

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 24, 2018

ADMA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36728
(Commission
File Number)

56-2590442
(IRS Employer
Identification No.)

465 State Route 17, Ramsey, New Jersey
(Address of principal executive offices)

07446
(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):

- 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 April 24, 2018, ADMA Biologics, Inc. issued a press release announcing that it has successfully completed the manufacturing and release, and has made commercial sales, of its first batch of Nabi-HB® (Hepatitis B Immune Globulin, Human) produced under its leadership.

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

<u>Exhibit No.</u>	<u>Description</u>
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99.1	<u>ADMA Biologics, Inc. Press Release, dated April 24, 2018.</u>
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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 24, 2018

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Vice President and Chief Financial Officer



ADMA Biologics Announces the Release of its First Commercial Batch of Nabi-HB Manufactured Under its Ownership

Operational Leadership Team Executes on Production and Commercialization of the Company's Immune Globulin Product for the Treatment of Hepatitis B Infection

RAMSEY, N.J. and BOCA RATON, FL.,— April 24, 2018 – ADMA Biologics, Inc. (NASDAQ: ADMA) (“ADMA” or the “Company”), today announced that it has successfully completed the manufacturing, release and has made commercial sales of its first batch of Nabi-HB® (“Hepatitis B Immune Globulin, Human”), produced under its leadership. 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 (“PID”) and the prevention and treatment of certain infectious diseases.

“We are pleased to announce that our team has successfully manufactured, released and generated sales of our first production lot of Nabi-HB® produced under ADMA’s leadership since the BTBU acquisition. We are continuing to make progress with our Compliance Enhancement Program to appropriately address the outstanding compliance issues that we inherited from Biotest Pharmaceuticals when we purchased the Boca facility, and we continue to generate revenues from the sale of commercial product and from our contract manufacturing services,” said Adam Grossman, ADMA’s President and Chief Executive Officer. “We plan to provide updates on our manufacturing progress at the appropriate time.”

As part of the Company’s acquisition of the Biotest Therapy Business Unit (“BTBU”), ADMA acquired the worldwide rights to Nabi-HB®, along with raw materials and finished commercial inventory, from which ADMA has generated accretive sales since closing the acquisition in June 2017. The commercially-released batch of Nabi-HB® enables the Company to fulfill ongoing demand for this specialty product.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is a vertically integrated commercial biopharmaceutical and specialty immunoglobulin manufacturing company that currently manufactures, markets and develops specialty plasma-based biologics for the treatment of immune deficiencies and prevention 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 and 9,815,886 related to certain aspects of its lead product candidate, RI-002. For more information, please visit www.admabiologics.com.

About Nabi-HB®

Nabi-HB® is a hyperimmune globulin that is rich in antibodies to the Hepatitis B virus. Nabi-HB® is a purified human polyclonal antibody product collected from plasma donors who have been previously vaccinated with a Hepatitis B vaccine. Nabi-HB® is indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen (“HBsAg”), prenatal exposure to infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection. Hepatitis B is a potentially life-threatening liver infection caused by the Hepatitis B virus. It is a major global health problem and can cause chronic infection and put people at high risk of death from cirrhosis and liver cancer. Nabi-HB® has a well-documented record of long-term safety and effectiveness since its initial market introduction. FDA approval for Nabi-HB® was received on March 24, 1999. Biotest acquired Nabi-HB® from Nabi Biopharmaceuticals in 2007. ADMA resumed production of Nabi-HB® in the third quarter of 2017, as substantially all of the Nabi-HB® inventory received as part of the Biotest Transaction has been sold in the normal course of business.

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.

COMPANY CONTACT:

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INVESTOR RELATIONS CONTACT:

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