

ADMA BIOLOGICS, INC.
Form 8-K
December 20, 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): December 20, 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 7.01 Regulation FD Disclosure.

As reported in a Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission (the “SEC”) on December 20, 2018, on December 19, 2018, ADMA Biologics, Inc., a Delaware corporation (the “Company”), issued a press release announcing that the U.S. Food and Drug Administration has issued a Complete Response Letter (the “CRL”) for the drug substance Prior Approval Supplement (“PAS”) submission for BIVIGAM® (Intravenous Immune Globulin [Human], 10%) (“BIVIGAM®”) and previously approved the drug product PAS submission for BIVIGAM®.

On December 20, 2018, the Company held a conference call at 9:00am Eastern Time (the “Conference Call”) to provide more detail about the CRL.

A copy of the transcript of that call is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information set forth in this Item 7.01 and contained in the transcript furnished as Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and is not incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about the Company. These forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements concerning the Company’s plans to develop, manufacture, market, launch and expand its commercial infrastructure, the expected timing of, and the Company’s ability to, obtain and maintain regulatory approvals of its current products and product candidates and the Company’s expectations for future capital requirements. Actual events or results may differ materially from those events or results that may be implied by these forward-looking statements due to a number of important factors. There can be no assurances that the forward-looking statements included will prove to be accurate. Except to the extent required by applicable laws or rules, the Company does not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements. Forward-looking statements are subject to many risks, uncertainties and other factors that could cause our actual results, and the timing of certain events, to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, the risks and uncertainties described in the Company’s filings with the SEC, including the Company’s most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.

Item 8.01

Other Events.

On December 20, 2018, the Company issued a press release announcing that it would be hosting the Conference Call to discuss the CRL received on December 19, 2018.

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 | <u>Transcript of Conference Call held on December 20, 2018.</u> |
| 99.2 | <u>ADMA Biologics, Inc. Press Release, dated December 20, 2018.</u> |

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.

December 20, 2018 ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer