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): May 9, 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. ☐

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	ADMA	Nasdaq Capital Market

Item 8.01 Other Events.

On May 10, 2019, ADMA Biologics, Inc., a Delaware corporation (the "Company"), issued a press release announcing that the U.S. Food and Drug Administration has approved the Company's Prior Approval Supplement ("PAS") for BIVIGAM® (immune globulin intravenous (human), 10% liquid) ("BIVIGAM®"). The FDA's approval of the PAS for BIVIGAM® approves the use of the Company's optimized intravenous immune globulin manufacturing process and enables the Company to commence the marketing of BIVIGAM® in the United States to patients with Primary Humoral Immunodeficiency.

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 May 10, 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.

May 10, 2019

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

FDA Approves Prior Approval Supplement for BIVIGAM®

ADMA Announces it will Commence Commercial Sales of BIVIGAM®

RAMSEY, N.J. and BOCA RATON, FL., – May 10, 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 that the U.S. Food and Drug Administration ("FDA") has approved the Company's Prior Approval Supplement ("PAS") for BIVIGAM® (immune globulin intravenous (human), 10% liquid). The FDA's approval of the PAS for BIVIGAM® approves the use of the Company's optimized intravenous immune globulin ("IVIG") manufacturing process and enables ADMA to commence the marketing of BIVIGAM® in the U.S. to patients with Primary Humoral Immunodeficiency ("PI").

"This FDA approval for ADMA's third commercial product is a significant milestone, and we look forward to commencing sales of BIVIGAM® in the near-term," stated Adam Grossman, President and Chief Executive Officer of ADMA. "The FDA's approval of BIVIGAM®'s modified manufacturing process validates our commitment to optimizing the ADMA IVIG manufacturing process and signifies the extensive and successful remediation and turnaround of our Boca Raton, Florida manufacturing facility."

"We are pleased to re-introduce BIVIGAM® into the market, where demand for IVIG therapy continues to outpace supply." Mr. Grossman continued, "The $6 billion U.S. market for IVIG continues to grow and the relaunch of BIVIGAM® can help to alleviate a portion of the tight supply for this important patient population, where dependable and consistent supply of IVIG is critical to patients' well-being."

BIVIGAM® received its initial FDA approval in December 2012. The BIVIGAM® pivotal clinical study was a prospective, open-label, single-arm multicenter trial, which achieved its primary endpoints for safety, efficacy and tolerability. The results were published by Dr. Richard Wasserman, et al. in the Journal of Clinical Immunology in 2014. In December 2016, Biotest Pharmaceuticals Corporation ("BPC") voluntarily suspended commercial production of BIVIGAM® due to certain manufacturing and compliance issues. Subsequent to ADMA's acquisition of the Biotest Therapy Business Unit ("BTBU") assets in June 2017, of which BIVIGAM® was a part, ADMA resumed production of BIVIGAM® during the fourth quarter of 2017, successfully manufacturing three conformance lots using the Company's optimized IVIG manufacturing process. ADMA anticipates the re-launch of BIVIGAM® for commercial sale during the second half of 2019.

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 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 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.

Additional Important Safety Information for BIVIGAM® [Immune Globulin Intravenous (Human), 10% Liquid]

BIVIGAM® [Immune Globulin Intravenous (Human), 10% Liquid] is indicated for the treatment of primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin intravenous (IGIV) products, including BIVIGAM. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, a history of venous or arterial thrombosis, the use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with the administration of Immune Globulin Intravenous (Human) (IGIV) products in predisposed patients.**
- **Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. BIVIGAM does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction, or renal failure, administer BIVIGAM at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

BIVIGAM is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin and in IgA-deficient patients with antibodies to IgA and history of hypersensitivity.

Thrombosis may occur following treatment with IGIV products, including BIVIGAM. Thrombosis may occur in the absence of known risk factors.

Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/ markedly high triacylglycerols (triglycerides), or monoclonal gammopathies. For patients at risk of thrombosis, administer BIVIGAM at the minimum dose and infusion rate practicable.

In patients at risk of developing acute renal failure, renal function, including blood urea nitrogen (BUN), serum creatinine, and urine output need to be monitored.

Hyperproteinemia, increased serum viscosity, and hyponatremia or pseudohyponatremia can occur in patients receiving IGIV therapy. Aseptic meningitis syndrome (AMS) has been reported with IGIV treatments; AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV.

As hemolysis can develop subsequent to treatment with IGIV products, monitor patients for hemolysis and hemolytic anemia. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]). If TRALI is suspected, test the product and patient for antineutrophil antibodies.

Because BIVIGAM is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Passive transfer of antibodies with IGIV treatment may yield positive serological testing results, with the potential for misleading interpretation.

Serious adverse reactions observed in clinical trial subjects receiving BIVIGAM were vomiting and dehydration in one subject. The most common adverse reactions to BIVIGAM (reported in ≥ 5% of clinical study subjects) were headache, fatigue, infusion site reaction, nausea, sinusitis, blood pressure increase, diarrhea, dizziness, and lethargy.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

For more information about BIVIGAM, please see full Prescribing Information.

You are encouraged to report side effects of prescription drugs to ADMA Biologics @ 1-800-458-4244 or the FDA. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

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.

COMPANY CONTACT:
Brian Lenz
Executive Vice President and Chief Financial Officer | 201-478-5552 | www.admabiologics.com

INVESTOR RELATIONS CONTACT:
Jeremy Feffer
Managing Director, LifeSci Advisors, LLC | 212-915-2568 |