claims into the record, and the Opposition Division upheld the amended claims, which are narrower in scope than the originally granted claims. A due date has not yet been set for the parties to file their appeals. 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 contract expires in September 2011. Although we are currently in discussions with HHS for a multi-year procurement contract, our existing and prior contracts with HHS and the DoD do not necessarily increase the likelihood that we will secure this multi-year contract or 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, and 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. 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 and, if applicable, perform such contract awards, our growth strategy and our business, financial condition and operating results could be materially and 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 political considerations and stringent budgetary constraints. 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 exercisable 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, which could in turn harm our operating results.

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 Food and Drug Administration, or 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. For example, we incurred a net loss of $21.4 million for the first quarter of 2011. Our profitability is substantially dependent on BioThrax product sales. 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 March 31, 2011, we had $46.6 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. In the event that our ability to sell BioThrax to the U.S. government is interrupted for an extended period of time, we will utilize our cash balances to help fund our ongoing operations.

As of March 31, 2011, we had $143.3 million of cash, cash equivalents and investments. 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 level of participation of collaborative partners in our development programs, including those recently acquired in our acquisition of Trubion Pharmaceuticals, Inc., or Trubion;
- 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 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 market acceptance and sales growth of any of our products or product candidates upon regulatory approval;
- the extent to which our growth generates increased administrative costs;
- 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 or technologies;
- the effect of competing technological and market developments; and
- 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.

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 the Biomedical Advanced Research and Development Authority, or BARDA, in July 2010 for scale-up, qualification and validation to manufacture BioThrax.

Additionally, in 2009, we acquired a facility in Baltimore, Maryland which 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. We may also need to hire and train significant numbers of employees to staff our facility. Start-up costs can be large and scale-up entails

significant risks related to process development and manufacturing yields. 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 or cell banks and preventing drift, obtaining materials, seed or cell 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 may 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.

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 data.

Additionally, potency testing of each lot of BioThrax is performed against a qualified reference lot that we maintain. We continually monitor the status of our reference lot and periodically produce and qualify a new reference lot to replace the existing reference lot. For example, we are currently in the process of preparing and qualifying a new reference lot to replace our existing, qualified reference lot, which we expect to complete later this year. If we are not able to satisfy the FDA’s requirements for release of BioThrax, our ability to sell BioThrax would be impaired until such time as we become able to meet such requirements, which would significantly impact our revenues, require us to utilize our cash balances to help fund our ongoing operations and otherwise harm our business.

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. If our existing BioThrax filler were 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. 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 requires use of a significant number of doses of BioThrax for consistency lots and stability testing. We have projected that once testing is complete we will be able to recognize revenue from these lots in 2011 from delivery to the SNS. In the event we are not able to sell these lots, or if testing takes longer than anticipated, we will not be able to recognize these revenues.

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, or third party manufacturers with whom we may contract, 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 or supplies for our manufacture of BioThrax 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, we currently depend on contract manufacturers for certain biopharmaceutical development and manufacturing services for TRU-016, our clinical candidate that we are developing in collaboration with Abbott Laboratories, or Abbott, and plan to have Abbott perform certain TRU-016 manufacturing services in 2011. We also rely on third-party manufacturers for filling and finishing services for our product candidates. Any significant delay in obtaining adequate supplies of our product candidates could adversely affect our ability to develop or commercialize these product candidates. For example, in 2008 the initial manufacturer of Thravixa 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 and we will rely on those manufacturers to comply with a wide variety of rules and regulations. The manufacture and delivery of sufficient quantities of pharmaceutical products is a time-consuming and complex process. If our contract manufacturers are unable to scale-up production to generate enough materials for commercial launch, if manufacturing is of insufficient quality or not compliant with applicable rules and regulations, 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.

Reliance on contract manufacturers, other vendors and collaborators limits our control regarding many aspects of the manufacturing and delivery process and therefore exposes us to a variety of significant risks, including:

- limitations on our ability to schedule production with contract suppliers when needed to supply clinical trials;
- reliance on contract suppliers for legal and regulatory compliance and quality assurance;
- lack of obligation by a contract supplier to accept a purchase order;
- contract supplier's insistence on exclusivity, minimum or maximum levels of supply and related restrictions on our ability to increase or decrease supply, including provisions whereby we pay a penalty if we fail to order a minimum amount;
- breach of agreements by contract suppliers; and
- termination, price increases, or non-renewal of agreements by contract suppliers, based on other business priorities, at times that are costly or inconvenient for us.

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. Third party manufacturers may also be unable or unwilling to accommodate our production scheduling requests, or may insist on exclusivity or minimum or maximum levels of supply, or may raise prices or decline to renew contracts. If any third party terminates or declines to renew its agreement with us, or otherwise fails to fulfill our purchase orders on terms acceptable to us, 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 may not be able to reach agreement on reasonable terms, if at all, with these manufacturers.

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 we or third parties are unable to manufacture our product candidates in compliance with regulatory requirements, in sufficient quantities, at an acceptable cost and according to applicable timelines, our clinical trials could be delayed,

production costs could be significantly increased and the development prospects and commercial viability of our product candidates could be harmed.

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.

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

Our research and development and manufacturing processes involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we, the third parties that conduct clinical trials on our behalf, and the third parties that manufacture our product candidates 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, including those 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 and U.S. Department of Agriculture our possession, use or transfer of select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires increased safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel and establishes a comprehensive national database of registered entities.

We also are subject to export control regulations governing the export of BioThrax and technology and materials used to develop and manufacture BioThrax and our product candidates. 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. In addition, we cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of hazardous materials. In the event of injury or a future contamination event, we could be held liable for resulting damages, and any liability could significantly impact our financial position.

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. We may be unable to maintain existing insurance or obtain new coverage or increase limits in the future on reasonable terms or at all. Circumstances may arise where we face liabilities that are not covered by our insurance policies, or where our coverage is not adequate, which may expose us to significant liabilities and significantly and adversely affect our business or financial position.

Risks Related to Product Development

Our business depends significantly on our success in completing development and commercialization of our product candidates at acceptable costs. If we are unable to commercialize these product candidates, or experience significant delays or 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 and the acquisition of additional therapeutic product candidates. In addition to BioThrax sales, our ability to generate near term revenue is dependent on the success of our development programs and collaboration 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 our 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 Anthrivig. We are currently in negotiations with that contract manufacturer for a longer-term resolution regarding commercial the 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 depend on our collaborative relationships with Pfizer and Abbott to develop, manufacture, and commercialize certain of our recently acquired product candidates.

We are party to collaboration agreements with each of Pfizer Inc., or Pfizer, and Abbott. Under the terms of the Pfizer collaboration, Pfizer is responsible for regulatory approval of and any subsequent commercialization of SBI-087. Under the Abbott collaboration for the development and commercialization of TRU-016, 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 Pfizer or Abbott 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.

Our collaboration with Pfizer also initially included another product candidate for development, an investigational drug in Phase II evaluation for the treatment of Rheumatoid Arthritis, or RA. In June 2010, Pfizer decided to discontinue development of TRU-015 based on preliminary results from the study, which, although consistent with previous studies and similar to other B-cell-depleting therapies, did not meet the internally predefined primary endpoint of the Phase II study. 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 targets other than CD20 that have been established pursuant to our collaboration agreement with Pfizer. 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 with Pfizer 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 Corporation, or Facet, for the joint worldwide development and commercialization of TRU-016, a product candidate in Phase I clinical development for chronic lymphocytic leukemia, or CLL, and other CD37-directed protein therapeutics. Facet became a wholly-owned subsidiary of Abbott in April 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, and development and commercialization expenses incurred by both companies in the development and commercialization of TRU-016 are shared equally. 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. 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 could delay the development of TRU-016, which may harm our business.

Additionally, Abbott may terminate the collaboration agreement without cause, and would not be obligated to pay us a termination fee. Abbott also has the right upon 90 days' written notice to terminate the agreement for any uncured material breach by us. 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 with respect to the product. 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, 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.

While SBI-087 or TRU-016 may never be successfully developed or commercialized, if either Pfizer or Abbott were to fail to perform its obligations in a timely manner or were to terminate or opt out of its collaboration with us, the development and commercialization of the affected product would be substantially delayed and may be otherwise adversely affected, which could have a material adverse effect on our results of operations.

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 and our collaborative partners 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. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials.

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, or our collaborators, 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;
- we or a collaborative partner may experience delay in beginning the clinical trial;
- we may experience competition in recruiting clinical investigators;
- 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;
- regulatory requirements, policy and guidelines could change;
- we may experience limitations in our ability to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials;
- we or our collaborators may fail to adequately manage the increasing number, size and complexity of our clinical trials;
- any or all of our collaborators, the FDA and foreign regulatory agencies may interpret data differently;
- third parties conducting and overseeing the operations of our clinical trials may fail to perform their contractual or regulatory obligations in a timely fashion;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials or may experience delays in patient enrollment and variability in the number and types of patients available for 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, or the Secretary, can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the Secretary 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.

If our drug discovery and development programs do not progress as anticipated, our revenue and stock price could be negatively impacted.

We estimate the timing of a variety of preclinical, clinical, regulatory and other milestones for planning purposes, including when a drug candidate is expected to enter clinical trials, when a clinical trial will be completed, when and if additional clinical trials will commence, or when an application for regulatory approval will be filed. We base our estimates on facts that are currently known to us and on a variety of assumptions that may prove not to be correct for a variety of reasons, many of which are beyond our control. For example, delays in the development of drugs by us or our collaborators may be caused by many factors, including regulatory or patent issues, negative or inconclusive interim or final results of on-going clinical trials, scheduling conflicts with participating clinics and the rate of patient enrollment in clinical trials and the development priorities of our collaborators. In addition, in preparing these estimates we rely on the timeliness and accuracy of information and estimates reported or provided to us by our collaborators concerning the timing, progress and results of clinical trials or other development activities they conduct under our collaborations with them. If we or our collaborators do not achieve milestones when anticipated, we may not achieve our planned revenue and our stock price could decline. In addition, any delays in obtaining approvals to market and sell drugs may result in the loss of competitive advantages in being on the market sooner than, or in advance of, competing products, which may reduce the value of these products and the potential revenue we receive from the eventual sale of these products, either directly or under agreements with our partners.

Our product development efforts could also result in large and immediate write-offs, significant milestone payments, incurrence of debt and contingent liabilities or amortization of expense related to intangible assets, any of which could negatively impact our financial results, Additionally, if we were unable to develop our product candidates into viable commercial products, we will be reliant solely on sales of our currently approved product BioThrax for our revenues, thus limiting our growth opportunities and diversification.

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 future potential increased demand 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.

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 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 Securities and Exchange Commission 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 additional 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 Guillain-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.

The commercial success of many of our product candidates, including our oncology and autoimmune therapeutic product candidates, will depend upon, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments.

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:

- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- availability, relative cost and relative efficacy of alternative and competing 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;
- publicity concerning our products or competing products and treatments; and
- the sufficiency of coverage or reimbursement by third parties.

If our products and product candidates do not become widely accepted by potential government customers, physicians, patients, third-party payors and other members of the medical community, our business, financial condition and operating results could be materially and adversely affected.

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. We do not believe that the death of Osama bin Laden will have any actual effect on the risk of bioterrorism, but could result in a public perception that risk is reduced. 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, enter into collaborations with third parties able to perform these services 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.

In addition, we are a party to a collaboration agreement with Pfizer to develop and commercialize therapeutics directed to CD20 and to a collaboration agreement with Abbott to develop and commercialize therapeutics directed to CD37.

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. In addition, if we do not enter into collaborative agreements with respect to product candidates not covered by the Pfizer or Abbott collaborations, or if any of our product candidates are the subject of collaborative agreements with third parties that are not able to commercialize such product candidates, we may need to further expand our sales, marketing and distribution infrastructure to effectively commercialize these product candidates.

Our efforts to develop our sales, marketing and distribution infrastructure are subject to the following risks:

- § potential difficulties in recruiting, training and retaining adequate numbers of effective sales and marketing personnel;
- § the potential that the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities could be delayed, resulting in us incurring related expenses too early relative to the product launch and causing personnel retention issues;
- § our limited experience in the commercialization of pharmaceutical products other than BioThrax;
- § difficulties in establishing an effective distribution network, including entering into marketing and distribution agreements with third parties on acceptable terms;
- § the inability of sales personnel to obtain access to or persuade adequate numbers of potential government customers to purchase our product and physicians to prescribe our products;
- § the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- § unforeseen costs and expenses associated with creating a sales and marketing organization.

If we are not successful in our efforts to expand our sales and marketing capability, our ability to market and sell BioThrax and any other product candidates that we successfully develop will be impaired, which could negatively impact our business, financial condition and operating results.

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 biopharmaceutical products is highly competitive and subject to rapid technological advances. 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. They may also devote greater resources to market or sell their products, adapt more quickly to new technologies and scientific advances, initiate or withstand substantial price competition more successfully than we can, more effectively negotiate third-party

licensing and collaborative arrangements and take advantage of acquisition or other opportunities more readily than we can. Any therapeutic product candidate that we successfully develop and commercialize is likely to compete with currently marketed products 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 particular, any new product candidate that competes with a generic market-leading product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome severe price competition and be commercially successful.

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. Specifically with respect to oncology and autoimmune disease, our competitors include Amgen, Pfizer, Takeda, Centocor Ortho Biotech, Merck, Mitsubishi Tanabe, Abbott, Eisai, Bristol-Myers Squibb, UCB, Otsuka, Roche, Chugai, Genentech, Biogen Idec, Spectrum Pharmaceuticals, Inc., Bayer Schering AG, GSK, Genzyme, Cephalon Oncology, Genmab, Boehringer Ingleheim and ImmunoGen, Inc.

We face competition for our biodefense product candidates. Although BioThrax is the only anthrax vaccine approved by the FDA for the prevention of anthrax infection, the U.S. 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. 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 products or product candidates in development that would compete with the commercial product candidates for which we are seeking to obtain marketing approval. If approved for the treatment of rheumatoid arthritis, or 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 ® (JNJ and Merck), Actemra ® (Roche and Chugai) and Rituxan ® (Genentech, Roche and Biogen Idec). If approved for the treatment of systemic lupus erythematosus, or SLE, our product candidates will compete with Benlysta (Human Genome Sciences and GSK) and other B cell depleting therapies, including CD20-directed therapeutics.

If approved for the treatment of CLL, non-Hodgkin's lymphoma, or NHL, or other B cell malignancies, we anticipate that our product candidates would compete with other B cell depleting therapies and related therapeutics. Non-CD37-directed therapeutics marketed for the treatment of NHL or CLL, or both, include Rituxan ® (Genentech), Zevalin ® (Spectrum Pharmaceuticals, Inc. and Bayer Schering AG), Bexxar ® (GlaxoSmithKline), Campath ® (Genzyme and Bayer Schering AG), Treanda ® (Cephalon Oncology) and Arzerra ® (GlaxoSmithKline and Genmab). In addition, Boehringer Ingelheim and ImmunoGen, Inc. are both developing antibody therapies directed to CD37.

With respect to our vaccine product candidates, 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 we are not able to compete effectively against our current and future competitors, our business may not grow, and our financial condition and operating results may suffer.

Legislation and contractual provisions limiting or restricting liability of manufacturers or providing for indemnification 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 Anthrivig as covered countermeasures.

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. We are currently entitled to the benefits of the SAFETY Act through July 31, 2011, and have submitted an application for renewal of those benefits. We cannot be certain that our application for renewal will be approved on a timely basis or at all, and we may not be entitled to those benefits on a continuing basis. Additionally, although we are currently

entitled and may continue to be entitled to the benefits of the SAFETY Act, it may not provide adequate protection from any claims made against us.

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.

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.

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 help mitigate our liability exposure for BioThrax.

A successful product liability claim or series of claims brought against us could cause our stock price to fall and could decrease our financial resources and materially and adversely affect our business.

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 biosciences 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.

Our future revenues and profitability will be adversely affected if third party payors do not sufficiently cover and reimburse the cost of future drug products we may market. If these entities do not provide coverage and reimbursement for our products, or if they provide an insufficient level of coverage and reimbursement, our products may be too costly for use, and physicians may not prescribe them or may prescribe them less frequently. In this manner, levels of reimbursement for drug products by government authorities, private health insurers and other organizations, such as Health Maintenance Organizations, may have a material adverse effect on our business, financial condition, cash flows and results of operations.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably and increase competition.

In both the U.S. and in foreign jurisdictions, legislative and regulatory actions may reduce the revenues that we derive from our future products. In particular, 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 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, increases the minimum Medicaid drug rebates for pharmaceutical companies 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. Our results of operations could be adversely affected by current and potential future healthcare reforms.

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 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 retain and hire a significant number of qualified technical and commercial personnel, including scientific, clinical development, manufacturing and process development, regulatory, marketing and sales executives and field sales personnel, as well as additional administrative personnel. Our ability to achieve

our business strategies, including advancing drug candidates through later stage development or commercialization, depends on our ability to hire and retain high caliber scientists and other qualified 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.

Risks Related to Our Acquisition Strategy

If we fail to successfully manage any acquisitions, including our acquisition of Trubion, 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 our acquisition of Trubion, 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; and
- amortization expenses related to other intangible assets.

We also may face significant challenges in effectively integrating entities and businesses that we acquire, such as Trubion, and we may not realize the benefits anticipated from such acquisitions. Achieving the anticipated benefits of our acquisition of Trubion and any other acquired entities or businesses will depend in part upon whether we can integrate them in an efficient and effective manner. 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 pre-acquisition business;
- greater administrative burdens and operating costs;
- difficulty and expense in assimilating and integrating the operations, products, technology, information systems, culture or personnel of the acquired entities or businesses;
- potential loss of key collaborators;
- entering markets in which we have limited or no direct experience;
- diversion of management's time and attention from other business concerns;
- difficulty in implementing uniform standards, controls, procedures and policies;
- the assumption of known and unknown liabilities of the acquired entities or businesses, including intellectual property claims;
- increased exposure to uncertainties inherent in developing and commercializing new products;
- impairment of acquired intangible assets as a result of technological advances or worse-than-expected clinical results or performance of the acquired company or the partnered assets;
- challenges and costs associated with reductions in work force; and
- potential loss of key personnel.

If we are unable to successfully integrate acquired entities and businesses, including Trubion, our ability to develop new products and continue to expand our product pipeline may be limited and we may experience material adverse consequences to our business, financial condition or results of operations.

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 acquisition of substantially all of the assets, for cash, of ViVacs GmbH in 2006. More recently, we acquired additional pipeline product candidates as a result of our acquisition of Trubion 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. 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. 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.

Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote resources to potential acquisitions that are never completed. If we are unable to successfully obtain rights to suitable products and product candidates and manage the risks and costs of pursuing an acquisition strategy, our business, financial condition and prospects for growth could

suffer.

We may fail to manage our growth and increased breadth of our activities effectively.

We have expanded the scope of our business in recent years. We have acquired several drug candidates and have been advancing pre-clinical and multiple clinical stage product candidates. We also have grown our employee base substantially. We plan to continue adding products and product candidates through internal development, in-licensing and acquisition over the next several years and to continue developing our existing product candidates that demonstrate the requisite efficacy and safety to advance into and through clinical trials. To manage the existing and planned future growth and the increasing breadth and complexity of our activities, we will need to continue building our organization and making significant additional investments in personnel, infrastructure, information management systems and resources. Our ability to develop and advance the commercialization of our products and product candidates, achieve our research and development objectives, add and integrate new products, and satisfy our commitments under our collaboration and acquisition agreements depends on our ability to respond effectively to these demands and expand our internal organization and infrastructure to accommodate additional anticipated growth. If we are unable to effectively manage and advance these activities, our ability to maximize the value of one or more of our product candidates could suffer, which could materially and adversely affect our business.

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, including those 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 and 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 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 and our collaborative partners 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 and our collaborators 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 a Biologics license application, or BLA, to the FDA. 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. For example, this will be the case with respect to any BLA that we may file in the future with respect to our oncology and auto-immune disease product candidates. 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, Anthrivig, PreviThrax, Thravixa, and NuThrax. 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 we experience any of these post-approval events, our business, financial condition and operating results could be materially and adversely affected.

If our competitors are able to obtain orphan drug exclusivity for any products that are competitive with 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 Thravixa, from the FDA and in the European Union for Anthrivig and in the European Union for our tuberculosis vaccine product candidate; however, none of our other products or product candidates have 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 and for Anthrivig and Thravixa. 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 and data review. 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, or may include different or additional risks. 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. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in another jurisdiction, including approval by the FDA. For example, in 2010 the United Kingdom Medicines and Healthcare products Regulatory Authority, or MHRA, informed us that a provision of the European Pharmacopoeia may prevent licensure of our tuberculosis vaccine product candidate in the European Union unless such provision can be interpreted in a manner consistent with our product candidate's manufacturing process, despite the fact that the FDA had provided recent guidance to the contrary. We are continuing to work with the MHRA and outside advisors to clarify the provision but we cannot be certain that our efforts will be successful, which could preclude our ability to commercialize this product candidate in the European Union. We and our collaborators may not be able to obtain regulatory approvals to commercialize our products in any market. The failure to obtain regulatory approval in foreign jurisdictions could materially harm our business.

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, in June 2010 Pfizer decided to discontinue development of TRU-015 based on preliminary results from a Phase II study. Even though these results were consistent with previous studies and similar to other B-cell-depleting therapies, they did not meet the internally predefined endpoint of the study. 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:

- we may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of product candidates;
- our collaborators may delay clinical trials, design clinical trials in a manner with which we do not agree, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new version of a product candidate for clinical testing;
- 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;

- our collaborators may decide not to pursue further development and commercialization of products and product candidates resulting from the collaboration, or may elect to discontinue research and development programs, which could delay development and increase the cost of developing our product candidates;
- our collaborators may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;
- we may experience difficulties in the day-to-day activities required by collaboration including close and frequent communications between several different teams, technology transfer and a collaborative sharing of responsibilities;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- our collaborators may experience financial difficulties;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations; and
- our collaborators could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

Any of these potential outcomes could harm our business reputation and adversely affect us financially including by resulting in lower than expected revenues, delaying development, leading to a loss of market opportunities or impairing the value of the related product candidate.

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 third parties, such as 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. We may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult. If we must replace any contract research organization, our trials may have to be suspended until we find another contract research organization that offers comparable services. The time that it takes us to find alternative organizations may cause delay in the commercialization of our product candidates or may cause us to incur significant expenses to replicate data that may be lost. Although we do not believe that the contract research organizations on which we rely offer services that are not available elsewhere, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost. Any delay in or inability to complete our clinical trials could significantly compromise our ability to secure regulatory approval of the relevant product candidate and preclude our ability to commercialize the product, thereby limiting our ability to generate revenue from the sales of product candidates, which may result in a decrease in our stock price. 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, in certain cases, we encourage government entities and non-government organizations to conduct studies of, and pursue other development efforts for, our product candidates. For example, we expect to rely on data from clinical trials conducted by third parties seeking marketing approval for certain of our product candidates, including 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.

We face potential liability related to the privacy of health information we obtain from research institutions.

Most health care providers, including research institutions from which we or our collaborators obtain patient information, are subject to privacy regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA. Our clinical research efforts are not directly regulated by HIPAA. However, conduct by a person that may not be prosecuted directly under HIPAA’s criminal provisions could potentially be prosecuted under aiding and abetting or conspiracy laws. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we receive individually identifiable health information from a health care provider or research institution that has not satisfied HIPAA’s disclosure standards. In addition, international data protection laws including the European Union Data Protection Directive and member state implementing legislation may apply to some or all of the clinical data obtained outside of the U.S. Furthermore, certain privacy laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our use and dissemination of individuals’ health information.

Moreover, patients about whom we or our collaborators obtain information, as well as the providers who share this information with us, may have contractual rights that limit our ability to use and disclose the information. Claims that we have violated individuals’ privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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 biosciences 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, products and product candidates, including those which are the subject of collaborations. 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, we know that other entities have filed patent applications in various jurisdictions that relate to several areas in which we are developing products. Some of these patent applications have already resulted in patents and some are still pending. If use of technology incorporated into or used to produce our product candidates is challenged, or if our processes or product candidates conflict with patent rights of others, third parties could bring legal actions against us in Europe, the U.S. and elsewhere claiming damages and seeking to enjoin manufacturing and marketing of the affected products. Further, 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.

Should third parties file patent applications or obtain patents claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial costs to us and an adverse decision as to the priority of our inventions. An unfavorable outcome in an interference proceeding could require us to cease using the technology or to license rights from prevailing third parties. We cannot assure you that any prevailing party would offer us a license or that we could acquire any license made available to us on commercially acceptable terms.

The cost of litigation to uphold the validity of patents to prevent infringement or to otherwise protect our proprietary rights could be substantial. Some of our competitors may be better able to sustain the costs of complex patent litigation because they may have substantially greater resources. Intellectual property lawsuits are expensive and unpredictable and would consume time and other resources, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also a risk that, even if the validity of a patent were upheld, a court would refuse to stop the other party from using the invention(s), including on the grounds that its activities do not infringe the patent. If any of these events were to occur, our business, financial condition and operating results could be materially adversely affected.

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 recombinant protective antigen product candidate and NuThrax from Coley Pharmaceutical Group, Inc., or Coley. Coley, which was subsequently acquired by Pfizer 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.

We also will rely on current and future trademarks to establish and maintain recognized brands. If we fail to acquire and protect such trademarks, our ability to market and sell our products, and therefore our business, financial condition and operating results, could be materially and adversely affected.

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 or our collaborators must obtain licenses from third parties, fees must be paid for such licenses, which would reduce the revenues and royalties we may receive on commercialized products.

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 may 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, which 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, modified vaccinia Ankara, or MVA,-based vaccines have been the subject of significant intellectual property litigation. Specifically, 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. 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 lawsuit was settled in January 2010 by agreement between the parties. We are also involved in several patent oppositions filed in the European Patent Office against certain of Bavarian Nordic's patents covering certain aspects of MVA technology. In each of the opposition proceedings, the subject patents have also been opposed by

one or more additional parties, including Sanofi Pasteur, Transgene, Baxter, Virbac, and Innogenetics.

The strain of MVA that we use in our platform technology is a distinct lineage from the strains used by Acambis and Oxford BioMedica; however, we cannot be certain that we will not become the target of an infringement action. We also cannot be certain that the oppositions pending in the European Patent Office will be resolved in our favor. If we are sued for infringement, we could incur expensive legal costs, development delays or other costs and delays that could harm our business.

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 in our significant stockholders. As of April 29, 2011, Mr. El-Hibri was the beneficial owner of approximately 31% of our outstanding common stock. Because Mr. El-Hibri has significant influence over the election of the members of our board, and because of his substantial control of our capital stock, Mr. El-Hibri will likely have the ability to delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

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

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

These provisions include:

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

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

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

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

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

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

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

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through April 29, 2011 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 of 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 and success in our research and development programs;
- 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;
- public concern as to the safety of drugs developed by us or others;
- announcements of issuances of common stock or acquisitions by us;
- the announcement and timing of new product introductions by us or others;
- termination or delay of development program(s) by our collaborative partners, or delay in achievement of collaboration milestones;
- announcements of technological innovations or new therapeutic products or methods by us or others;
- acts or omissions of our licensees, collaborators and suppliers;
- 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 or other external factors, such as disaster or crisis; and
- the other factors described in this "Risk Factors" section.

In the past, securities class action litigation often has been instituted following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in potential liabilities, substantial costs and the diversion of management's attention and resources, regardless of whether we win or lose.

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 April 29, 2011 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

Not applicable.

ITEM 6. EXHIBITS

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

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

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

Date: May 6, 2011

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

Date: May 6, 2011

EXHIBIT INDEX

Exhibit Number	Description
10.1	Letter Agreement, dated February 17, 2011, between the Registrant and East West Resources Corporation (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 23, 2011 (File No. 001-33137))
31.1	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002