

ADMA BIOLOGICS, INC.
Form 8-K
January 07, 2019

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): January 7, 2019

ADMA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware 001-36728 56-2590442
(State or other jurisdiction (Commission (IRS Employer

of incorporation) File Number) 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company “

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. “

Item 7.01 Regulation FD Disclosure.

ADMA Biologics, Inc. (the “Company”) has updated its investor presentation (the “Investor Presentation”) and a copy of the slides comprising the Investor Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Investor Presentation may also be accessed under the “Investor Relations” tab on the Company’s website at www.admabiologics.com.

In accordance with General Instruction B.2 on Form 8-K, the information set forth in this Item 7.01 and the Investor Presentation slides, attached to this report as Exhibit 99.1, are “furnished” and shall not be deemed to be “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 such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Please refer to Exhibit 99.1 for a discussion of certain forward-looking statements included therein and the risk and uncertainties related thereto.

Item 8.01

Other Events.

On January 7, 2019, the Company issued a press release announcing that the Company has submitted responses to the U.S. Food and Drug Administration (“FDA”) Complete Response Letter received on December 19, 2018 for BIVIGAM®’s (Intravenous Immune Globulin [Human], 10%) (“BIVIGAM®”) Prior Approval Supplement (“PAS”). The Company anticipates receiving an acknowledgement letter from the FDA within 30 days, and plans to provide appropriate updates on the progress of the BIVIGAM® PAS review.

The full text of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01

Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

- 99.1 ADMA Biologics, Inc. January 2019 Investor Presentation.
- 99.2 ADMA Biologics, Inc. Press Release, dated January 7, 2019.

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.

January 7, 2019 ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer