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): July 26, 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 July 26, 2018, ADMA Biologics, Inc., a Delaware corporation (the "Company"), issued a press release announcing that it successfully closed-out the April 2018 U.S. Food and Drug Administration ("FDA") compliance inspection of the Company's Boca Raton, Florida facility (the "Boca Facility") and that the Company has received the first FDA Establishment Inspection Report for the Boca Facility since 2012.

The full text of the press release is filed as Exhibit 99.1 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. Press Release, dated July 26, 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.

July 26, 2018

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics Reports Successful Close-Out of its April 2018 FDA Compliance Inspection

FDA Establishment Inspection Report ("EIR") Received

RAMSEY, N.J. and BOCA RATON, FL., – July 26, 2018 – ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA" or the "Company"), a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-based biologics for the prevention and treatment of certain infectious diseases, announces that the Company has received formal notice from the U.S. Food and Drug Administration (the "FDA" or the "Agency") of the successful close-out for the April 2018 compliance inspection of the Boca Raton, FL production facility. This is the first EIR issued to the site since 2012.

The EIR received by the Company contains detailed information about the April 2018 FDA inspection, discussions had with the investigators, requests for clarification and information, as well as a summary of potential next steps for the review of the Prior Approval Supplement ("PAS") for BIVIGAM®. According to FDA guidance, when the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d) (3), it releases a copy of the EIR to the inspected establishment.

The EIR discusses many improvements and resolutions made by the Company to the majority of observations previously existing from the 2014 and 2016 FDA inspections of the Boca Raton, FL facility while owned and operated by Biotest Pharmaceuticals Corporation ("Biotest"). The Agency has requested specific clarification to certain historical inspectional deficiencies (from 2014 and 2016), some of which, the Company believes, will be addressed during the ongoing review of the PAS for BIVIGAM®. The EIR states that the FDA investigators were unable to review real time production of BIVIGAM® during the inspection and the report notes that the PAS had not yet been on file at the time of the April 2018 inspection. The Company believes that in order for FDA to make a final determination regarding the 2014 Warning Letter Close-Out, a review of the PAS submission for BIVIGAM® as well as a potential Pre-Approval Inspection ("PAI") of the manufacturing process may be required. Based on separate informal correspondence received between the Company and FDA staff within the Center for Biologics Evaluation and Research ("CBER"), the Company has been informed that its compliance status is currently Voluntary Action Indicated ("VAI"), which remains to be confirmed with CBER's Office of Compliance and Biologics Quality ("OCBQ"). In addition, the FDA has stated to the Company that the 483 responses have been reviewed and corrective actions will be assessed at the next FDA inspection of the establishment, which is anticipated by the Company to occur on or before the end of April 2020.

The Company’s assessment of the information received by FDA results in the following determinations:

1. The April 2018 compliance inspection of the Boca Raton, FL manufacturing facility has been successfully closed out. ADMA intends to implement the corrective actions represented to FDA in its accepted 483 response.
2. The current compliance status of the Boca Raton, FL facility is “VAI”.
3. In order for FDA to make an official determination regarding the close-out of the 2014 Warning Letter, the Company believes a complete review of the PAS and a potential PAI for BIVIGAM® should occur. The Company has been informed that the target action date for the PAS is October 25, 2018.

“We are pleased that the FDA has determined our responses to be satisfactory for the April 2018 FDA compliance inspection and that the FDA has accepted our plan for remediation to their observations and closed this inspection. We believe that we have successfully remediated the production and significant compliance issues identified in the 2014 Warning Letter and subsequent 2016 cGMP inspection issued to Biotest as evidenced by the successful production of three conformance batches for BIVIGAM®, which were the basis for our June 2018 PAS submission. Furthermore, we believe that once the FDA has reviewed the PAS and performed an inspection of the manufacturing operations for BIVIGAM®, we will be in position to relaunch BIVIGAM in the U.S. and further improve our compliance status,” stated Adam Grossman, President and Chief Executive Officer of ADMA Biologics, Inc.

Mr. Grossman further stated, “We are thankful for the extraordinary efforts of our dedicated and hard-working employees who have been relentlessly committed to improving the Company’s FDA compliance status.”

The receipt of this EIR does not change the Company’s previously reported timelines for activities, regulatory submissions and approvals. The Company remains on target to have the BIVIGAM® PAS approved and the BLA for RI-002 refiled with the FDA during the second half of 2018.

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.

About BIVIGAM®

BIVIGAM® is an intravenous immune globulin indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These primary immunodeficiencies (“PI”) are a group of genetic disorders. Initially thought to be very rare, it is now believed that as many as 250,000 people in the U.S. have some form of PI. BIVIGAM® contains a broad range of antibodies similar to those found in normal human plasma. These antibodies are directed against bacteria and viruses, and help to protect PIDD patients against serious infections. BIVIGAM® is a purified, sterile, ready-to-use preparation of concentrated polyclonal Immunoglobulin (“IgG”) antibodies. Antibodies are proteins in the human immune system that work to defend against infections and disease. FDA approval for BIVIGAM® was received by Biotest Pharmaceuticals Corporation (“BPC” or “Biotest”) on December 19, 2012, and production of BIVIGAM® was halted by Biotest in December 2016. ADMA Biologics obtained ownership and all rights, title and interest in BIVIGAM® on June 6, 2017 as part of the Biotest Therapy Business Unit (“BTBU”) asset acquisition. ADMA optimized the production process for BIVIGAM® and submitted a Prior Approval Supplement (“PAS”) to the United States Food and Drug Administration (“FDA”) to amend the Biologics License Application (“BLA”) for BIVIGAM® in June of 2018, with a target action date of October 25, 2018 under the Prescription Drug User Fee Act (“PDUFA”). If the PAS is approved by the FDA, ADMA expects to be able to relaunch the product for commercial sale by the end of the first quarter of 2019.

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 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/therapies and 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.

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, our ability to realize increased prices for plasma growth in the plasma collection industry and our expectations for future capital requirements. 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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