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 17, 2018

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 ý

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 17, 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 acknowledged the receipt of the Company's Biologics License Application ("BLA") resubmission for RI-002. The FDA stated that it considers the RI-002 BLA resubmission 'a complete, Class 2 response' and has established an action due date of April 2, 2019, under 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 17, 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 17, 2018

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics Receives PDUFA Date for RI-002

Resubmission of Biologics License Application ("BLA") Reinforces the Company's Commitment to Commercialize Novel Therapies for Immune Compromised Patients to Address Unmet Medical Needs

RAMSEY, NJ & BOCA RATON, FL– October 17, 2018 – ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA" or the "Company"), a vertically integrated commercial biopharmaceutical company that develops, manufactures and markets specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease ("PIDD") and the prevention and treatment of certain infectious diseases, announces that the U.S. Food and Drug Administration ("FDA") has acknowledged the receipt of ADMA's September 28, 2018 BLA resubmission for RI-002. The FDA stated that it considers the RI-002 BLA resubmission 'a complete, Class 2 response' and has established an action due date of April 2, 2019, under the Prescription Drug User Fee Act ("PDUFA").

"We are excited to receive the action date for RI-002 and look forward to working closely with the FDA during their review, with the goal of approval on or prior to April 2, 2019. We believe that RI-002, if approved by the FDA, has great potential to address unmet medical needs for PIDD patients as well as offers clinicians a much needed treatment option in their immune globulin armamentarium," stated Adam Grossman, President and CEO of ADMA Biologics.

About RI-002

ADMA's lead portfolio product candidate, RI-002, which has demonstrated positive Phase III pivotal clinical trial data, is a specialty plasma-derived, polyclonal, intravenous immune globulin ("IVIG") derived from human plasma containing naturally occurring polyclonal antibodies (e.g., Streptococcus pneumoniae, H. influenza type B, cytomegalovirus ("CMV"), measles, tetanus, etc.) as well as plasma from donors tested to have high levels of neutralizing antibodies to respiratory syncytial virus ("RSV"). ADMA is pursuing an indication for the use of this specialty polyclonal IVIG product for treatment of patients diagnosed with PIDD. Polyclonal antibodies are the primary active component of IVIG products. Polyclonal antibodies are proteins that are used by the body's immune system to neutralize microbes, such as bacteria and viruses and prevent against infection and disease. Data review which has been published in peer reviewed journals indicates that the polyclonal antibodies present in RI-002 support its ability to prevent infections in immune-compromised patients. This data and other information about RI-002 or ADMA Biologics products can be found on the Company website at: www.admabiologics.com. RI-002 is protected by U.S. Patents: 9,107,906, 9,714,283, 9,815,886 and 9,969,793, the latter of which affords the Company patent exclusivity for the use of an immune globulin as a prevention and/or treatment for any type of respiratory infection.

About Primary Immune Deficiency Disease (PIDD)

PIDD is a class of inherited genetic disorders that causes an individual to have a deficient or absent immune system. According to the World Health Organization, there are approximately 350 different genetic mutations encompassing PIDD. Some disorders present at birth or in early childhood, the disorders can affect anyone regardless of age or gender. Some affect a single part of the immune system, others may affect one or more components of the system. PIDD patients are vulnerable to infections and more likely to suffer complications from these infections as compared to individuals with a normal functioning immune system. The infections may occur in any part of the body. As patients suffering from PIDD lack a properly functioning immune system, they typically receive monthly treatment with polyclonal immune globulin products. Without this exogenous antibody replacement, these patients would remain vulnerable to persistent and chronic infections. PIDD has an estimated prevalence of 1:1,200 in the United States, or approximately 250,000 people in the U.S.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease (“PIDD”) and the prevention and treatment of certain infectious diseases. ADMA's mission is to develop and commercialize plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases. The target patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disease, or who may be immune-compromised for other medical reasons. ADMA has received U.S. Patents 9,107,906, 9,714,283, 9,815,886 and 9,969,793 related to certain aspects of its lead product candidate, RI-002. For more information, please visit www.admabiologics.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements" pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about ADMA Biologics, Inc. ("we“, “our” or the “Company”). Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words "estimate," “project,” "intend," “forecast,” "target,” ”anticipate,” “plan,” “planning,” “expect,” “believe,” “will," “is likely,” “will likely,” “should,” “could,” "would," "may," or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements also include, but are not limited to, statements concerning our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products, the safety, efficacy and expected timing of, and our ability to, obtain and maintain regulatory approvals of our current products and product candidates, and the labeling or nature of any such approvals, the success of our work with our third party vendors and the U.S. Food and Drug Administration (the “FDA”) in furtherance of and progress towards an approval of our Biologics License Application for specialty plasma-based biologics and the ability of such third parties to respond adequately or in a timely manner to the issues raised by the FDA, our ability to successfully pursue commercialization and prelaunch activities, the timeframe within which we may receive approval from the FDA for specialty plasma-based biologics, if at all, the potential of our specialty plasma-based biologics to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease or other indications and our ability to realize increased prices for plasma growth in the plasma collection industry. Actual events or results may differ materially from those described in this document due to a number of important factors. Current and prospective security holders are cautioned that there also can be no assurance that the forward-looking statements included in this press release will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by ADMA or any other person that the objectives and plans of ADMA will be achieved in any specified time frame, if at all. Except to the extent required by applicable laws or rules, ADMA 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 our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.

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