

Emergent BioSolutions Inc.
Form 8-K
April 16, 2009

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): **April 15, 2009**

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.)

2273 Research Boulevard, Suite 400, Rockville, Maryland
(Address of Principal Executive Offices)

20850
(Zip Code)

Registrant's telephone number, including area code **(301) 795-1800**

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 8.01. Other Events.

This current report on Form 8-K relates to the proposal submitted by Emergent BioSolutions Inc. (Emergent) in response to the Request for Proposal (RFP-BARDA-08-15) issued by the U.S. Department of Health and Human Services (HHS) for an Anthrax Recombinant Protective Antigen (rPA) Vaccine for the Strategic National Stockpile (the RFP).

On April 15, 2009, HHS issued an amendment to the RFP that requires us, along with all other bidders, to submit a comprehensive plan to the U.S. Food and Drug Administration (the FDA) outlining the regulatory strategy for our rPA vaccine. Information requested includes, but is not limited to, the timing, type, and content of meetings and submissions, critical non-clinical and clinical studies, completion of assay and process validation, manufacturing and stability milestones, and submission of data to support an emergency use authorization and a BLA application, when appropriate. We have also been requested to submit data typical of a pre-IND meeting package with supporting data and information on preclinical studies, cGMP manufacturing, release and stability testing of our rPA vaccine.

We have been advised that the FDA has agreed to review our plan and will provide comments to HHS. We anticipate that we would submit a revised proposal to reflect any comments that FDA may have.

HHS has not indicated how this new requirement will affect the timing of an award decision.

The information in this Form 8-K shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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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: April 16, 2009

EMERGENT BIOSOLUTIONS INC.

By: /s/ Denise Esposito

Denise Esposito

SVP, General Counsel and Secretary