Emergent BioSolutions Inc.
Form 8-K
December 08, 2016
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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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	001-33137	14-1902018
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

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

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

Exhibit No.	Description
99	Press Release dated December 8, 2016.

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.

/s/ ROBERT G. KRAMER
By: Robert G. Kramer
Executive Vice President and Chief Financial Officer