Emergent BioSolutions Inc.
Form 10-Q
May 08, 2015
UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q
(Mark
One)

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

For the quarterly period ended March 31, 2015

OR

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.)
400 Professional Drive, Suite 400 Gaithersburg, Maryland	20879
(Address of Principal Executive Offices)	(Zip Code)

(240) 631-3200
(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. Yes 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). Yes 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):

Large accelerated filer Accelerated filer Non-accelerated filer 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). Yes No

As of April 30, 2015, the registrant had 38,356,600 shares of common stock outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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. We generally identify forward-looking statements by using words like "believes," "expects," "anticipates," "intends," "plans," "forecasts," "estimates" and similar expressions in conjunction with, among other things, discussions of financial performance or financial condition, growth strategy, product sales, manufacturing capabilities, product development, regulatory approvals or expenditures. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. You should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. You are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements, including, among others:

appropriations for the procurement of BioThrax® (Anthrax Vaccine Adsorbed), our FDA-licensed anthrax vaccine;
our ability to perform under our contracts with the U.S. government related to BioThrax, including the timing of deliveries;
our ability to obtain new BioThrax sales contracts or modifications to existing contracts;
the availability of funding for our U.S. government grants and contracts;
our ability to successfully execute our growth strategy and achieve our financial and operational goals;
our ability to successfully integrate and develop the products or product candidates, programs, operations and personnel of any entities or businesses that we acquire;
our ability to perform under our contract with the U.S. government to develop and obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55, our large-scale vaccine manufacturing facility in Lansing, Michigan;
our ability to identify and acquire companies or in-license products or late-stage product candidates that satisfy our selection criteria;
our ability to realize synergies and benefits from acquisitions or in-licenses within expected time periods or at all;
our ability to selectively enter into collaboration arrangements;
our ability to achieve milestones in our out-license and collaboration contracts;
our ability to obtain and maintain intellectual property protection for our products and product candidates;
our ability and plans to expand our manufacturing facilities and capabilities;
our ability and the ability of our contractors and suppliers to maintain compliance with cGMP and other regulatory obligations;
the results of regulatory inspections;
our ability to meet operating and financial restrictions placed on us and our subsidiaries under our senior secured credit facility;
the rate and degree of market acceptance and clinical utility of our products;
the success of our ongoing and planned development programs, non-clinical activities and clinical trials of our product candidates;
the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
the success of our commercialization, marketing and manufacturing capabilities and strategy; and
the accuracy of our estimates regarding future revenues, expenses, capital requirements and needs for additional financing.

The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. New factors emerge from time to time and it is not possible for management to predict all such factors, nor can it assess the impact of any such factor on the business or the extent to which any factor, or combination of factors, may cause results to differ materially from those contained in any forward-looking statement. You should consider this cautionary statement, the risk factors identified in the section entitled "Risk Factors" in this quarterly report on Form 10-Q and the risk factors identified in our other periodic reports filed with the Securities and Exchange Commission when evaluating our 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, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$216,515	$280,499
Accounts receivable	64,059	58,834
Inventories	82,134	65,674
Deferred tax assets, current portion, net	1,656	1,710
Income tax receivable, net	17,023	1,357
Prepaid expenses and other current assets	24,424	24,101
Total current assets	405,811	432,175
Property, plant and equipment, net	315,489	313,979
In-process research and development	77,800	77,800
Intangible assets, net	56,202	58,344
Goodwill	41,984	41,984
Deferred tax assets, long-term portion, net	12,863	12,764
Other assets	7,696	8,216
Total assets	$917,845	$945,262
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$40,583	$40,930
Accrued expenses and other current liabilities	4,606	6,274
Accrued compensation	20,818	31,654
Contingent consideration, current portion	6,860	6,487
Provisions for chargebacks	2,164	2,246
Deferred revenue, current portion	5,266	5,345
Total current liabilities	80,297	92,936
Contingent consideration, net of current portion	41,594	41,170
Long-term indebtedness	251,000	251,000
Deferred revenue, net of current portion	5,806	5,713
Other liabilities	1,270	1,242
Total liabilities	379,967	392,061
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	-	-

Common stock, $0.001 par value; 100,000,000 shares authorized, 38,745,536 shares issued and 38,325,347 shares outstanding at March 31, 2015; 38,129,872 shares issued and 37,709,683 shares outstanding at December 31, 2014	38	38
Treasury stock, at cost, 420,189 common shares at both March 31, 2015 and December 31, 2014	(6,320)	(6,320)
Additional paid-in capital	280,653	274,222
Accumulated other comprehensive loss	(3,242)	(3,008)
Retained earnings	266,749	288,269
Total stockholders' equity	537,878	553,201
Total liabilities and stockholders' equity	$917,845	$945,262

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,	
	2015 (Unaudited)	2014
Revenues:		
Product sales	$18,291	$35,767
Contract manufacturing	12,243	2,726
Contracts, grants and collaborations	33,099	15,391
Total revenues	63,633	53,884
Operating expense:		
Cost of product sales and contract manufacturing	18,748	18,997
Research and development	38,702	30,256
Selling, general and administrative	34,493	30,089
Loss from operations	(28,310)	(25,458)
Other income (expense):		
Interest income	82	40
Interest expense	(1,661)	(3,535)
Other income (expense), net	100	512
Total other income (expense)	(1,479)	(2,983)
Loss before benefit from income taxes	(29,789)	(28,441)
Benefit from income taxes	(8,269)	(8,205)
Net loss	$(21,520)	$(20,236)
Loss per share - basic		
Loss per share - diluted	$(0.57)	$(0.55)
	$(0.57)	$(0.55)
Weighted-average number of shares - basic	37,949,358	36,854,370
Weighted-average number of shares - diluted	37,949,358	36,854,370

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

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Statements of Comprehensive Loss
(in thousands)

	Three Months Ended March 31,	
	2015	2014
	(Unaudited)	
Net loss	$(21,520)	$(20,236)
Foreign currency translations, net of tax	(234)	74
Comprehensive loss	$(21,754)	$(20,162)

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,	
	2015	2014
Cash flows from operating activities:	(Unaudited)	
Net loss	$(21,520)	$(20,236)
Adjustments to reconcile to net cash used in operating activities:		
Stock-based compensation expense	3,798	2,650
Depreciation and amortization	8,532	6,835
Current and deferred income taxes	(7,261)	(8,052)
Change in fair value of contingent consideration	1,559	412
Write off of debt issuance costs	-	1,831
Excess tax benefits from stock-based compensation	(5,414)	(4,570)
Other	17	453
Changes in operating assets and liabilities:		
Accounts receivable	(5,225)	17,590
Inventories	(16,460)	(4,006)
Income taxes	(12,160)	(3,753)
Prepaid expenses and other assets	(249)	556
Accounts payable	1,102	(10,713)
Accrued expenses and other liabilities	(1,641)	1,546
Accrued compensation	(10,883)	(8,720)
Provision for chargebacks	(82)	159
Deferred revenue	14	(1,227)
Net cash used in operating activities	(65,873)	(29,245)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(9,082)	(4,590)
Acquisition of Cangene Corporation, net of acquired cash	-	(178,167)
Net cash used in investing activities	(9,082)	(182,757)
Cash flows from financing activities:		
Proceeds from convertible debenture, net of bank fees	-	241,654
Proceeds from long-term debt obligations	-	1,000
Issuance of common stock upon exercise of stock options	6,344	8,137
Excess tax benefits from stock-based compensation	5,414	4,570
Principal payments on long-term indebtedness	-	(62,000)
Contingent obligation payments	(762)	(487)
Net cash provided by financing activities	10,996	192,874
Effect of exchange rate changes on cash and cash equivalents	(25)	5
Net decrease in cash and cash equivalents	(63,984)	(19,123)
Cash and cash equivalents at beginning of period	280,499	179,338
Cash and cash equivalents at end of period	$216,515	$160,215

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

EMERGENT BIOSOLUTIONS INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Summary of significant accounting policies

Basis of presentation and consolidation

The accompanying unaudited consolidated financial statements include the accounts of Emergent BioSolutions Inc. (the "Company" or "Emergent") and its 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 issued by the Securities and Exchange Commission ("SEC"). 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, 2014, as filed with the SEC.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of March 31, 2015; the results of operations and comprehensive loss for the three months ended March 31, 2015 and 2014; and cash flows for the three months ended March 31, 2015 and 2014. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

There have been no significant changes to the Company's summary of significant accounting policies, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC, during the three months ended March 31, 2015.

2. Acquisitions

On December 17, 2014, the Company acquired the EV-035 series of molecules from Evolva Holding SA ("Evolva") for approximately $1.5 million in cash along with contingent value right obligations to Evolva. The EV-035 series of molecules is a series of novel small molecule broad spectrum antibiotics of the 4-oxoquinolizine class and targets bacterial type IIa topoisomerase. The lead molecule in the series, GC-072, has demonstrated protection in vivo from lethal B. pseudomallei infection when administered orally. GC-072 is being developed as a potential oral and intravenous treatment for B. pseudomallei under a three-year, $15.0 million contract with the Defense Threat Reduction Agency ("DTRA") of the U.S. Department of Defense. B. pseudomallei is a gram-negative pathogen classified by the Centers for Disease Control and Prevention ("CDC") as a Category B bioterrorism agent and a priority threat capable of being easily weaponized and disseminated. The acquisition diversifies the Biodefense segment by adding a preclinical stage product candidate that is currently being funded through preclinical development, and has been accounted for as a business acquisition.

The contingent values rights are based on the novation of the DTRA contract ($4.0 million) along with the achievement of certain development ($15.0 million) and regulatory filing ($50.0 million) milestones. In addition, the Company is required to make sales-based royalty payments of between 5 % - 8 % through December 2036, based on levels of annual net sales. During the three months ended March 31, 2015, the Company received novation of the DTRA contract and paid the $4.0 million milestone in April 2015.

The total preliminary purchase price is summarized below:

(in thousands)	
Amount of cash paid to Evolva Holding SA	$1,500
Fair value of contingent consideration	28,200
Total purchase price	$29,700

The table below summarizes the preliminary allocation of the purchase price based upon fair values of assets acquired. As of the date of this filing, the valuation of acquired intangible assets and other fair value adjustments are not complete as the Company is obtaining and analyzing additional information related to the aforementioned items. As such, the purchase price allocation is subject to change.

(in thousands)	
Acquired intangible assets	$27,700
Goodwill	2,000
Total purchase price	$29,700

The intangible asset associated with in-process research and development ("IPR&D") acquired from Evolva consisted of the EV-035 series of molecules. Management determined that the estimated acquisition-date fair value of intangible assets related to IPR&D was $27.7 million. The estimated fair value was determined using the income approach, which discounts expected future cash flows to present value. The Company estimated the fair value using a present value discount rate of 12%. The Company believes this rate is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value this IPR&D. The projected cash flows for EV-035 was based on key assumptions including: estimates of revenues and operating profits considering its stage of development on the acquisition date; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate, such as obtaining marketing approval from the U.S. Food and Drug Administration ("FDA") and other regulatory agencies; and risks related to the viability of and potential for alternative treatments in any future target markets. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts.

3. Fair value measurements

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

	March 31, 2015			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Investment in money market funds (1)	$119,063	$ -	$-	$119,063
Total assets	$119,063	$ -	$-	$119,063
Liabilities:				
Contingent consideration	$-	$ -	$48,454	$48,454
Total liabilities	$-	$ -	$48,454	$48,454

	At December 31, 2014			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				

Investment in money market funds (1)	$111,912	$ -	$-	$111,912
Total assets	$111,912	$ -	$-	$111,912
Liabilities:				
Contingent consideration	$-	$ -	$47,657	$47,657
Total liabilities	$-	$ -	$47,657	$47,657

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

For the periods ended March 31, 2015 and 2014, the Company did not have any transfers between Level 1 and Level 2 assets or liabilities.

The fair value of contingent purchase consideration obligations, which is included in the contingent consideration line of the Company's consolidated balance sheets, are based on management's assessment of changes as a result of adjustments to the discount rates and updates in the assumed and actual achievement of future net sales for RSDL and HepaGam B, which are inputs that have no observable market (Level 3). For the three months ended March 31, 2015 and 2014, the contingent purchase consideration obligations increased by $0.8 million and $0.4 million, respectively, primarily due to an adjustment to the actual and expected timing of RSDL and HepaGam B sales. This increase resulted in a charge that is classified in the Company's statement of operations as cost of product sales and contract manufacturing.

The fair value of contingent value rights obligations, which is included in the contingent consideration line of the Company's consolidated balance sheets, are based on management's assessment of certain development and regulatory milestones, along with updates in the assumed achievement of potential future net sales for EV-035, which are inputs that have no observable market (Level 3). For the three months ended March 31, 2015, the contingent value rights obligation increased by $0.8 million primarily due to the novation of DTRA contract, the estimated timing of achievement for certain development and regulatory milestones and the estimated timing of potential future sales of EV-035. This increase resulted in a charge that is classified in the Company's statement of operations as both selling, general and administrative and research and development expense.

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) during the three months ended March 31, 2015.

(in thousands)	
Balance at December 31, 2014	$47,657
Expense included in earnings	1,559
Settlements	(762)
Purchases, sales and issuances	-
Transfers in/(out) of Level 3	-
Balance at March 31, 2015	$48,454

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a nonrecurring basis. During the three months ended March 31, 2015, the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis. During the three months ended March 31, 2014, the assets acquired and liabilities assumed as part of the February 2014 acquisition of Cangene Corporation were measured at fair value on a nonrecurring basis.

4. MorphoSys collaboration agreement

In August 2014, the Company entered into a collaboration agreement ("MorphoSys Agreement") with MorphoSys AG ("MorphoSys") for the joint worldwide development and commercialization of MOR209/ES414, a targeted immunotherapeutic protein, which activates host T-cell immunity specifically against cancer cells expressing prostate

specific membrane antigen, an antigen commonly overexpressed on prostate cancer cells. MOR209/ES414 was constructed using the Company's proprietary ADAPTIR technology platform,

The collaboration provides for sharing of development and clinical costs, with the Company responsible for 36% of such costs and MorphoSys responsible for the remainder. For the three months ended March 31, 2015, the Company has recorded a reduction to research and development expense of $1.8 million for the reimbursement of amounts greater than 36% of the total costs incurred for the period. For the three months ended March 31, 2015, the Company received a $5.0 million milestone payment due to the initiation of a Phase I clinical study to evaluate the safety, tolerability, and clinical activity of MOR209/ES414 in patients with metastatic castration-resistant prostate cancer. The Company recorded this payment in contracts, grants and collaborations revenue within the Company's statement of operations.

As of March 31, 2015, accounts receivable related to the MorphoSys Agreement was $1.9 million. As of March 31, 2015, deferred revenue related to the MorphoSys Agreement consisted of $0.8 million and $3.4 million of current and long-term deferred revenue, respectively.

5. Inventories

Inventories consist of the following:

(in thousands)	March 31, 2015	December 31, 2014
Raw materials and supplies	$17,016	$ 17,375
Work-in-process	40,812	33,477
Finished goods	24,306	14,822
Total inventories	$82,134	$ 65,674

6. Intangible assets, in-process research and development and goodwill

As of March 31, 2015, the Company had $50.1 million of IPR&D assets included in the Biosciences business segment. This includes $41.8 million related to the Company's otlertuzumab product candidate and $8.3 million related to the Company's IXINITY product candidate. In addition, the Company had $27.7 million of IPR&D assets included in the Biodefense segment related to EV-035.

On April 29, 2015, the FDA approved IXINITY for the treatment of Hemophilia B in adults and children. As a result, IXINITY is considered a definite-lived intangible asset from that date.

Intangible assets consist of the following:

(in thousands)	RSDL	Manufacturing Agreement	Corporate Tradename	Marketed Products	Licensed Products	Biodefense Products	Contract Manufacturing	Total
Cost basis								
Balance at December 31, 2014	$28,621	$ 3,478	$ 2,800	$ 8,100	$ 3,100	$ 16,700	$ 5,500	$68,299
Additions	-	-	-	-	-	-	-	-
Balance at March 31, 2015	$28,621	$ 3,478	$ 2,800	$ 8,100	$ 3,100	16,700	$ 5,500	$68,299
Accumulated amortization								

Balance at December 31, 2014	$(4,987)	$ (1,642)	$ (478)	$ (692)	$ (378)	$ (1,191)	$ (587)	$(9,955)
Amortization	(880)	(290)	(140)	(203)	(111)	(346)	(172)	(2,142)
Balance at March 31, 2015	$(5,867)	$ (1,932)	$ (618)	$ (895)	$ (489)	$ (1,537)	$ (759)	$(12,097)
Net book value at March 31, 2015	$22,754	$ 1,546	$ 2,182	$ 7,205	$ 2,611	$ 15,163	$ 4,741	$56,202

For the three months ended March 31, 2015 and 2014, the Company recorded amortization expense of $2.1 million and $1.6 million, respectively, for intangible assets, which has been recorded in selling, general and administrative and cost of product sales and contract manufacturing. Amortization expense of $0.6 million and $0.2 million, respectively, was recorded within the Biosciences segment for the three months ended March 31, 2015 and 2014. Amortization expense of $1.5 million and $1.4 million, respectively, was recorded within the Biodefense segment for the three months ended March 31, 2015 and 2014. At March 31, 2015, the weighted average amortization period remaining for intangible assets in Biodefense and Biosciences segments was 94 and 86 months, respectively.

The following table is a summary of changes in goodwill:

(in thousands)	Biosciences therapeutics	Biosciences contract manufacturing	Biodefense therapeutics	Biodefense medical device	Total
Cost Basis					
Balance at December 31, 2014	$ 13,902	$ 6,736	$ 11,430	$ 9,916	$41,984
Additions	-	-	-	-	-
Balance at March 31, 2015	$ 13,902	$ 6,736	$ 11,430	$ 9,916	$41,984

7. Equity awards

As of March 31, 2015, the Company had two stock-based employee compensation plans, the Third Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan") and the Emergent BioSolutions Employee Stock Option Plan (the "2004 Plan") (together, the "Emergent Plans").

The following is a summary of stock 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, 2014	3,837,993	$ 20.04	43,156	$ 10.28	$29,181,534
Granted	678,821	28.98	-	-	
Exercised	(387,249)	16.38	-	-	
Forfeited	(35,664)	19.69	-	-	
Outstanding at March 31, 2015	4,093,901	$ 21.86	43,156	$ 10.28	$29,195,837
Exercisable at March 31, 2015	2,299,336	$ 19.06	43,156	$ 10.28	$23,104,074

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

	Number of Shares	Weighted-Average Grant Price	Aggregate Intrinsic

			Value
Outstanding at December 31, 2014	927,356	$ 22.44	$25,251,904
Granted	369,071	28.98	
Vested	(356,683)	21.05	
Forfeited	(7,830)	23.44	
Outstanding at March 31, 2015	931,914	$ 25.25	$26,801,847

8. Earnings per share

The following table presents the calculation of basic and diluted net loss per share utilizing the if-converted method:

	Three Months Ended March 31,	
(in thousands, except share and per share data)	2015	2014
Numerator:		
Net loss	$(21,520)	$(20,236)
Interest expense applicable to convertible debt, net of tax	-	-
Amortization of debt issuance costs, net of tax	-	-
Adjusted net loss	$(21,520)	$(20,236)
Denominator:		
Weighted-average number of shares—basic	37,949,358	36,854,370
Dilutive securities—equity awards	-	-
Dilutive securities—convertible debt	-	-
Weighted-average number of shares—diluted	37,949,358	36,854,370
Loss per share-basic	$(0.57)	$(0.55)
Loss per share-diluted	$(0.57)	$(0.55)

Due to the Company's net loss for the three months ended March 31, 2015 and 2014, basic and diluted loss per share are both computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. No adjustment to the net loss was computed under the if-converted method as the effect would have been anti-dilutive.

For the three months ended March 31, 2015 and 2014, outstanding stock options to purchase approximately 5.1 million and 5.2 million shares of common stock, along with 7.7 million shares, respectively, related to the Company's convertible debt, were excluded from the calculation of diluted loss per share.

9. Segment information

For financial reporting purposes, the Company reports financial information for two business segments: Biodefense and Biosciences. The Company's two business segments, or divisions, engage in business activities for which discrete financial information is provided to and resources are allocated by the chief operating decision maker. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies. The Company's reportable segments are business units that offer different products and product candidates, contract manufacturing services and are managed separately because they manufacture and develop distinct products with different manufacturing and development processes, along with having separate and distinct sales and marketing processes.

The Biodefense division is a specialty biopharmaceutical business focused on countermeasures that address CBRNE (Chemical, Biological, Radiological, Nuclear and Explosives) threats and consists of two business units: vaccines/therapeutics and medical devices. Revenues in this segment are primarily from sales of the Company's FDA-licensed product, BioThrax® (Anthrax Vaccine Adsorbed), to the U.S. government. The Biosciences division is a specialty biopharmaceutical business directed to commercial opportunities and primarily targets hematology/oncology, transplantation and infectious diseases, and consists of three business units, therapeutics, vaccines and contract manufacturing. 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 activities that are not classified as Biodefense or Biosciences.

	Reportable Segments			
(in thousands)	Biodefense	Biosciences	All Other	Total
Three Months Ended March 31, 2015				
External revenue	$43,627	$ 20,006	$-	$63,633
Net loss	(11,321)	(8,018)	(2,181)	(21,520)
Three Months Ended March 31, 2014				
External revenue	$47,439	$ 6,445	$-	$53,884
Net income (loss)	1,412	(19,510)	(2,138)	(20,236)

10. Subsequent events

Beginning in January 2015, during standard quality inspections performed in accordance with customary procedures, the Company discovered foreign particles in a limited number of vials in two manufactured lots of BioThrax. In order to determine the source of the foreign particles, the Company investigated its operations as well as those of its suppliers and contract manufacturers. Under the Company's quality standards, these two BioThrax lots were rejected. On April 22, 2015, the Company announced that it has resumed full manufacturing operations of BioThrax after completing its internal manufacturing investigation.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this quarterly report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, including information with respect to our plans and strategy for our business and financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this quarterly report on Form 10-Q 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

Emergent BioSolutions Inc. is a global specialty biopharmaceutical company seeking to protect and enhance life by offering specialized products to healthcare providers and governments for use in addressing medical needs and emerging health threats. We have two operating divisions: Biodefense and Biosciences. For financial reporting purposes, we operate in two business segments that correspond to these two divisions.

Biodefense

Our Biodefense division is a specialty biopharmaceutical business focused on countermeasures that address CBRNE (Chemical, Biological, Radiological, Nuclear and Explosives) threats. The U.S. government is the primary purchaser of our Biodefense products and often provides us with substantial funding for the development of our Biodefense product candidates. Operations that support this division include manufacturing, regulatory affairs, quality assurance, quality control, international sales and marketing, and domestic government affairs in support of our marketed products, as well as product development and manufacturing infrastructure in support of our investigational stage product candidates. Our Biodefense portfolio consists of five marketed products and various investigational stage product candidates.

Our Biodefense division marketed products are:

- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or the FDA, for the prevention of anthrax disease;
- BAT™ (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-Equine), the only heptavalent therapeutic licensed by the FDA for the treatment of botulinum disease;
- Anthrasil™ (Anthrax Immune Globulin Intravenous (Human)), the only polyclonal antibody therapeutic licensed by the FDA for the treatment of anthrax disease;
- VIGIV (Vaccinia Immune Globulin Intravenous (Human)), the only therapeutic licensed by the FDA to address adverse events from smallpox vaccination; and
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only device cleared by the FDA for the removal or neutralization of chemical agents, T-2 toxin and many pesticide-related chemicals from the skin.

Our Biodefense division investigational stage product candidates include the following:

- NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), a next generation anthrax vaccine;
- PreviThrax™ (recombinant protective antigen anthrax vaccine, purified), a next generation anthrax vaccine; and
- GC-072, the lead compound in the EV-035 series of broad spectrum antibiotics, which we acquired from Evolva Holding SA, or Evolva, in December 2014.

On March 25, 2015, the FDA approved Anthrasil for treatment of inhalational anthrax in combination with appropriate antibacterial drugs. Achievement of this milestone triggered a $7.0 million payment to us under a development contract with the Biomedical Advanced Research and Development Authority, or BARDA, which is recorded in product sales revenue within our statement of operations. Anthrasil has received Orphan Drug designation and as a result of this approval, the product qualifies for seven years of market exclusivity.

Our Biodefense division also has programs aimed at providing solutions to the current Ebola outbreak in West Africa, including an MVA-Ebola vaccine candidate, anti-Ebola monoclonal antibody product candidates and an Ebola hyperimmune product candidate.

We have responded to Task Order Requests issued by BARDA for the manufacture of Ebola medical countermeasures as part of our Center for Innovation in Advanced Development and Manufacturing, or CIADM, program. In addition, we have a license agreement for the manufacture of VAX161C, a clinical stage recombinant pandemic influenza vaccine product candidate being developed by VaxInnate, Inc., as part of our CIADM program.

Our Biodefense segment has generated net income for each of the last five years.

Biosciences

Our Biosciences division is a specialty biopharmaceutical business focused on therapeutics and vaccines in hematology/oncology, transplantation, infectious disease and autoimmunity. Our Biosciences portfolio of products

consists of marketed products as well as various investigational stage product candidates, platform technologies and a contract manufacturing services business. Operations that support this division include manufacturing, quality, regulatory affairs, medical affairs, and sales and marketing in support of our marketed products, as well as additional product development capabilities in support of our investigational stage product candidates.

Our Biosciences division marketed products are:

- WinRho® SDF [Rh_o(D) Immune Globulin Intravenous (Human)], for treatment of autoimmune platelet disorder, also called immune thrombocytopenic purpura or ITP, and, separately, for the treatment of hemolytic disease of the newborn, or HDN;
- HepaGam B® [(Hepatitis B Immune Globulin Intravenous (Human)], for post-exposure prophylactic treatment of hepatitis-B;
- VARIZIG® [Varicella Zoster Immune Globulin (Human)], for post-exposure prophylactic treatment of varicella zoster virus, which causes chickenpox and shingles;
- IXINITY® (coagulation factor IX (recombinant)), for the prevention of bleeding episodes in people with Hemophilia B (approved by the FDA in April 2015) ; and
- episil® (oral liquid), for relief of pain and soothing oral lesions of various etiologies, including oral mucositis/stomatitis caused by chemotherapy or radio therapy.

Our Biosciences division investigational stage product candidates include the following:

- MOR209/ES414, being developed for metastatic castration-resistant prostate cancer under our collaboration with MorphoSys AG, or MorphoSys, entered into in August 2014; and
- otlertuzumab, being developed for Chronic Lymphocytic Leukemia.

Our Biosciences division platform technologies include:

- ADAPTIR™ (modular protein technology);
- MVAtor™ (modified vaccinia virus Ankara vector); and
- hyperimmune specialty plasma product manufacturing.

Our Biosciences segment has generated revenue for each of the last five years through product sales, development contracts and collaborative funding but has incurred a net loss for those years.

Product Sales

We have derived the majority of our historical product sales revenues from BioThrax sales to the U.S. government. We are currently a party to a contract with the Centers for Disease Control and Prevention, or CDC, an operating division of the U.S. Department of Health and Human Services, or HHS, to supply up to 44.75 million doses of BioThrax for placement into the Strategic National Stockpile, or SNS, over a five-year period ending September 30, 2016. We expect to continue to derive a majority of product sales revenues from our sales of BioThrax to the U.S. government. We are focused on increasing the sales of our Biodefense products to U.S. government customers and expanding the market for our product portfolio to other customers domestically and internationally.

Contract Manufacturing

We provide contract manufacturing services, including biopharmaceutical product development and filling services for injectable and other sterile products, as well as process design, technology transfer, manufacturing validation, laboratory support, aseptic filling, lyophilization and accelerated and ongoing stability studies. We produce finished units of commercial drugs for a variety of customers ranging from small biopharmaceutical companies to major multinationals. We are focused on increasing services to third party biopharmaceutical companies, both domestically

and internationally.

Contracts, Grants and Collaborations

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. In addition, we perform certain ongoing product-related services for which we receive funding. We continue to actively pursue additional government sponsored development contracts and grants and commercial collaborative relationships. We also encourage both governmental and non-governmental agencies and philanthropic organizations to provide funding for non-clinical activities and to conduct clinical studies of our product candidates.

Financial Operations Overview

Revenues

We entered into a contract with the CDC effective as of September 30, 2011 to supply up to 44.75 million doses of BioThrax to the CDC over a five-year period. The period of performance under the award is from September 30, 2011 through September 30, 2016. The maximum amount that could be paid to us under the contract is up to $1.25 billion, subject to availability of funding by the U.S. government. To date, the U.S. government has committed approximately $911 million for the procurement of BioThrax doses under this contract. Through March 31, 2015, we have delivered and, upon CDC acceptance, recognized revenue on approximately 27 million doses, representing approximately $722 million in revenue under this contract.

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

Development Programs	Funding Source	Award Date	Performance Period
Post-Exposure Prophylaxis indication for BioThrax (PEP)	BARDA	Sep-07	9/2007 — 3/2016
Large-scale manufacturing for BioThrax	BARDA	Jul-10	7/2010 — 7/2015
NuThrax	NIAID	Jul-10	8/2010 — 4/2015
PreviThrax	BARDA	Sep-10	9/2010 — 9/2015
CIADM	BARDA	Jun-12	6/2012 — 6/2037
BAT	CDC	Jan-03	1/2003 — 1/2015
BAT	BARDA	May-06	5/2006 — 5/2026
Anthrasil	BARDA	Sep-05	9/2005 — 4/2021
Anthrasil	BARDA	Sep-02	9/2002 — 12/2015
Anthrasil	BARDA	Sep-13	9/2013 — 9/2018
VIGIV	CDC	Aug-12	8/2012 — 8/2017
NuThrax	NIAID	Aug-14	8/2014 — 10/2019
NuThrax	BARDA	Mar-15	3/2015 — 8/2017

Our revenue, operating results and profitability have varied, and we expect that they will continue to vary on a quarterly basis, primarily due to the timing of sales of our products and timing of work completed under new and existing grants, development contracts and collaborative relationships.

Cost of Product Sales and Contract Manufacturing

The primary expense that we incur to deliver our vaccines and therapeutics to our customers and in our contract manufacturing operations, is manufacturing costs, consisting of fixed and variable costs. Variable manufacturing costs consist primarily of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff, contract manufacturing and filling operations, and sales-based royalties. Fixed manufacturing costs include

facilities, utilities and amortization of intangible assets. We determine the cost of product sales for products sold during a reporting period based on the average manufacturing cost per unit in the period those units were manufactured. In addition to the fixed and variable manufacturing costs described above, the cost of product sales depends on utilization of available manufacturing capacity.

The primary expense that we incur to deliver our medical device, RSDL, to our customers is the cost per unit of production from our third-party contract manufacturer. Other associated expenses include sales-based royalties, amortization of intangible assets, shipping, logistics and the cost of support functions.

Research and Development Expenses

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

§ personnel-related expenses;
§ fees to professional service providers for, among other things, analytical testing, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies;
§ costs of contract manufacturing services for clinical trial material; and
§ costs of materials used in clinical trials and research and development.

We intend to focus our product development efforts on promising late-stage candidates that we believe satisfy well-defined criteria and seek to utilize collaborations or non-dilutive funding. We plan to seek funding for development activities from external sources and third parties, such as governments and non-governmental organizations. We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development spending, the number of product candidates under development, the size, structure and duration of any follow-on clinical programs that we may initiate, the 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 involving BioThrax conducted by the CDC.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel-related costs and professional fees in support of our executive, sales and marketing, business development, government affairs, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales and contract manufacturing or research and development expense.

In-process Research and Development

IXINITY

The intangible asset associated with in-process research and development, or IPR&D, in the acquisition of Cangene Corporation, or Cangene, is the IXINITY product candidate. As part of the purchase price allocation our management determined that the estimated acquisition date fair value related to the IXINITY IPR&D asset was $8.3 million. The estimated fair value was determined using the income approach, which discounts expected future cash flows to present value. We estimated the fair value using a present value discount rate of 16%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of Cangene. We believe this rate is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would likely use to value this type of IPR&D asset. The projected cash flows from IXINITY were based on key assumptions, including: estimates of revenues and operating profits considering its stage of development on the acquisition date; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and

uncertainties in developing a product candidate such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential alternative treatments in any future target markets. The IXINITY asset was considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. On April 29, 2015, IXINITY was approved by the FDA. As a result, IXINITY is considered a definite-lived intangible asset from that date.

EV-035

The intangible asset associated with IPR&D acquired from Evolva Holding SA, or Evolva, in December 2014, is the EV-035 series of molecules, or EV-035. As part of the preliminary purchase price allocation, management determined that the estimated acquisition date fair value related to EV-035 IPR&D asset was $27.7 million. The estimated fair value was determined using the income approach, which discounts expected future cash flows to present value. We estimated the fair value using a present value discount rate of 12%, which we believe is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would likely use to value the EV-035 asset. The projected cash flows from the EV-035 project were based on key assumptions, including: estimates of revenues and operating profits considering its stage of development on the acquisition date; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential alternative treatments in any future target markets. The EV-035 asset is considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts.

Provision for Chargebacks

We record sales for our Biosciences products, primarily WinRho and HepaGam, net of provisions for chargebacks, administration fees, rebates and other adjustments. These provisions are primarily estimated based on historical experience, future expectations, contractual arrangements with wholesalers and indirect customers, and other factors known to management at the time of accrual. Provisions for chargebacks, administration fees, rebates and other adjustments require varying degrees of subjectivity. While rebates generally are based on contractual terms and require minimal estimation, chargebacks require management to make more subjective assumptions.

The provision for chargebacks is a significant and complex estimate used in the recognition of revenue. Primarily, we sell our products directly to large commercial wholesale distributors. We also sell our products indirectly to group-purchasing organizations, physician practice-management groups and hospitals, collectively referred to as "indirect customers." We enter into agreements with our indirect customers to establish pricing for certain of our products. The indirect customers then independently select a wholesaler from which to purchase the products. If the price paid by the indirect customers is lower than the price paid by the wholesaler, we will provide a credit, called a chargeback, to the wholesaler for the difference between the contractual price with the indirect customers and the wholesaler purchase price. The provision for chargebacks is based on expected sell-through levels by our wholesale customers to the indirect customers and estimated wholesaler inventory levels.

As sales to the large wholesale customers fluctuate the reserve for chargebacks will also generally fluctuate in the same direction. However, the degree of the fluctuation depends on product mix and the amount of sales made to indirect customers with which we have specific chargeback agreements.

On a quarterly basis management reviews actual payments for provisions, wholesaler and distributor sales to our indirect customers, inventory balances at the wholesalers and distributors, as well as any known market factors that may impact our estimate, and we make adjustments when we believe that actual chargebacks may differ from the actual chargeback reserve.

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, 2015. Refer to the Critical Accounting Policies and Estimates section in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission.

Results of Operations

Three Months Ended March 31, 2015 Compared to Three Months Ended March 31, 2014

Revenues

Product Sales:

Product sales revenues decreased by $17.5 million, or 49%, to $18.3 million for the three months ended March 31, 2015 from $35.8 million for the three months ended March 31, 2014. Product sales revenues included:

- BioThrax - minimal sales for the three months ended March 31, 2015 as compared to $24.5 million for the three months ended March 31, 2014;
- Other Biodefense products - $11.9 million for the three months ended March 31, 2015 as compared to $8.1 million for the three months ended March 31, 2014; and
- Biosciences product sales (acquired in February 2014) - $6.3 million for the three months ended March 31, 2015 as compared to $3.3 million for the three months ended March 31, 2014.

The decrease in BioThrax sales was due to our decision to suspend shipments to the CDC in the first quarter of 2015 following the discovery of foreign particles in a limited number of vials in two manufactured lots of BioThrax in January 2015. As a result, there were no revenues for BioThrax product sales to the CDC for the three months ended March 31, 2015. BioThrax product sales revenues during the three months ended March 31, 2014 primarily consisted of sales to the CDC of $24.1 million.

Contract Manufacturing:

Contract manufacturing revenues increased by $9.5 million to $12.2 million for the three months ended March 31, 2015 from $2.7 million for the three months ended March 31, 2014. The increase in contract manufacturing revenues for the three months ended March 31, 2015 was primarily due to revenues from our fill/finish facility, acquired from Cangene in February 2014, for the entire three month period. In addition, contract manufacturing revenue increased by $3.8 million due to services related to the production of an MVA Ebola vaccine candidate.

Contracts, Grants and Collaborations:

Contracts, grants and collaborations revenues increased by $17.7 million to $33.1 million for the three months ended March 31, 2015 from $15.4 million for the three months ended March 31, 2014. The increase was primarily due to:

- increased development funding of $14.8 million for Anthrasil related to plasma collection; and
- recognition of a $5.0 million milestone payment from our collaboration with MorphoSys AG from the initiation of a Phase I clinical study to evaluate the safety, tolerability and clinical activity of MOR209/ES414 in patients with metastatic castration-resistant prostate cancer.

These increases were partially offset by decreased revenue of $3.9 million under our development contracts for BAT and large-scale manufacturing of BioThrax primarily due to the timing of development efforts, along with a payment received in 2014 for our PEP indication for BioThrax related to the progress of development activities.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing decreased by $0.2 million, or 1%, to $18.7 million for the three months ended March 31, 2015 from $19.0 million for the three months ended March 31, 2014.

Research and Development Expenses

Research and development expenses increased by $8.4 million, or 28%, to $38.7 million for the three months ended March 31, 2015 from $30.3 million for the three months ended March 31, 2014. This increase primarily reflects higher contract service costs and includes increased expenses of $11.2 million for product candidates and manufacturing development categorized in the Biodefense segment, partially offset by decreased expenses of $2.5 million for product candidates and technology platform development activities categorized in the Biosciences segment. Net of contracts, grants and collaborations revenues, we incurred net research and development expenses of $5.6 million and $14.9 million, during the three months ended March 31, 2015 and 2014, respectively.

Our principal research and development expenses for the three months ended March 31, 2015 and 2014 are shown in the following table:

	Three Months Ended March 31,	
(in thousands)	2015	2014
Biodefense:		
Large-scale manufacturing for BioThrax	$2,748	$3,484
BioThrax related programs	691	2,327
PreviThrax	1,765	2,530
NuThrax	2,829	2,407
Pandemic influenza	1,117	1,187
Anthrasil	10,608	700
Botulinum antitoxin	1,439	646
Other Biodefense	5,677	2,422
Total Biodefense	26,874	15,703
Biosciences:		
MOR209/ES414	659	4,499
IXINITY	5,361	1,247
otlertuzumab	1,195	3,245
Other Biosciences	3,043	3,790
Total Biosciences	10,258	12,781
Other	1,570	1,772
Total	$38,702	$30,256

The decrease in spending for large-scale manufacturing for BioThrax was primarily due to the timing of manufacturing development activities. The decrease in spending for BioThrax related programs was primarily related to the timing of clinical studies to support applications for label expansion for BioThrax. The decrease in spending for PreviThrax was primarily due to the timing of non-clinical studies. The spending for NuThrax was primarily for clinical trial activities. The spending for pandemic influenza was primarily for manufacturing development activities. The spending for our Anthrasil program (which we acquired from Cangene in February 2014) was primarily for plasma collection services. The spending for our Botulinum Antitoxin program (which we acquired from Cangene) was primarily for stability testing. The increase in spending for our Other Biodefense activities was primarily due to increased spending related to manufacturing development.

The decrease in spending for our MOR209/ES414 product candidate was primarily due to the timing of manufacturing development along with reimbursement for clinical material from MorphoSys. The increase in spending for our IXINITY product candidate was primarily for manufacturing activities. The decrease in spending for our otlertuzumab product candidate was primarily related to the timing of clinical trial activities. The decrease in spending for our Other Biosciences activities was primarily due to decreased costs associated with the development of platform technologies along with reduced costs associated with other programs acquired from Cangene.

The spending for Other activities was primarily due to centralized research and development activities attributable to product candidates.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $4.4 million, or 15%, to $34.5 million for the three months ended March 31, 2015 from $30.1 million for the three months ended March 31, 2014. This increase includes additional post-acquisition selling, general and administrative costs of $4.0 million associated with the operations acquired from Cangene in February 2014.

Selling, general and administrative expenses attributable to our Biodefense segment increased by $1.4 million, or 8%, to $18.3 million during the three months ended March 31, 2015 from $16.9 million during the three months ended March 31, 2014. Selling, general and administrative expenses related to our Biosciences segment increased by $3.0 million, or 23%, to $16.2 million for the three months ended March 31, 2015 from $13.2 million for the three months ended March 31, 2014.

Total Other Income (Expense)

Total net other expense decreased by $1.5 million, or 50%, to $1.5 million for the three months ended March 31, 2015 from $3.0 million for the three months ended March 31, 2014. The decrease was primarily due to $1.8 million of costs associated with the termination of our $125 million term loan facility in the first quarter of 2014.

Income Taxes

Benefit from income taxes increased by $0.1 million, or 1%, to $8.3 million for the three months ended March 31, 2015 from $8.2 million for the three months ended March 31, 2014.

Liquidity and Capital Resources

Sources of Liquidity

From inception through March 31, 2015, we have funded our cash requirements principally with a combination of revenues from sales of BioThrax, debt financings, development funding from government entities and non-government and philanthropic organizations and collaborative partners, the net proceeds from our initial public offering and the sale of our common stock upon exercise of stock options. We have operated profitably for each of the five years ended December 31, 2014. As of March 31, 2015, we had cash and cash equivalents of $216.5 million.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2015 and 2014:

Three Months Ended

(in thousands)	March 31, 2015	2014
Net cash provided by (used in):		
Operating activities(i)	$(65,898)	$(29,240)
Investing activities	(9,082)	(182,757)
Financing activities	10,996	192,874
Net decrease in cash and cash equivalents	$(63,984)	$(19,123)

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

Net cash used in operating activities of $65.9 million for the three months ended March 31, 2015 was primarily due to our net loss of $21.5 million, a decrease in income taxes of $19.4 million related to timing differences, a decrease in accrued compensation of $10.9 million primarily related to the payment of 2014 bonuses and an increase in inventory of $16.5 million due to minimal shipments of BioThrax in the first quarter of 2015.

Net cash used in operating activities of $29.2 million for the three months ended March 31, 2014 was primarily due to our net loss of $20.2 million, a decrease in income taxes of $11.8 million related to timing differences, a decrease in accrued compensation of $8.7 million primarily related to the payment of 2013 bonuses and a decrease in accounts payable of $10.7 million, primarily due to acquisition related activities, partially offset by a decrease in accounts receivable of $17.6 million related to the timing of collection of amounts billed primarily to the CDC.

Net cash used in investing activities of $9.1 million for the three months ended March 31, 2015 was due to infrastructure and equipment investments.

Net cash used in investing activities of $182.8 million for the three months ended March 31, 2014 was primarily due to the acquisition of Cangene for $178.2 million, which is net of $43.6 million of acquired cash, and capital expenditures of $4.6 million for infrastructure and equipment investments.

Net cash provided by financing activities of $11.0 million for the three months ended March 31, 2015 was primarily due to $6.3 million in proceeds from the issuance of common stock pursuant to employee equity plans and $5.4 million in excess tax benefits from the exercise of stock options.

Net cash provided by financing activities of $192.9 million for the three months ended March 31, 2014 was primarily due to proceeds from long-term indebtedness of $251 million, of which $241.7 million (net of $8.3 million of transaction costs) was from our 2.875% Convertible Senior Notes due 2021, or Notes, $8.1 million in proceeds from the issuance of common stock pursuant to employee equity plans and $4.6 million in excess tax benefits from the exercise of stock options, partially offset by a principal payment on indebtedness of $62.0 million under our revolving credit facility.

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 product sales, development contract and grant funding, and our revolving credit facility and any other lines of credit we may establish from time to time. There are numerous risks and uncertainties associated with product sales and with the development and commercialization of our product candidates. We may seek additional external financing to provide additional financial flexibility. Our future capital requirements will depend on many factors, including:

§ the level, timing and cost of product sales;
§ the extent to which we acquire or invest in and integrate companies, businesses, products or technologies;
§ the acquisition of new facilities and capital improvements to new or existing facilities;

- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs; and
- the costs of commercialization activities, including product marketing, sales and distribution.

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements. We have an effective shelf registration statement on file with the SEC that allows us to issue up to an aggregate of $180 million of equity, debt and certain other types of securities through one or more future offerings. If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank 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, pursuing acquisition opportunities or declaring dividends. If we raise 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.

We are not restricted under the terms of the indenture governing the Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing our Notes that could have the effect of diminishing our ability to make payments on our indebtedness.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is currently confined to our cash and cash equivalents and our long-term indebtedness. We currently do not hedge interest rate exposure or foreign currency exchange exposure, and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, we believe that an increase in market rates would likely not have a significant impact on the realized value of our investments, but any increase in market rates 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, 2015. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under 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, 2015, 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

During the quarter ended March 31, 2015, the controls and procedures of Cangene Corporation, acquired in February 2014, have been integrated into the Company's internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act), and the Company is currently evaluating the design and operational effectiveness of these controls and procedures. There have been no other changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation required by Rule 13a-15(d) under the Exchange Act has occurred during the period covered by this report 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

Not applicable.

ITEM 1A. RISK FACTORS

You should carefully consider, among other matters, the following risk factors in addition to the other information in this Quarterly Report on Form 10-Q when evaluating our business because these risk factors may have a significant impact on our business, financial condition, operating results or cash flow. If any of the risks described below or in subsequent reports we file with the SEC actually occur, they may materially harm our business, financial condition, operating results or cash flow. Additional risks and uncertainties that we have not yet identified or that we presently consider to be immaterial may also materially harm our business, financial condition, operating results or cash flow.

GOVERNMENT CONTRACTING RISKS

We derive the majority of our revenue from sales of BioThrax to our principal customer, the U.S. government. If the U.S. government's demand for BioThrax is reduced, our business, financial condition, operating results and cash flow could be materially harmed.

We have derived and expect for the foreseeable future to derive the majority of our revenue from sales of BioThrax, our FDA-licensed anthrax vaccine, to the U.S. government. We are currently party to a contract with the Centers for Disease Control and Prevention, or CDC, for the supply of up to 44.75 million doses of BioThrax for placement into the Strategic National Stockpile, or SNS, over a five-year period ending in September 2016.

The procurement of doses of BioThrax by the CDC is subject to the availability of funding. Our existing contract with the CDC does not guarantee that funding for the procurement of doses will be made available. If the SNS priorities change, funding to procure doses of BioThrax may be limited or not available, and our business, financial condition and operating results would be materially harmed. The success of our business and our operating results for the foreseeable future are significantly dependent on funding for the procurement of BioThrax and the terms of our BioThrax sales to the U.S. government, including the price per dose, the number of doses and the timing of deliveries.

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

Our principal customer for BioThrax, BAT, Anthrasil, VIGIV and RSDL is the U.S. government. We anticipate that the U.S. government will also be a principal customer for other biodefense products that we successfully acquire or develop. Additionally, a significant portion of our revenue comes from U.S. government development contracts and grants. Over its lifetime, a U.S. government procurement or development program may be implemented through the award of many different individual contracts and subcontracts. The funding for such government programs is subject

to Congressional appropriations, generally made on a fiscal year basis, even for programs designed to continue for several years. These appropriations can be subject to political considerations and stringent budgetary constraints. For example, sales of BioThrax supplied under our multi-year procurement contract with the CDC are subject to available funding, mostly from annual appropriations. Additionally, our government-funded development contracts typically give the U.S. government the right, exercisable in its sole discretion, to extend these contracts for successive option periods following a base period of performance. The value of the services to be performed during these option periods may constitute the majority of the total value of the underlying contract. For example, the development contract we were awarded in August 2014 for development of a dry formulation of PreviThrax consists of an approximately two-year base period of performance valued at approximately $7.3 million and thirteen successive one-year option periods valued at a total of approximately $29 million. 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, or if the U.S. government otherwise declines to exercise its options under our contracts, our business, revenues and operating results would suffer.

The government contracting process is typically a competitive bidding process and involves unique risks and requirements.

We expect that a significant portion of our near-term business will be under government contracts and grants, which may be awarded through competitive bidding. Competitive bidding for government contracts presents a number of risks and requirements, some of which 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
- in the event our competitors protest or challenge contract or grant awards made to us pursuant to competitive bidding, the potential that we may incur expenses or delays, and that any such protest or challenge would result in the resubmission of bids based on modified specifications, or in the termination, reduction or modification of the awarded contract.

The U.S. government may choose not to award us future contracts for the development of our Biodefense product candidates or for the procurement of our Biodefense products, 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 or resources that will be required to secure and, if applicable, perform under such contract awards, our growth strategy and our business, financial condition and operating results could be materially and adversely affected.

Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws could result in significant civil and criminal penalties and materially damage our relationship with the U.S. government.

We must comply with numerous laws and regulations relating to the procurement, formation, administration and performance of government contracts. Among the most significant government contracting regulations that affect the business of our Biodefense division are:

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

- the Defense Federal Acquisition Regulations, or DFARs, and agency-specific regulations supplemental to the DFAR, which comprehensively regulate the procurement, formation, administration and performance of Department of Defense, or DoD, government contracts;
- 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, the Procurement Integrity Act, the False Claims Act and the Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

U.S. government agencies routinely audit and investigate government contractors for compliance with applicable laws and standards. If we are audited and such audit were to uncover improper or illegal activities, we could be subject to civil and criminal penalties, administrative sanctions, including suspension or debarment from government contracting and significant reputational harm.

The amount we are paid under our fixed price government procurement contracts is based on estimates we have made of the time, resources and expenses required for us to perform under those contracts. If our actual costs exceed our estimates, we may not be able to earn an adequate return or may incur a loss under these contracts, which could harm our operating results and materially reduce our net income.

Some of our current contracts with the U.S. Health & Human Services, or HHS, and the DoD for the procurement of our Biodefense products are fixed price contracts. We expect that our potential future contracts with the U.S. government for our Biodefense products 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. 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 such a contract or cause a loss, which could harm our operating results and materially reduce our net income.

Unfavorable provisions in government contracts, some of which may be customary, may subject our business to material limitations, restrictions and uncertainties and may have a material adverse impact on our financial condition and operating results.

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

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including by imposing equitable price adjustments;
- cancel multi-year contracts and related orders, if funds for contract performance for any subsequent year become unavailable;
- decline, in whole or in part, to exercise an option to purchase product under a contract or renew a contract;
- claim rights to facilities or to products, including intellectual property, developed under the contract;
- require repayment of contract funds spent on construction of facilities in the event of contract default;
- 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 civil or criminal remedies under acts such as the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

Generally, government contracts, including our contract for procurement of BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the U.S. government's convenience. Under general principles of government contracting law, if the U.S. government terminates a contract for convenience, the government contractor may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the U.S. government terminates a contract for default, the government contractor 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. Our CDC contract for the procurement of BioThrax is, and our future U.S. government procurement and development contracts are likely to be, terminable at the U.S. government's convenience with these potential consequences.

Our U.S. government contracts grant the U.S. government the right to use technologies developed by us under the government contract or the right to share data related to our technologies, for or on behalf of the U.S. government. Under our U.S. government contracts, we might not be able to prohibit third parties, including our competitors, from accessing such technology or data, including intellectual property, in providing products and services to the U.S. government.

COMMERCIALIZATION RISKS

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 may face future competition with respect to our products, any products that we acquire, our current product candidates and any products we may seek to develop or commercialize in the future from other companies and governments, universities and other non-profit research organizations. Our competitors may develop products that are safer, more effective, more convenient or less costly than any products that we may develop or market. Our competitors may devote greater resources to market or sell their products, adapt more quickly to new technologies, scientific advances or patient preferences and needs, initiate or withstand substantial price competition more successfully than we can, or more effectively negotiate third-party licensing and collaborative arrangements.

There are a number of companies with biodefense products or product candidates competing with us for both U.S. government procurement and development resources. For example, in terms of additional procurement of licensed countermeasures, HHS awarded a development and SNS procurement contract to GlaxoSmithKline plc for ABThrax™ (raxibacumab), an anthrax monoclonal antibody therapeutic.

We believe that our most significant competitors in the hematology/oncology and transplantation markets include: AbbVie Inc., Amgen Inc., Baxter International Inc., CSL Behring, a subsidiary of CSL Limited, Genentech Inc. (a subsidiary of F. Hoffmann-La Roche Ltd.), Gilead Sciences, Inc., Grifols USA LLC, Johnson & Johnson and Novartis AG.

Any reduction in demand for our products as a result of a competing product could lead to reduced revenues, reduced margins, reduced levels of profitability and loss of market share for our products. These competitive pressures could adversely affect our business and operating results.

We rely on third parties to distribute some of our products and those third parties may not perform.

A portion of our revenues from product sales is derived from sales through exclusive distributors in Canada and international markets. For example, in Canada, only two distributors have rights to our WinRho SDF, HepaGam B and VARIZIG products. As a result, we rely on the sales and marketing strength of these distributors and the distribution channels through which they operate for a portion of our revenues. We may not be able to retain these distribution relationships indefinitely and these distributors may not adequately support the sales, marketing and distribution

efforts of our products in these markets. If third parties do not successfully carry out their contractual duties in maximizing the commercial potential of our products, or if there is a delay or interruption in the distribution of our products, it could negatively impact our revenues from product sales.

The commercial success of our Biosciences products will depend upon the degree of market acceptance by government customers, physicians, patients, healthcare payors and others in the medical community.

Our Biosciences products may not gain or maintain market acceptance by potential government customers, physicians, patients, third-party payors and others in the medical community. In particular, the success of our Biosciences products, including our hyperimmune specialty products, 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 of our products do not achieve and maintain an adequate level of acceptance, we may not generate material revenues from sales of these products. The degree of market acceptance of our products 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 products 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.

Changes in health care systems and payor reimbursement policies could result in a decline in our potential sales and a reduction in our expected revenue from our products.

The revenues and profitability of biopharmaceutical companies like ours may be affected by the continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means. For example, in certain foreign markets, the pricing or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. Recent U.S. legislation, rules and regulations instituted significant changes to the U.S. healthcare system that could have a material adverse effect on our business, financial condition and profitability. We cannot predict what effects, if any, this legislation might have on our company and our products as this legislation continues to be further implemented over the next few years, nor can we predict whether additional legislative or regulatory proposals may be adopted.

In addition, in the United States and elsewhere sales of therapeutic and other pharmaceutical products depend, in part, on the availability of reimbursement from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. Third-party payors may limit access to biopharmaceutical products through the use of prior authorizations and step therapy. Any reimbursement granted may not be maintained, or limits on reimbursement available from third parties may reduce the demand for or negatively affect the price and profitability of those products. Payors may pursue aggressive cost cutting initiatives such as comparing the effectiveness, benefits and costs of similar treatments, which could result in lower reimbursement and therefore demand for these products. Policies that decrease reimbursement would likely have a material adverse effect on our business, financial condition and results of operations. Our ability to successfully

commercialize our products and product candidates and the demand for our products depend, in part, on the extent to which reimbursement and access is available from such third-party payors.

Our Biologic Products may face risks of competition from biosimilar manufacturers.

Competition for BioThrax, WinRho SDF, BAT, Anthrasil, HepaGam B, VARIZIG and VIGIV, or our "Biologic Products," may be affected by follow-on biologics, or "biosimilars," in the United States and other jurisdictions. Regulatory and legislative activity in the United States and other countries may make it easier for generic drug manufacturers to manufacture and sell biological drugs similar or identical to our Biologic Products, which might affect the profitability or commercial viability of our Biologic Products. Under the Biologics Price Competition and Innovation Act of 2010, the FDA cannot approve a biosimilar application until the 12-year exclusivity period for the innovator biologic has expired. Regulators in the European Union and in other foreign jurisdictions have already approved biosimilars, although the European Medicines Agency has expressly excluded blood or plasma-derived products and their recombinant alternatives from the biosimilar pathway for a period of time. Vaccine and allergen products are considered on a case-by-case basis. The specific regulatory framework for this new approval pathway, whether the FDA will permit biosimilars for blood products and vaccines, and the extent to which an approved biosimilar would be substituted for the innovator biologic are not yet clear and will depend on many factors that are currently unknown. If a biosimilar version of one of our Biologic Products were approved, it could have a material adverse effect on the sales and gross profits of the affected Biologic Product and could adversely affect our business and operating results.

Political or social factors may delay or impair our ability to market our products and may require us to spend significant management time and financial resources to address these issues.

Products developed to treat diseases caused by or to combat CBRNE (Chemical, Biological, Radiological, Nuclear and Explosives) threats are subject to changing political and social environments. The political responses and social awareness of the risks of biowarfare and bioterrorism attacks on military personnel or civilians may vary over time. If the threat of terrorism were to decline, then the public perception of the risk of bioterrorism may be reduced. This perception, as well as political or social pressures, could delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, any of which could negatively affect our revenues.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Lawsuits brought against us by third parties or activists, even if not successful, could require us to spend significant management time and financial resources defending the related litigation and could potentially damage the public's perception of us and our products. Any publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of our Biodefense products and thereby limit the demand for our Biodefense products, which would adversely affect our revenues.

REGULATORY AND COMPLIANCE RISKS

Our long term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize product candidates and, if we are not successful, our business and operating results may suffer.

Our product candidates and the activities associated with their development, including testing, manufacture, recordkeeping, storage and approval, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Except under limited circumstances related to certain government sales, failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have limited experience in preparing, filing and prosecuting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process.

In the United States, to obtain approval from the FDA to market any of our future biologic products, 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 efficacy in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted.

However, NuThrax and PreviThrax are subject to a different regulatory approval pathway. Specifically, because humans are rarely exposed to anthrax toxins under natural conditions, and cannot be intentionally exposed, statistically significant efficacy for these product candidates cannot be demonstrated in humans. Instead, efficacy must be demonstrated, in part, by utilizing animal models instead of testing in humans. This is known as the FDA's "Animal Rule." We cannot guarantee that the FDA will permit us to proceed with licensure of NuThrax, or PreviThrax or any Biodefense 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 to support approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. Furthermore, products approved under the Animal Rule are subject to certain additional post-marketing requirements. For example, to the extent feasible and ethical, manufacturers of products approved pursuant to the Animal Rule must conduct post-marketing studies, such as field studies, to verify and describe the drug's clinical benefit and to assess its safety when used as indicated. We cannot guarantee that we will be able to meet this regulatory requirement even if one or more of our product candidates is approved under the Animal Rule.

The process of obtaining these 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 candidate involved. Changes in the regulatory approval process 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 to support 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.

Even after regulatory approval is received, if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, they could be subject to restrictions, penalties or withdrawal from the market.

Any vaccine, therapeutic product or medical device 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. Our approved products are subject to these requirements and ongoing review. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, current good manufacturing practices, or cGMP, requirements relating to quality control, quality assurance, restrictions on advertising and promotion, import and export restrictions and recordkeeping requirements. In addition, various state laws require that companies that manufacture and/or distribute drug products within the state obtain and maintain a manufacturer or distributor license, as appropriate. Because of the breadth of these laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

The FDA enforces its cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect domestic manufacturing facilities without prior notice at reasonable times and in a reasonable manner. The FDA conducts periodic inspections of our facilities. For example, our Lansing facility was inspected most recently in November 2013 and our Winnipeg manufacturing facility was inspected most recently in July 2014. Following each of these inspections, the FDA has issued inspectional observations, some of

which were significant, but all of which are being addressed through corrective actions. 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, the FDA may undertake enforcement action against us, which may include:

- warning letters and other communications;
- product seizure or withdrawal of the product from the market;
- restrictions on the marketing or manufacturing of a product;
- suspension or withdrawal of regulatory approvals or refusal to approve pending applications or supplements to approved applications;
- fines or disgorgement of profits or revenue; and
- injunctions or the imposition of civil or criminal penalties.

Similar action may be taken against us should we fail to comply with regulatory requirements, or later discover previously unknown problems with our products or manufacturing processes. 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. If we experience any of these post-approval events, our business, financial condition and operating results could be materially and adversely affected.

Failure to obtain or maintain regulatory approval in international jurisdictions could prevent us from marketing our products abroad and could limit the growth of our business.

We currently sell and intend to sell our products 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. Approval by the FDA does not ensure approval by foreign regulatory authorities. The approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review. We and our collaborators may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and therefore we may be unable to commercialize our products internationally.

Our international operations increase our risk of exposure to potential claims of bribery and corruption.

As we expand our commercialization activities outside of the United States, we are subject to an increased risk of inadvertently conducting activities in a manner that violates the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act, Canada's Corruption of Foreign Public Officials Act, or other similar foreign laws, which prohibit corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. In the course of establishing and expanding our commercial operations and seeking regulatory approvals outside of the United States, we will need to establish and expand business relationships with various third parties and will interact more frequently with foreign officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be foreign officials under the FCPA or similar foreign laws. If our business practices outside the United States are found to be in violation of the FCPA or similar foreign laws, we and our senior management may be subject to significant civil and criminal penalties, potential debarment from public procurement and reputational damage, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

MANUFACTURING RISKS

Our biologic products and product candidates are complex to manufacture and ship, which could cause us to experience delays in product manufacturing or development and resulting delays in revenues.

BioThrax, WinRho SDF, BAT, Anthrasil, HepaGam B, VARIZIG, VIGIV and many of our current 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. Problems may arise during manufacturing for a variety of reasons, including problems with raw materials, equipment malfunction and failure to follow specific protocols and procedures. In addition, slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation, contamination including from, among other things, particulates, filtration, filling, labeling, packaging, storage and shipping, and quality control testing, may result in lot failures or manufacturing shut-down, delays in the release of lots, product recalls, spoilage or regulatory action. Such deviations may require us to revise manufacturing processes or change manufacturers. Additionally, 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. Success rates can also 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, damage our reputation and negatively impact our business.

For example, FDA approval is required for the release of each lot of BioThrax. A "lot" is approximately 186,000 doses. We are not able to sell any lots that fail to satisfy the release testing specifications. For example, we must provide the FDA with the results of certain tests, including potency tests, before lots are released for sale. Potency testing of each lot of BioThrax is performed against a qualified control lot that we maintain. We have one mechanism for conducting this potency testing that is reliant on a unique animal strain for which we currently have no alternative. We continually monitor the status of our control lot and periodically produce and qualify a new control lot to replace the existing control lot. If we are not able to produce and qualify a new control lot or otherwise 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 the FDA's 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.

We are contractually required to ship our biologic products at a prescribed temperature range and variations from that temperature range could result in loss of product and could significantly impact our revenues. 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 potential clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

We are in the process of expanding our manufacturing facilities. Delays in completing our facilities, or delays or failures in obtaining regulatory approvals for our new manufacturing facilities, could impact our future revenues.

We have constructed Building 55, a large-scale manufacturing facility on our Lansing, Michigan campus for which we received a development contract from BARDA in July 2010 to fund the scale-up, qualification and validation of manufacturing BioThrax at an expanded scale. Additionally, in 2009, we acquired a facility in Baltimore, Maryland, which we intend to utilize for certain product development or manufacturing projects, including projects performed under a separate development contract from BARDA to establish a Center for Innovation in Advanced Development and Manufacturing. The process for qualifying and validating these facilities 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 cGMP regulations or similar foreign regulatory requirements for sales of our products may be significant. In addition, if we experience delays, we may be in breach of the obligations under our government-funded

development contracts. We have experienced such delays in the past and may experience further delays in the future. If our facility licensure activities are delayed, we may not be able to utilize Building 55 to increase our production of BioThrax or manufacture product candidates in our Baltimore facility, which could significantly impact our future revenues.

Currently, only Building 12, our small-scale manufacturing facility in Lansing, Michigan, has regulatory approval to manufacture BioThrax. A significant interruption of the ability of this facility to manufacture BioThrax would reduce our revenues and materially harm our business, financial condition, operating results and cash flow.

We currently rely on our manufacturing facility at a single location in Lansing, Michigan, Building 12, for the production of BioThrax. Any interruption in manufacturing operations at this location could result in our inability to satisfy the product demand of the U.S. government or other BioThrax customers. A number of factors could cause interruptions, including:

§ equipment malfunctions or failures;
§ technology malfunctions;
§ cyber-attacks;
§ work stoppages or slow-downs;
§ protests, including by animal rights activists
§ damage to or destruction of the facility; or
§ product contamination or tampering.

Providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. The U.S. government has designated both our Lansing, Michigan and our Biodefense Baltimore facility as facilities requiring additional security. Although, we continually evaluate and update security measures, there can be no assurance that any additional security measures would protect our facilities from terrorist efforts determined to disrupt our manufacturing activities.

The factors listed above could also cause disruptions at our other facilities, including our manufacturing facility in Winnipeg, Manitoba, Canada. Any such disruption, damage, or destruction of these facilities could impede our ability to manufacture our Biologic Products and our product candidates, result in losses and delays, including delay in the performance of our contractual obligations or delay in our clinical trials, any of which could be costly to us and materially harm our business, financial condition and operating results.

If we are unable to obtain supplies for the manufacture of BioThrax or our other products and product candidates in sufficient quantities and at an acceptable cost, our ability to manufacture BioThrax or to develop and commercialize our other products and product candidates could be impaired, which could harm our revenues, lead to a termination of one or more of our contracts, lead to delays in clinical trials or otherwise harm our business.

We depend on certain single-source suppliers for key materials and services necessary for the manufacture of BioThrax and our other products and product candidates. For example, we rely on a single-source supplier to provide us with Alhydrogel in sufficient quantities to meet our needs to manufacture BioThrax and NuThrax. We also rely on single-source suppliers for the sponge applicator device and the active ingredient used to make RSDL and the specialty plasma in our hyperimmune specialty plasma products. 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 and product candidates could be adversely affected and could harm our revenues, cause us to fail to satisfy contractual commitments, lead to a termination of one or more of our contracts or lead to delays in our clinical trials, any of which could be costly to us and otherwise harm our business, financial condition and operating results.

We are currently dependent on third-party manufacturers for the manufacture of RSDL and episil®. Certain of our third-party manufacturers currently constitute the sole source supplier for these products, and we have and will continue to have limited control over the manufacturing process and costs of these products.

Third-party manufacturers currently supply a significant amount of RSDL and episil® pursuant to contractual arrangements. Certain manufacturers currently constitute the sole source for RSDL and episil®. For example, E-Z-EM Canada Inc. (dba Therapex) is our sole source manufacturer for RSDL. Because of contractual restraints and the lead-time necessary to obtain FDA approval of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of these products to our customers.

We have a limited ability to control the manufacturing process or costs related to the third-party manufacture of our products. Increases in the prices we pay our manufacturers, interruptions in the supply of our products or lapses in quality could adversely impact our margins, profitability and cash flows. We are reliant on our third-party manufacturers to maintain the facilities at which they manufacture our products in compliance with all FDA and other applicable regulatory requirements. If these manufacturers fail to maintain compliance with FDA or other applicable regulatory requirements, they could be ordered to cease manufacturing, which could have a materially adverse impact on our revenues and operating results.

We may be forced to consider entering into additional manufacturing arrangements with other third-party manufacturers. In each case, we will incur significant costs and time in obtaining the regulatory approvals for these third-party facilities and in taking the necessary steps to prepare these third parties for the manufacture of our products.

Our operations, including our use of hazardous materials, chemicals, bacteria and viruses, require us to comply with regulatory requirements and expose us to significant potential liabilities.

Our operations involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. Under the Federal Select Agent Program, pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act, we are required to register with and be inspected by the CDC and the Animal and Plant Health Inspection Service if we have in our possession, or if we use or transfer, 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 stringent 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 are also subject to a variety of environmental and occupational health and safety laws. Compliance with current or future laws and regulations can require significant costs and we could be subject to substantial fines and penalties in the event of noncompliance. In addition, the risk of contamination or injury from these materials cannot be completely eliminated. In such event, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials. From time to time, we have been involved in remediation activities and may be so involved in the future. Any related cost or liability might not be fully covered by insurance, could exceed our resources and could have a material adverse effect on our business. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS, U.S. Department of Agriculture and the DoD, as well as regulatory authorities in Canada.

PRODUCT DEVELOPMENT RISKS

Our business depends on our success in developing and commercializing our product candidates. If we are unable to commercialize these product candidates, or experience significant delays or unanticipated costs in doing so, our

business would be materially and adversely affected.

We have invested significant efforts and financial resources in the development of our vaccines, therapeutics and medical device product candidates and the acquisition of additional product candidates. In addition to our product sales, our ability to generate revenue is dependent on a number of factors, including the success of our development programs, the U.S. government's interest in providing development funding for or procuring certain of our Biodefense division product candidates, the interest of non-governmental organizations and other commercial entities in providing grant funding for development of certain of our Biosciences division product candidates and the commercial viability of our acquired or developed 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 manufacturing that meets FDA requirements;
- successful completion of clinical or non-clinical development, including toxicology studies and studies in approved animal models;
- receipt of marketing approvals from the FDA and equivalent foreign regulatory authorities;
- establishment of commercial manufacturing processes and product supply arrangements;
- training of a commercial sales force for the product, whether alone or in collaboration with others;
- successful registration and maintenance of relevant patent and/or other proprietary protection; and
- acceptance of the product by potential government customers, physicians, patients, healthcare payors and others in the medical community.

If we are delayed or prevented from developing or commercializing a product candidate in a profitable manner, or if doing so requires us to incur significant unanticipated costs, our growth could be materially and adversely affected.

Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. We must invest substantial amounts of time and financial resources in these trials, which may not yield viable products.

Before obtaining regulatory approval for the sale of our product candidates, we and our collaborative partners where applicable must conduct extensive preclinical studies and clinical trials to establish proof of concept and demonstrate the 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 is uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing.

For certain of our Biodefense product candidates, we expect to rely on the Animal Rule to obtain regulatory approval. The Animal Rule permits, in certain limited circumstances, the use of animal efficacy studies, together with human clinical safety and immunogenicity trials, to support an application for marketing approval. For a product approved under the Animal Rule, certain additional post-marketing requirements apply. For example, to the extent feasible and ethical, applicants must conduct post-marketing studies, such as field studies, to verify and describe the drug's clinical benefit and to assess its safety when used as indicated. 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 product candidates in humans. Under the Project BioShield Act of 2004, the Secretary of HHS can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the FDA commissioner to authorize the emergency use of medical products that have not yet been approved by the FDA under an Emergency Use Authorization, or EUA. If our Biodefense product candidates are not selected under this Project BioShield authority, they generally will have to be approved by the FDA through traditional regulatory mechanisms.

We may experience unforeseen events or issues during, or as a result of, preclinical testing, clinical trials or animal efficacy studies. These issues and events, which could delay or prevent our ability to receive regulatory approval for a

product candidate, include, among others:

- our inability to manufacture sufficient quantities of materials for use in trials;
- the unavailability or variability in the number and types of subjects for each study;
- safety issues or inconclusive or incomplete testing, trial or study results;
- lack of efficacy of product candidates during the trials;
- government or regulatory restrictions or delays; and
- greater than anticipated costs of trials.

For example, in February 2013, we announced results of a Phase IIb clinical trial evaluating the safety and efficacy of MVA85A in preventing tuberculosis in infants, which indicated that a single dose of MVA85A was not sufficient to confer statistically significant protection against tuberculosis in infants. As a consequence of these results, we ceased further development work on MVA85A.

We depend on third parties to conduct our clinical and non-clinical trials. If these third parties 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 and non-clinical trials required to obtain regulatory approval for our product candidates. 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. Our reliance on these service providers does not relieve us of our regulatory responsibilities, including ensuring that our trials are conducted in accordance with good clinical practice regulations and the plan and protocols contained in the relevant regulatory application. In addition, these organizations may not complete these activities on our anticipated or desired timeframe. We also 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, which may prove difficult, costly and result in a delay of our trials. Any delay in or inability to complete our trials could delay or prevent the development, approval and commercialization of our product candidates.

In certain cases, government entities and non-government organizations conduct studies of our product candidates, and we may seek to rely on these studies in applying for marketing approval for certain of our product candidates. 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. Furthermore, government entities depend on annual Congressional appropriations to fund their development efforts.

If we are unable to obtain any necessary third-party services on acceptable terms or if these service providers do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for our product candidates may be delayed or prevented.

We may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.

We continue to evaluate our business strategy and, as a result, may modify our strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different product candidates or may delay or halt the development of various product candidates. For example, in February 2013, as a consequence of clinical trial results, we ceased further development work on MVA85A, our tuberculosis vaccine candidate. As a result of changes in our strategy, we may change or refocus our existing product development, commercialization and manufacturing activities. This could require changes in our facilities and our personnel. Any product development changes that we

implement may not be successful. In particular, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates. Our decisions to allocate our research and development, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate product development programs may also prove to be incorrect and could cause us to miss valuable opportunities.

INTELLECTUAL PROPERTY RISKS

If we are unable to protect our proprietary rights, our business could be harmed.

Our success, particularly with respect to the Biosciences business and small molecule product candidates, will depend, in large part, on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology, products and product candidates. Obtaining and maintaining this protection is very costly. The patentability of technology in the field of vaccines, therapeutics and medical devices 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 inadvertently lapse or 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. In the past, we have abandoned the prosecution and/or maintenance of patent applications related to patent families in the ordinary course of business. In the future we may choose to abandon such prosecution and/or maintenance in a similar fashion. If these patent rights are later determined to be valuable or necessary to our business, our competitive position may be adversely affected. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the United States and in other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, or result in costly defensive measures.

The cost of litigation to uphold the validity of patents to prevent infringement or to otherwise protect or enforce our proprietary rights could be substantial and, from time to time, our patents are subject to opposition proceedings. Some of our competitors may be better able to sustain the costs of complex patent litigation because they may have substantially greater financial resources. Intellectual property lawsuits are expensive and unpredictable and would consume management's time and attention 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 covered by or incorporating them. 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 and 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 intellectual property rights in which we have an interest and, although we may have the right to assume the maintenance and defense of such intellectual property rights if these third parties do not do so, our ability to maintain and defend such intellectual property rights may be compromised by the acts or omissions of these third parties. For example, we license from Pfizer, Inc. an oligonucleotide adjuvant, CPG 7909, for use in our anthrax vaccine product candidate NuThrax.

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.

Third parties may choose to file patent infringement claims against us; defending ourselves from such allegations would be costly, time-consuming, distracting to management and could materially 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 sufficient 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 United States and abroad. These third parties may have substantially greater financial resources than us and could bring claims against us that could cause us to incur substantial expenses to defend against these claims 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, we could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit. Intellectual property litigation in the biopharmaceutical industry is common, and we expect this trend to continue.

As a result of patent infringement or other similar claims, or to avoid potential claims, we 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 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 are unable to enter into licenses on acceptable terms, if at all, or if an injunction is granted against us, which could harm our business significantly.

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. 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 and/or sue us for breach, which could cause us to not be able to market any product that is covered by the licensed patents and may be subject to damages.

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 any of our current products, our only intellectual property protection for these products, other than trademarks, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and unique starting materials. However, these types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, through agreements with our employees, consultants and third parties as well as confidentiality policies and audits, although these may not be successful in protecting our trade secrets and confidential information.

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, including through a potential cyber security breach, or may 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.

RISKS RELATED TO STRATEGIC ACQUISITIONS AND COLLABORATIONS

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

Our business strategy includes growing our business through acquisition and in-licensing transactions. We may not be successful in identifying, effectively evaluating, acquiring or in-licensing, and developing and commercializing additional products on favorable terms, or at all. Competition for attractive product opportunities is intense and may require us to devote substantial resources, both managerial and financial, to an acquisition opportunity. A number of more established companies are also pursuing strategies to acquire or in-license products in the vaccine and therapeutic field. These companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote significant resources to potential acquisitions that are never completed. Even if we are successful in acquiring a product or company, it may not result in a successfully developed or commercialized product or, even if an acquired product is commercialized, competing products or technologies could render a product noncompetitive, uneconomical or obsolete. Moreover, the cost of acquiring other companies or in-licensing products could be substantial, and in order to acquire companies or new products, we may need to incur substantial debt or issue dilutive securities. For example, in part to fund our acquisition of Cangene Corporation, we issued $250 million of senior convertible notes in January 2014. If we are unsuccessful in our efforts to acquire other companies or in-license and develop additional products, or if we acquire or in-license unproductive assets, it could have a material adverse effect on the growth of our business.

Our failure to successfully integrate acquired assets into our operations could adversely affect our ability to realize the benefits of such acquisitions and, therefore, to grow our business.

We may not be able to integrate any acquired business successfully or operate any acquired business profitably. In addition, cost synergies, if achieved at all, may be less than we expect, or may take greater time to achieve than we anticipate.

Issues that could delay or prevent successful integration or cost synergies of an acquired business include, among others:

§ retaining existing customers and attracting new customers;
§ retaining key employees;
§ diversion of management attention and resources;
§ conforming internal controls, policies and procedures, business cultures and compensation programs;
§ consolidating corporate and administrative infrastructures;
§ consolidating sales and marketing operations;
§ identifying and eliminating redundant and underperforming operations and assets;
§ assumption of known and unknown liabilities;
§ coordinating geographically dispersed organizations; and
§ managing tax costs or inefficiencies associated with integrating operations.

If we are unable to successfully integrate future acquisitions with our existing businesses, or operate any acquired business profitably, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect the growth of our business.

We may not be successful in establishing and maintaining collaborations that leverage our capabilities in pursuit of developing and commercializing our product candidates.

For each of our product candidates, including otlertuzumab, our humanized anti-CD37 therapeutic (formerly known as TRU-016), we plan to evaluate the merits of entering into collaboration arrangements with third parties, including leading biopharmaceutical companies or non-governmental organizations. We expect to selectively pursue collaboration arrangements with third parties that have particular technology, expertise or resources for the

development or commercialization of our product candidates or for accessing particular markets. We face, and will continue to face, significant competition in seeking appropriate partners for our product candidates. If we are unable to identify partners whose capabilities complement and integrate well with ours and reach collaboration arrangements with such partners on acceptable terms, or if the arrangements we establish are unproductive for us, we may fail to meet our business objectives for the particular product candidate.

Any collaboration that we enter into may not be successful and 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 any of our collaborations include, among others:

- our collaborators may not commit adequate resources to the development, marketing and distribution of any collaboration products, limiting our potential revenues from these products;
- our collaborators may experience financial difficulties and may therefore be unable to meet their commitments to us;
- our collaborators may pursue a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- our collaborators may terminate our relationship.

For example, in 2011, our previous collaboration partner Abbott Laboratories terminated its collaboration with us for the development of otlertuzumab (formerly TRU-016) following a portfolio reprioritization process by Abbott.

Failure of any of our future collaboration partners to perform as expected could place us at a competitive disadvantage and adversely affect us financially, including delay and increased costs of development, loss of market opportunities, lower than expected revenues and impairment of the value of the related product candidate.

FINANCIAL RISKS

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our operations to pay our substantial debt.

As of March 31, 2015, our total consolidated indebtedness was $251 million, including $250 million of obligations under our senior convertible notes. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the senior convertible notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Our current indebtedness and any additional debt financing may restrict the operation of our business and limit the cash available for investment in our business operations.

In addition to our current debt, we also have a senior secured revolving credit facility with available capacity of up to $100 million, effective until December 11, 2018 (or such earlier date to the extent required by the terms of this facility). We may seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing could have significant adverse consequences for our business, including:

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- requiring us to dedicate a substantial portion of any cash flow from operations to payment on our debt, which would reduce the amounts available to fund other corporate initiatives;
- increasing the amount of interest that we have to pay on debt with variable interest rates, if market rates of interest increase;
- subjecting us, as under our senior secured revolving credit facility, to restrictive covenants that may reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing;
- requiring us to pledge our assets as collateral, which could limit our ability to obtain additional debt financing;
- limiting our flexibility in planning for, or reacting to, general adverse economic and industry conditions; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

We may not have sufficient funds or be able to obtain additional financing to pay the amounts due under our indebtedness. In addition, failure to comply with the covenants under our debt instruments could result in an event of default under those instruments. An event of default could result in the acceleration of amounts due under a particular debt instrument and a cross default and acceleration under other debt instruments, and we may not have sufficient funds or be able to obtain additional financing to make any accelerated payments. Under these circumstances, our lenders could seek to enforce security interests, if any, in our assets securing our indebtedness.

We may require significant additional funding and may be unable to raise capital when needed or on acceptable terms, which would harm our ability to grow our business, results of operations and financial condition.

We may require significant additional funding to grow our business, including to acquire other companies or products, in-license and develop additional products, enhance our manufacturing capacity, support commercial marketing activities or otherwise provide additional financial flexibility. We may also require additional funding to support our ongoing operations in the event that our ability to sell BioThrax to the U.S. government is interrupted for an extended period of time, reducing our BioThrax revenues and decreasing our cash balances.

As of March 31, 2015, we had approximately $216.5 million of cash and cash equivalents. Our future capital requirements will depend on many factors, including, among others:

- the level, timing and cost of product sales;
- the extent to which we acquire or invest in and integrate companies, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs; and
- the costs of commercialization activities, including product marketing, sales and distribution

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements. We have a shelf registration statement on file with the Securities and Exchange Commission, effective until June 2015 that allows us to issue up to an aggregate of $180 million of equity, debt and certain other types of securities through one or more future offerings. If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our senior secured revolving credit facility, limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities or declaring dividends. If we raise 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. We are not restricted under the terms of the indenture governing our senior convertible notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that could have the effect

of diminishing our ability to make payments on our indebtedness.

Current economic conditions may make it difficult to obtain financing on attractive terms, or at all. If financing is unavailable or lost, our business, results of operations and financial condition would be adversely affected and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

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 in the first quarters of 2015, 2014, 2013 and 2012. Our profitability has been substantially dependent on BioThrax product sales, which historically have fluctuated significantly from quarter to quarter, and we expect that they will continue to fluctuate significantly based primarily on the timing of our fulfillment of 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.

OTHER BUSINESS RISKS

We face product liability exposure, which could cause us to incur substantial liabilities and negatively affect our business, financial condition and results of operations.

We face an inherent risk of product liability exposure related to the sale of our products, any other products that we successfully acquire or develop and the testing of our product candidates in clinical trials.

One measure of protection against such lawsuits is coverage under the Public Readiness and Emergency Preparedness Act, or PREP Act, which was signed into law in December 2005. The PREP Act 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 federal or state law for loss arising out of the administration or use of a covered countermeasure. The Secretary of HHS has issued PREP Act declarations identifying BioThrax, BAT, Anthrasil and VIGIV as covered countermeasures. These declarations expire in 2015. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct. We cannot predict whether the Secretary of HHS will renew the declarations when they expire, whether Congress will fund the relevant PREP Act compensation programs, or whether the necessary prerequisites for immunity would be triggered with respect to our products or product candidates.

Additionally, BioThrax and RSDL are certified anti-terrorism products covered under the protections of the Support Anti-Terrorism by Fostering Effective Technology Act of 2002, or SAFETY Act. The SAFETY Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. Although we are entitled to the benefits of the SAFETY Act for BioThrax and RSDL, the SAFETY Act may not provide adequate protection from claims made against us.

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

§ decreased demand or withdrawal of a product;
§ injury to our reputation;
§ withdrawal of clinical trial participants;

§ costs to defend the related litigation;
§ substantial monetary awards to trial participants or patients;
§ loss of revenue; and
§ an inability to commercialize products that we may develop.

The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Further product liability insurance may be difficult and expensive to obtain. 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 all potential liabilities. For example, we may not have sufficient insurance against potential liabilities associated with a possible large scale deployment of BioThrax as a countermeasure to a bioterrorism threat. We rely on PREP Act protection for BioThrax, BAT, Anthrasil and VIGIV and SAFETY Act protection for BioThrax and RSDL in addition to our insurance coverage to help mitigate our product liability exposure for these products. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

We rely significantly on information technology systems and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively or result in data leakage of proprietary and confidential business and employee information.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to interruption, invasion, computer viruses, destruction, malicious intrusion and additional related disruptions, which may result in the impairment of production and key business processes.

In addition, our systems are potentially vulnerable to data security breaches—whether by employee error, malfeasance or other disruption—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information, including sensitive personal information, of our employees, clinical trial patients, customers and others.

A significant business disruption or a breach in security resulting in misappropriation, theft or sabotage with respect to our proprietary and confidential business and employee information could result in financial, legal, business or reputational harm to us, any of which could adversely affect our business, financial condition and operating results.

Our success is dependent on our continued ability to attract, motivate and retain key personnel, and any failure to attract or retain key personnel may negatively affect our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel. If we are unable to retain the services of one or more of the principal members of senior management or other key employees, our ability to implement our business strategy could be materially harmed. We face intense competition for qualified employees from biopharmaceutical companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. We believe part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including equity incentive awards. If we cannot offer a competitive compensation package or otherwise attract and retain the qualified personnel necessary for the continued development of our business, we may not be able to maintain our operations or grow our business.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

Fuad El-Hibri, executive chairman of our Board of Directors, has significant influence over us through his substantial beneficial ownership of our common stock, including an ability to influence the election of the members of our Board of Directors, or delay or prevent a change of control of us.

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his substantial beneficial ownership of our common stock. As of April 30, 2015, Mr. El-Hibri was the beneficial owner of approximately 15% of our outstanding common stock. As a result, Mr. El-Hibri could 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. In addition, Mr. El-Hibri's significant beneficial ownership of our shares could present the potential for a conflict of interest.

Provisions in our certificate of incorporation and by-laws and under Delaware law may discourage acquisition proposals, delay a change in control or prevent transactions that stockholders may consider favorable.

Provisions in 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 of candidates for election to the Board 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 a 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 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 the corporation's 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 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 or 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. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this "Risk Factors" section, or for reasons unrelated to our operations, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as industry conditions and general financial, economic and political instability. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through April 30, 2015, our common stock has traded as high as $31.33 per share and as low as $4.40 per share. The stock market in general as well as the market for biopharmaceutical 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, among others:

§ decisions and procurement policies by the U.S. government affecting BioThrax;
§ the success of competitive products or technologies;
§ results of clinical and non-clinical trials of our product candidates;
§ announcements of acquisitions, collaborations, financings or other transactions by us;
§ public concern as to the safety of our products;
§ termination or delay of a development program;
§ the recruitment or departure of key personnel;
§ variations in our product revenue and profitability; and
§ the other factors described in this "Risk Factors" section

Because we currently do not pay dividends, investors will benefit from an investment in our common stock only if it appreciates in value.

We currently do not pay dividends on our common stock. Our senior secured credit facility 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 shares may be sold into the market at any time. This could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 6 million shares of our common stock outstanding as of April 30, 2015, have the right to require us to register these shares of common stock under specified circumstances. In 2012, the SEC declared effective our shelf registration statement that included

registration of up to three million of these shares to be sold by these holders from time to time.

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. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

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

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

By: /s/DANIEL J. ABDUN-NABI
Daniel J. Abdun-Nabi
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 7, 2015

By: /S/ROBERT G. KRAMER
Robert G. Kramer
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Date: May 7, 2015

EXHIBIT INDEX

Exhibit Number	Description
12#	Ratio of Earnings to Fixed Charges.
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.
101. INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Calculation Linksbase Document.
101.DEF	XBRL Taxonomy Definition Linksbase Document.
101.LAB	XBRL Taxonomy Label Linksbase Document.
101.PRE	XBRL Taxonomy Presentation Linksbase Document.

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language):
(i) Condensed Consolidated Statements of Operations for the three months ended March 31, 2015 and 2014;
(ii) Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2015 and 2014;
(iii) Condensed Consolidated Balance Sheets at March 31, 2015 and December 31, 2014;
(iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014; and
(v) Notes to Consolidated Financial Statements.

In Accordance with Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this Quarterly Report on Form 10-Q is deemed filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, is deemed filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

#Filed herewith.