Emergent BioSolutions Inc.
Form 8-K
July 30, 2014

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): July 29, 2014
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.)

2273 Research Boulevard, Suite 400, Rockville, Maryland	20850
(Address of Principal Executive Offices)	(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))

Item 8.01 Other Events.

Emergent BioSolutions Inc. today announced that the U.S. Food and Drug Administration has issued a complete response letter for the New Drug Application of IXINITY™ [coagulation factor IX (recombinant)] for the control and prevention of bleeding episodes and perioperative management in adults and children, 12 years old and above, living with Hemophilia B.

The complete response letter requested additional analyses of data from completed studies and noted deficiencies in the CMC section of the license application, all of which must be resolved before approval can be granted by FDA. The company plans to engage with the FDA to better ascertain the requirements for approval, following which it will determine its next steps. The company does not anticipate launching the product in 2014.

Safe Harbor Statement

This disclosure 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 statements regarding our strategy, anticipated launch of IXINITY, 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 of this disclosure, 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 the success of our efforts to resolve the deficiencies noted by the FDA. 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.

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: July 30, 2014 EMERGENT BIOSOLUTIONS INC.

/s/A.B. Cruz

By: A.B. Cruz

Executive Vice President, General Counsel and Corporate Secretary