ADMA BIOLOGICS, INC.
Form 8-K
August 04, 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): July 29, 2016

ADMA BIOLOGICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-36728	56-2590442
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

465 State Route 17, Ramsey, New Jersey	07446
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (201) 478-5552

(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):

o 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 Matters.

On July 29, 2016, ADMA Biologics, Inc. (the "Company"), issued a press release announcing that the U.S. Food and Drug Administration ("FDA") issued a Complete Response Letter ("CRL") to the Company's biologics license application (BLA) for its lead product candidate, RI-002, an intravenous immune globulin for the treatment of patients with primary humoral immunodeficiency disease ("PIDD").

The CRL did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted by the Company in the BLA, nor did the FDA request any additional clinical studies be conducted prior to FDA approval of RI-002 for PIDD.

The FDA identified in the CRL certain outstanding inspection issues and deficiencies at the Company's third-party contract manufacturers, including its contract drug substance and product manufacturer, its contract fill and finisher and compliance issues with a third-party contract testing laboratory, and requested documentation of corrections for a number of those issues. The FDA also requested in the CRL, among other things, that the Company provide the FDA with certain additional information, including summaries or study reports, for, among other things various aspects of the manufacturing process. The Company will work with the agency to reach an agreement on acceptable language for the package insert and container and vial labeling, if and when approval is granted.

A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company dated July 29, 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.

August 4, 2016

ADMA Biologics, Inc.

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release of the Company dated July 29, 2016