ADMA BIOLOGICS, INC.
Form 8-K
April 03, 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): April 1, 2019

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))

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.

As previously disclosed, on April 1, 2019, ADMA Biologics, Inc., a Delaware corporation (the "Company"), announced that the U.S. Food and Drug Administration (the "FDA") has approved ASCENIV™, Immune Globulin Intravenous, Human – slra 10% Liquid ("ASCENIV™"), formerly referred to as RI-002. In connection with the approval of ASCENIV™, the FDA issued a Department of Health and Human Services U.S. license No. 2019 to the Company. On April 2, 2019, the Company received confirmation that the license covers the Company's Boca Raton, FL manufacturing facility which has demonstrated compliance with FDA requirements as well as authorizes ADMA to manufacture and enter into interstate commerce with ASCENIV™.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 ADMA Biologics, Inc. Press Release, dated April 2, 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.

April 2, 2019 ADMA Biologics, Inc.

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Executive Vice President and Chief Financial Officer