Emergent BioSolutions Inc.
Form 8-K
September 30, 2016
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): September 30, 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 September 30, 2016, Emergent Product Development Gaithersburg Inc., a wholly-owned subsidiary of Emergent BioSolutions Inc., entered into a contract with the U.S. Department of Health and Human Services, through the Biomedical Advanced Research and Development Authority (BARDA), for the advanced development and delivery of NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), also known as AV7909, the company's next generation anthrax vaccine candidate.

The contract, valued at up to approximately $1.6 billion, consists of a five-year base period of performance valued at approximately $200 million to develop NuThrax for post-exposure prophylaxis of anthrax disease and to deliver to the Strategic National Stockpile (SNS) an initial two million doses, following Emergency Use Authorization (EUA) pre-approval by the U.S. Food and Drug Administration (FDA). The company anticipates that the FDA could authorize NuThrax for emergency use as early as 2018, triggering deliveries of NuThrax to the SNS in 2019. The contract also includes procurement options for the delivery of an additional 7.5 million to 50 million doses of NuThrax to the SNS, valued from approximately $255 million to up to $1.4 billion, respectively, and options for an additional clinical study and post-marketing commitments valued at approximately $48 million, which if both were to be exercised in full, would increase the potential total contract value to up to approximately $1.6 billion.

Under the terms of the contract, activities to be completed under the base period of performance include licensure-enabling non-clinical and clinical studies, the manufacture and delivery of initial doses to the SNS, and submission of a Biologics License Application to the FDA with an expected FDA-licensure under the Animal Rule. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.

Item 7.01 Regulation FD Disclosure.

On September 30, 2016, the company issued a press release announcing that it had entered into a contract for the advanced development and delivery of NuThrax, the company's next generation anthrax vaccine candidate. A copy of the press release announcing the contract is attached hereto as Exhibit 99 and is incorporated herein by reference.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding the total potential realizable value of the contract, the anticipated timing of EUA eligibility, our strategy, future operations, prospects, plans and objectives with respect to NuThrax, and any other statements containing the words "believes," "expects," "anticipates," "intends," "plans," "estimates" and similar expressions, 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 appropriations for the development and procurement of NuThrax under the contract; our ability to secure EUA pre-authorization approval of NuThrax by the FDA within the anticipated timeframe, if at all; BARDA's decisions to exercise options under the contract; and our development and manufacturing capabilities and strategies. 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 September 30, 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: September 30, 2016 EMERGENT BIOSOLUTIONS INC.

/s/ ROBERT G. KRAMER

By: Robert G. Kramer
Executive Vice President and Chief Financial Officer