

ADMA BIOLOGICS, INC.
Form 8-K
October 11, 2018

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): October 10, 2018

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 07446
Jersey
(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 8.01 Other Events.

On October 11, 2018, ADMA Biologics, Inc., a Delaware corporation (the “Company”), issued a press release announcing that the Company received a formal communication from the U.S. Food and Drug Administration (the “FDA”) stating that the FDA considers the recent Prior Approval Statement (“PAS”) submission a major amendment. As a result, the FDA has extended the review period of the PAS submitted in June 2018 to amend the Biologics License Application (“BLA”) for BIVIGAM® by two months. The FDA established a target action date of December 18, 2018 for the PAS pursuant to the Prescription Drug User Fee Act (“PDUFA”).

The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item 8.01.

Item 9.01

Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 ADMA Biologics, Inc. Press Release, dated October 11, 2018.

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.

October 11, 2018 ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer