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 2, 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	ADMA	Nasdaq Capital Market

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 July 2, 2019, the Food and Drug Administration notified ADMA Biologics, Inc. (the "Company") that the licenses for BIVIGAM® and Nabi-HB® have been revoked from Biotest Pharmaceuticals Corporation and transferred and issued to the Company. On July 8, 2019, the Company issued a press release entitled "ADMA Biologics Receives FDA Approval for License Transfers for BIVIGAM® and Nabi-HB®." The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release dated July 8, 2019, entitled "ADMA Biologics Receives FDA Approval for License Transfers for BIVIGAM® and Nabi-HB®."

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 8, 2019

ADMA Biologics, Inc.

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

Exhibit 99.1

ADMA Biologics Receives FDA Approval for License Transfers for BIVIGAM® and Nabi-HB®

All Aspects of the Biotest Therapy Business Unit ("BTBU") Acquisition Are Successfully Completed

RAMSEY, N.J. and BOCA RATON, FL., – July 8, 2019 – ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA" or the "Company"), a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases, announces the United States Food and Drug Administration ("FDA") has notified ADMA the licenses for BIVIGAM® and Nabi-HB® have been revoked from Biotest Pharmaceuticals Corporation, ("BPC") U.S. License No. 1792 and transferred and issued to ADMA's U.S. License No. 2019.

"We are very pleased to announce the U.S. License transfer of BIVIGAM® and Nabi-HB® from BPC to ADMA, as this was the final remaining regulatory item from the acquisition of the Biotest Therapy Business Unit transaction," stated President and Chief Executive Officer, Adam Grossman. "It is important for patients, prescribers and investors to recognize that FDA regulatory licensing is complex, particularly with respect to ADMA's acquisition of the BTBU assets. Since ADMA's ownership and operation of the BTBU, we have received an acceptable FDA inspection classification, FDA approvals for two product submissions and now licenses issued in ADMA's name for two FDA approved biologic drugs. FDA's license transfer of BIVIGAM® and Nabi-HB® to ADMA's U.S. License 2019 constitutes a determination by FDA that the establishment and the products meet applicable requirements to ensure the continued safety, purity, and potency of the products. Those applicable requirements also include FDA's current Good Manufacturing Practice ("cGMP"). Going forward, ADMA will manufacture and introduce both BIVIGAM® and Nabi-HB® into interstate commerce under ADMA's U.S. License No. 2019 along with its recently approved patented Immune Globulin, ASCENIV®."

About ADMA Biologics, Inc. (ADMA)
ADMA Biologics is a vertically integrated biopharmaceutical manufacturer with three FDA approved commercial specialty plasma-based biologics. 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 and management of immune compromised patient populations. 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, 9,969,793 and 10,259,865 related to certain aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

About Primary Immune Deficiency Disease (“PI”)
PI 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 PI. 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. PI 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. Because patients suffering from PI 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. PI has an estimated prevalence of 1:1,200 in the United States, or approximately 250,000 people in the U.S.

About ASCENIV™ (Formerly referred to as RI-002)
ASCENIV™, Immune Globulin Intravenous, Human – slra 10% Liquid, is a plasma-derived, polyclonal, intravenous immune globulin (“IVIG”). ASCENIV™ is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886. ASCENIV™ is manufactured using our unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and plasma from donors tested using our proprietary microneutralization assay. ASCENIV™ contains naturally occurring polyclonal antibodies. ASCENIV™ is indicated for the treatment of Primary Humoral Immunodeficiency (“PI”) in adults and adolescents (12 to 17 years of age). ADMA received FDA approval for ASCENIV™ on April 1, 2019. 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. ASCENIV™ prevented serious bacterial infection among fifty-nine patients treated for twelve months during the pivotal investigation. The most common adverse reactions to ASCENIV™ (≥5% of study subjects) were headache, sinusitis, diarrhea, gastroenteritis viral, nasopharyngitis, upper respiratory tract infection, bronchitis, and nausea. ADMA anticipates the commercial launch of ASCENIV™ during the second half of 2019. Certain data and other information about ASCENIV™ or ADMA Biologics and its products can be found on the Company’s website at: www.admabiologics.com.

About BIVIGAM®
BIVIGAM® is an immune globulin intravenous (human), 10% liquid, indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, X-linked and congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These PIs 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 PI patients against serious infections. BIVIGAM® is a purified, sterile, ready-to-use preparation of concentrated human Immunoglobulin (“IgG”) antibodies. Antibodies are proteins in the human immune system that work to defend against infections and disease. FDA’s initial approval for BIVIGAM® was received by BPC in December 2012, and production of BIVIGAM® was halted by BPC in December 2016. ADMA obtained ownership and all rights, title and interest in BIVIGAM® in June 2017 as part of the Biotest Therapy Business Unit (“BTBU”) asset acquisition and resumed the production of BIVIGAM® during the fourth quarter of 2017. Using ADMA’s optimized IVIG manufacturing process, FDA approved a Pre-Approval Supplement (“PAS”) to amend the BLA for the product on May 9, 2019 allowing the Company to resume the supply of drug to the U.S. market. The FDA completed the license transfer for BIVIGAM® to ADMA on July 2, 2019. Certain data and other information about BIVIGAM® or ADMA Biologics and its products can be found on the Company’s website at: 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 obtained ownership and all rights, title and interest in Nabi-HB® in June 2017 as part of the BTBU asset acquisition and the FDA transferred the BLA to ADMA on July 2, 2019. Certain data and other information about Nabi-HB® or ADMA Biologics and its products can be found on the Company’s website at: 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, product expansions into new fields of use, indications and product candidates, and the labeling or nature of any such approvals, our ability to successfully pursue commercialization and prelaunch activities for our products, the potential of our specialty plasma-based biologics products and product candidates 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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