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Emergent BioSolutions Inc.

Form 10-Q

May 06, 2016

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, 2016

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

(State or Other Jurisdiction of
Incorporation or Organization)

14-1902018

(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 website, if any, every Interactive Data File required to be submitted and posted pursuant to 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)

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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 29, 2016, the registrant had 40,060,773 shares of common stock outstanding.

Emergent BioSolutions Inc.
Index to Form 10-Q

Part I. Financial Information

- Item 1. Unaudited Financial Statements
 - Consolidated Balance Sheets
 - Consolidated Statements of Operations
 - Consolidated Statements of Comprehensive Income (Loss)
 - Consolidated Statements of Cash Flows
 - Notes to Consolidated Financial Statements
- Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations
- Item 3. Quantitative and Qualitative Disclosures About Market Risk
- Item 4. Controls and Procedures

Part II. Other Information

- Item 1. Legal Proceedings
- Item 1A. Risk Factors
- Item 2. Unregistered Sales of Equity Securities and Use of Proceeds
- Item 3. Defaults Upon Senior Securities
- Item 4. Mine Safety Disclosures
- Item 5. Other Information
- Item 6. Exhibits
 - Signatures
 - Exhibit Index

BioThrax® (Anthrax Vaccine Adsorbed), RSDL® (Reactive Skin Decontamination Lotion Kit), BAT™ [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)], Anthrasil™ (Anthrax Immune Globulin Intravenous [human]), HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)], VARIZIG® [Varicella Zoster Immune Globulin (Human)], WinRho® SDF [Rh₀ (D) Immune Globulin Intravenous (Human)], NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), PreviThrax™ (recombinant protective antigen anthrax vaccine, purified), VIGIV [Vaccinia Immune Globulin Intravenous (Human)], IXINITY® (coagulation factor IX (recombinant)), Emergard™ and any and all Emergent BioSolutions Inc. brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent BioSolutions Inc. or its subsidiaries in the United States or other countries. All other brands, products, services and feature names or trademarks are the property of their respective owners.

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 the planned spin-off of certain assets of our biosciences business to create Aptevo Therapeutics Inc. as a separately-traded public company, the timing of any such spin-off, the future earnings and performance of Emergent or any of its businesses, including the Biodefense and Aptevo businesses on a standalone basis if the spin-off is completed, 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) and our other countermeasure products;
- 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;
- whether the planned spin-off of Aptevo Therapeutics Inc. is completed, as expected or at all, and the timing of any such spin-off;
- whether the conditions to the spin-off can be satisfied;
- whether the operational, marketing and strategic benefits of the spin-off can be achieved and the timing of any such benefits;
- whether the costs and expenses of the spin-off can be controlled within expectations;
- 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 the 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 and maintain collaboration arrangements;
- our ability to successfully identify and respond to new development contract with the U.S. government, as well as successfully maintain, through achievement of development milestones, current development contracts with the U.S. government;
- our ability to achieve milestones in our out-licensed 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;

the 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;

our ability to obtain and maintain regulatory approvals for our product candidates and the timing of any such approvals;

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, 2016	December 31, 2015
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$341,016	\$312,795
Accounts receivable, net	69,560	120,767
Inventories	88,200	76,936
Income tax receivable, net	3,771	6,573
Prepaid expenses and other current assets	25,613	20,339
Total current assets	528,160	537,410
Property, plant and equipment, net	342,083	331,856
In-process research and development	42,501	42,501
Intangible assets, net	55,010	57,375
Goodwill	54,902	54,902
Deferred tax assets, net	11,124	11,286
Other assets	2,117	2,154
Total assets	\$1,035,897	\$1,037,484
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$45,611	\$45,966
Accrued expenses and other current liabilities	4,187	6,229
Accrued compensation	26,528	34,683
Contingent consideration, current portion	2,580	2,553
Provisions for chargebacks	1,960	2,238
Deferred revenue, current portion	9,589	7,942
Total current liabilities	90,455	99,611
Contingent consideration, net of current portion	23,114	23,046
Long-term indebtedness	247,192	246,892
Deferred revenue, net of current portion	6,817	6,590
Other liabilities	1,337	1,328
Total liabilities	368,915	377,467
Stockholders' equity:		
Preferred stock, \$0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at both March 31, 2016 and December 31, 2015	-	-
Common stock, \$0.001 par value; 100,000,000 shares authorized, 40,257,241 shares issued and 39,834,411 shares outstanding at March 31, 2016; 39,829,408 shares issued and 39,406,578 shares outstanding at December 31, 2015	40	40

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Treasury stock, at cost, 422,830 common shares at both March 31, 2016 and December 31, 2015	(6,420)	(6,420)
Additional paid-in capital	322,384	317,971
Accumulated other comprehensive loss	(4,152)	(2,713)
Retained earnings	355,130	351,139
Total stockholders' equity	666,982	660,017
Total liabilities and stockholders' equity	\$1,035,897	\$1,037,484

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,	
	2016	2015
	(Unaudited)	
Revenues:		
Product sales	\$71,706	\$18,291
Contract manufacturing	7,587	12,243
Contracts, grants and collaborations	31,709	33,099
Total revenues	111,002	63,633
Operating expense:		
Cost of product sales and contract manufacturing	28,503	18,748
Research and development	34,154	38,702
Selling, general and administrative	39,784	34,493
Income (loss) from operations	8,561	(28,310)
Other income (expense):		
Interest income	186	82
Interest expense	(1,524)	(1,661)
Other income, net	116	100
Total other expense, net	(1,222)	(1,479)
Income (loss) before provision for (benefit from) income taxes	7,339	(29,789)
Provision for (benefit from) income taxes	3,348	(8,269)
Net income (loss)	\$3,991	\$(21,520)
Net income (loss) per share - basic	\$0.10	\$(0.57)
Net income (loss) per share - diluted (1)	\$0.10	\$(0.57)
Weighted-average number of shares - basic	39,542,656	37,949,358
Weighted-average number of shares - diluted	48,359,892	37,949,358

(1) See Note 7 "Earnings per share" for details on calculation.

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

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

	Three Months Ended March 31, 2016 2015 (Unaudited)	
Net income (loss)	\$3,991	\$(21,520)
Foreign currency translations, net of tax	(1,439)	(234)
Comprehensive income (loss)	\$2,552	\$(21,754)

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

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

	Three Months Ended March 31, 2016	2015
Cash flows from operating activities:	(Unaudited)	
Net income (loss)	\$ 3,991	\$ (21,520)
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	5,197	3,798
Depreciation and amortization	8,840	8,532
Income taxes	2,964	(7,261)
Change in fair value of contingent obligations	847	1,559
Excess tax benefits from stock-based compensation	(5,786)	(5,414)
Other	71	17
Changes in operating assets and liabilities:		
Accounts receivable	51,207	(5,225)
Inventories	(11,264)	(16,460)
Income taxes	(4,376)	(12,160)
Prepaid expenses and other assets	(5,555)	(249)
Accounts payable	385	1,102
Accrued expenses and other liabilities	(2,045)	(1,641)
Accrued compensation	(8,277)	(10,883)
Provision for chargebacks	(278)	(82)
Deferred revenue	1,874	14
Net cash provided by (used in) operating activities	37,795	(65,873)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(18,214)	(9,082)
	(18,214)	(9,082)

Net cash used in investing activities		
Cash flows from financing activities:		
Issuance of common stock upon exercise of stock options	3,595	6,344
Excess tax benefits from stock-based compensation	5,786	5,414
Contingent obligation payments	(752)	(762)
Net cash provided by financing activities	8,629	10,996
Effect of exchange rate changes on cash and cash equivalents	11	(25)
Net increase (decrease) in cash and cash equivalents	28,221	(63,984)
Cash and cash equivalents at beginning of period	312,795	280,499
Cash and cash equivalents at end of period	\$ 341,016	\$ 216,515

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

On August 6, 2015, Emergent BioSolutions Inc. (the "Company" or "Emergent"), announced its plan to separate into two independent publicly-traded companies, one a biotechnology company focused on novel oncology and hematology therapeutics to meaningfully improve patients' lives and the other a global specialty life sciences company focused on providing specialty products for civilian and military populations that address intentional and naturally emerging public health threats. In accordance with the separation plan, Emergent expects to spin off certain assets and liabilities of its biosciences business into Aptevo Therapeutics Inc. ("Aptevo") a wholly-owned subsidiary of Emergent that was incorporated in February 2016.

In anticipation of the planned spin-off, the Company realigned certain components of its biosciences business to the new Aptevo segment to be consistent with how the Company's chief operating decision maker ("CODM") allocates resources and makes decisions about the operations of the Company. Effective January 1, 2016, the Company changed its segment presentation to reflect this new structure, and recast all prior periods presented to conform to the new presentation. Upon separation, the historical results of Aptevo will be reported as discontinued operations.

The accompanying unaudited consolidated financial statements include the accounts of 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, 2015, 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, 2016; the results of operations and comprehensive income (loss) for the three months ended March 31, 2016 and 2015; and cash flows for the three months ended March 31, 2016 and 2015. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

During the three months ended March 31, 2016, 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, 2015, as filed with the SEC.

2. 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:

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(in thousands)	March 31, 2016			
	Level	Level	Level 3	Total
	1	2		
Assets:				
Investment in money market funds (1)	\$234	\$ -	\$-	\$234
Total assets	\$234	\$ -	\$-	\$234
Liabilities:				
Contingent consideration	\$-	\$ -	\$25,694	\$25,694
Total liabilities	\$-	\$ -	\$25,694	\$25,694

(in thousands)	December 31, 2015			
	Level	Level	Level 3	Total
	1	2		
Assets:				
Investment in money market funds (1)	\$3,323	\$ -	\$-	\$3,323
Total assets	\$3,323	\$		