

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **December 8, 2016**

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

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-33137**  
(Commission  
File Number)

**14-1902018**  
(IRS Employer  
Identification No.)

**400 Professional Drive, Suite 400,  
Gaithersburg, Maryland**  
(Address of Principal Executive Offices)

**20879**  
(Zip Code)

Registrant's telephone number, including area code: **(240) 631-3200**

**Not applicable**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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**Item 1.01 Entry into a Material Definitive Agreement.**

On December 8, 2016, Emergent Biodefense Operations Lansing LLC, a wholly-owned subsidiary of Emergent BioSolutions Inc., entered into a follow-on contract with the Centers for Disease Control and Prevention (CDC) to supply the Strategic National Stockpile (SNS) with approximately 29.4 million doses of BioThrax® (Anthrax Vaccine Adsorbed) over a period of five years for a total value of up to \$911 million. BioThrax, the only anthrax vaccine licensed by the U.S. Food and Drug Administration (FDA), is indicated for both pre-exposure prophylaxis and post-exposure prophylaxis of anthrax disease.

Initial deliveries under the contract are expected to commence in 2017, with deliveries scheduled to continue, subject to availability of funding, through September 2021. The contract contains a number of terms and conditions that are customary for government contracts of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience for any reason or no reason, to order the company to suspend all or any part of the work under the contract at the government's discretion or to audit and object to any contract-related costs on the grounds that they are not allowable under the Federal Acquisition Regulation and require the company to reimburse all such costs.

The foregoing summary of the contract does not purport to be complete and is qualified in its entirety by reference to the actual contract, a copy of which will be filed as an exhibit to the company's Annual Report on Form 10-K for the fiscal year ending December 31, 2016.

**Item 7.01 Regulation FD Disclosure.**

On December 8, 2016, the company issued a press release announcing that it has entered into a follow-on contract with the CDC to supply the SNS with approximately 29.4 million doses of BioThrax over a period of five years for a total value of up to \$911 million. In addition, the company announced that it has received a notice of intent from the Biomedical Advanced Research and Development Authority (BARDA) to procure approximately \$100 million of BioThrax for delivery into the SNS within 24 months from the date of contract award. The press release also includes re-established 2016 financial guidance. A copy of the press release is attached hereto as Exhibit 99 and is incorporated herein by reference.

**Forward-Looking Statements**

This Form 8-K includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including, without limitation, our financial guidance and any statements containing the words "believes," "expects," "anticipates," "intends," "plans," "targets," "forecasts," "estimates" and similar expressions in conjunction with, among other things, obtaining a BioThrax procurement contract from BARDA under the notice of intent, discussions of the company's outlook, financial performance or financial condition, growth strategy, product development, product sales, government development or procurement contracts or awards, government appropriations, manufacturing capabilities, Emergency Use Authorization or other regulatory approvals and plans to increase our operational efficiencies and cost structure are forward-looking statements. 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. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date hereof, 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 the company's actual results to differ materially from those indicated by such forward-looking statements, including our ability to obtain a BioThrax procurement contract from BARDA under the notice of intent; availability of funding and the exercise of options under our BioThrax contract with CDC and our NuThrax contract with BARDA, appropriations for procurement of BioThrax and NuThrax; our ability to secure EUA pre-authorization approval and licensure of NuThrax by FDA within the anticipated timeframe, if at all; our ability to achieve our planned operational efficiencies and targeted levels of cost savings; availability of funding for our U.S. government grants and contracts; whether the operational, marketing and strategic benefits of the spin-off of our biosciences business can be achieved; our ability to identify and acquire or in-license products or late-stage product candidates that satisfy our selection criteria; whether anticipated synergies and benefits from an acquisition or in-license are realized within expected time periods, if at all; our ability 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 outcome of the class action lawsuit filed against us and possible other future material legal proceedings; our ability to meet operating and financial restrictions placed on us and our subsidiaries that are contained in our senior credit facility; the rate and degree of market acceptance and clinical utility of our products; the success of our ongoing and planned development programs; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; and our commercialization, marketing and manufacturing capabilities and strategy. 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. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99	Press Release dated December 8, 2016.

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**SIGNATURE**

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 hereunto duly authorized.

Date: December 8, 2016

EMERGENT BIOSOLUTIONS INC.

By: /s/ ROBERT G. KRAMER

Robert G. Kramer  
Executive Vice President and Chief Financial Officer

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## **EMERGENT BIOSOLUTIONS TO SUPPORT HHS ANTHRAX PREPAREDNESS STRATEGY WITH UP TO \$1 BILLION IN BIOTHRAX DELIVERIES TO THE STRATEGIC NATIONAL STOCKPILE**

- Company signs follow-on contract with CDC valued at up to \$911 million to supply to the SNS approximately 29.4 million doses of BioThrax through September 2021
- BARDA issues notice of intent to separately procure approximately \$100 million of BioThrax for the SNS over 24 months from contract award, which is expected in 1H 2017
- These actions, together with the recently awarded BARDA contract for NuThrax, reflect the U.S. government's intention to transition the stockpile of anthrax vaccines from BioThrax to NuThrax
- Company re-establishes 2016 financial guidance

**GAITHERSBURG, Md., December 8, 2016** – Emergent BioSolutions Inc. (NYSE:EBS) today announced that the U.S. Department of Health and Human Services (HHS) is advancing its anthrax preparedness strategy with multiple contract actions for the company's anthrax vaccines.

- Today, Emergent signed a follow-on contract with the Centers for Disease Control and Prevention (CDC), under Solicitation No. 2016-N-17905, valued at up to \$911 million to supply approximately 29.4 million doses of BioThrax® (Anthrax Vaccine Adsorbed) to the Strategic National Stockpile (SNS) through September 2021. BioThrax is the only anthrax vaccine licensed by the U.S. Food and Drug Administration (FDA) and is indicated for both pre-exposure prophylaxis and post-exposure prophylaxis of anthrax disease.
- Also today, the Biomedical Advanced Research and Development Authority (BARDA), a division within the Office of the Assistant Secretary of Preparedness and Response at HHS, issued a notice of intent to procure approximately \$100 million of BioThrax for delivery into the SNS within 24 months from the date of contract award, which the company anticipates will be in the first half of 2017. This contract will be separate from and in addition to the follow-on procurement contract with CDC.
- On September 30, BARDA awarded Emergent a contract valued at up to \$1.6 billion for the development and procurement of NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), the company's next generation anthrax vaccine candidate. The initial procurement of NuThrax for inclusion in the SNS could be initiated in 2019 following Emergency Use Authorization (EUA) pre-approval by FDA, which based on the current plan, is anticipated at the end of 2018. The contract also includes procurement options for the delivery of an additional 7.5 million to 50 million doses of NuThrax to the SNS. The company anticipates amending this contract simultaneously with the execution of the BARDA BioThrax procurement contract, which will result in a revised total contract value of up to \$1.5 billion.

Taken together, the company believes that the CDC and BARDA contract actions reflect the government's intention to transition the stockpile of anthrax vaccines from BioThrax to NuThrax beginning in 2019.

"Emergent believes these actions reflect the U.S. government's continued assessment of anthrax as a high-priority threat and its firm commitment to protect the nation against bioterrorism," said Daniel J. Abdun-Nabi, president and chief executive officer of Emergent BioSolutions. "We are pleased to be able to make meaningful contributions to helping the government execute its strategy to achieve its preparedness goals."

### **Deliveries and Pricing**

Under these contract actions, the company plans to deliver approximately nine million doses of BioThrax in each of 2017 and 2018. In 2019, the company anticipates delivering approximately 10 million doses comprised of a combination of both BioThrax and NuThrax. BioThrax pricing in 2017 under the CDC follow-on contract is 2% higher than current levels and is subject to a 3% annual price escalation over the duration of the contract. Deliveries are scheduled to continue, subject to availability of funding, through September 2021.

The company expects that the BARDA procurement contract, which will be separate from and in addition to the follow-on procurement contract with CDC, will require the company to complete delivery of all BioThrax doses covered by that contract within 24 months from the date that the contract is awarded. BioThrax pricing under the BARDA procurement contract is anticipated to be the same as BioThrax pricing in 2017 under the CDC follow-on contract.

### **Financial Outlook**

#### **(I) 2016 Forecast**

The table below presents the company's guidance on a combined basis and on a continuing operations basis. The combined basis reflects the company's operations including the operations of the former biosciences business that was spun-off as Aptevo Therapeutics in August 2016. The continuing operations basis excludes Aptevo operations.

	<b>On a Combined Basis</b>	<b>On a Continuing Operations Basis</b>
Total Revenue	\$485M to \$505M	\$465M to \$485M
BioThrax® Sales	\$220M to \$235M	\$220M to \$235M
Net Income	\$35M to \$45M	\$50M to \$60M
Adjusted Net Income	\$55M to \$65M	\$65M to \$75M
EBITDA	\$90M to \$100M	\$120M to \$130M

## **(II) 2017 Forecast**

The company anticipates providing 2017 financial guidance in early January 2017, as part of its presentation at the JP Morgan Annual Healthcare Conference. The 2017 guidance will take into account the BioThrax revenues anticipated under the newly executed follow-on CDC contract and the expected BioThrax procurement contract with BARDA, as well as the company's plan to address its operational and administrative costs to ensure they are sized and aligned to support the company's growth.

## **(III) 2020 Financial Goals**

The company anticipates updating its 2016-2020 Growth Plan financial goals later in 2017.

## **Conference Call and Webcast Information**

Company management will host a conference call at 5:30 pm (Eastern Time) today, December 8, 2016, to discuss this announcement. This conference call can be accessed live by telephone or through Emergent's website: Live Teleconference Information: Dial in number: (855) 766-6521 International dial in: (262) 912-6157 Passcode: 36049167 Webcast Information: Live webcast feed can be accessed using this link: <http://edge.media-server.com/m/p/suud2ad>. A replay of the call can be accessed on Emergent's website [www.emergentbiosolutions.com](http://www.emergentbiosolutions.com) under "Investors."

## **RECONCILIATION OF GAAP NET INCOME TO ADJUSTED NET INCOME AND EBITDA ALL RELATED TO CONTINUING OPERATIONS**

This press release contains two financial measures (**Adjusted Net Income, and EBITDA**) that are considered "non-GAAP" financial measures under applicable Securities and Exchange Commission rules and regulations. These non-GAAP financial measures should be considered supplemental to and not a substitute for financial information prepared in accordance with generally accepted accounting principles. The company's definition of these non-GAAP measures may differ from similarly titled measures used by others. Adjusted Net Income adjusts for specified items that can be highly variable or difficult to predict, or reflect the non-cash impact of charges resulting from purchase accounting. EBITDA reflects net income excluding the impact of depreciation, amortization, interest expense and provision for income taxes. The company views these non-GAAP financial measures as a means to facilitate management's financial and operational decision-making, including evaluation of the company's historical operating results and comparison to competitors' operating results. These non-GAAP financial measures reflect an additional way of viewing aspects of the company's operations that, when viewed with GAAP results may provide a more complete understanding of factors and trends affecting the company's business.

The determination of the amounts that are excluded from these non-GAAP financial measures is a matter of management judgment and depends upon, among other factors, the nature of the underlying expense or income amounts. Because non-GAAP financial measures exclude the effect of items that will increase or decrease the company's reported results of operations, management strongly encourages investors to review the company's consolidated financial statements and publicly-filed reports in their entirety.

## **About Emergent BioSolutions**

Emergent BioSolutions is a global specialty biopharmaceutical company dedicated to one simple mission—to protect and enhance life. We develop, manufacture, and deliver a portfolio of medical countermeasures for biological and chemical threats as well as emerging infectious diseases. Through our work, we envision protecting and enhancing 50 million lives with our products by 2025. Additional information about the company may be found at [www.emergentbiosolutions.com](http://www.emergentbiosolutions.com). Follow us @emergentbiosolu.

## **Safe Harbor Statement**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including, without limitation, our financial guidance and any statements containing the words "believes," "expects," "anticipates," "intends," "plans," "targets," "forecasts," "estimates" and similar expressions in conjunction with, among other things, obtaining a BioThrax procurement contract from BARDA under the notice of intent, discussions of the company's outlook, financial performance or financial condition, growth strategy, product development, product sales, government development or procurement contracts or awards, government appropriations, manufacturing capabilities, Emergency Use Authorization or other regulatory approvals and plans to increase our operational efficiencies and cost structure are forward-looking statements. 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. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

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