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): August 22, 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 August 22, 2019, ADMA Biologics, Inc. issued a press release entitled "ADMA Biologics Announces Commercial Relaunch and its First Commercial Sales of BIVIGAM®." 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 August 22, 2019, entitled "ADMA Biologics Announces Commercial Relaunch and its First Commercial Sales of BIVIGAM®."

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.

August 22, 2019

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

Exhibit 99.1

ADMA Biologics Announces Commercial Relaunch and its First Commercial Sales of BIVIGAM®

RAMSEY, N.J. and BOCA RATON, FL., – August 22, 2019 – ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA" or the "Company"), a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures and markets three approved plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases, announces the commercial relaunch and its first commercial sales of BIVIGAM®.

As previously reported, BIVIGAM® had a Biologics License Application ("BLA") manufacturing change Prior Approval Supplement ("PAS") approved by the United States Food and Drug Administration ("FDA") on May 9, 2019, enabling ADMA to resume marketing BIVIGAM® to US- based prescribers and healthcare professionals. BIVIGAM® is approved for the treatment of patients diagnosed with 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.

"We are very excited to have received the timely FDA PAS approval allowing ADMA to reintroduce BIVIGAM® to market for PI patients in efforts to address their ongoing medical needs and to address reported US market Intravenous Immune Globulin ("IVIG") supply constraints. BIVIGAM's® relaunch is a result of the culmination of many important milestones, and we are grateful for the efforts of our dedicated staff at ADMA and of the FDA, which have enabled us to bring BIVIGAM® to market. ADMA looks forward to working with our distribution partner and the physician community as we are prepared and committed to provide a continuous supply of BIVIGAM® to PI patients," stated Adam Grossman, President and Chief Executive Officer.

Mr. Grossman continued, "As we have previously communicated to our stakeholders, the manufacturing, testing and final packaging for a complex biologic product like BIVIGAM typically takes anywhere from six to nine months and sometimes longer to deliver to customers and end users. ADMA believes it is doing everything in its power to ramp up production to a steady state to ensure the continuity of care for patients, while continuing to operate in accordance with the FDA's quality regulations and expectations. We want caregivers and patients to know that ADMA's top priority remains unchanged: providing safe, high-quality and efficacious products."

BIVIGAM® will be available through BioCare SD, our authorized distributor. Prescribers and healthcare professionals interested in purchasing BIVIGAM® for use with their PI patients should contact BioCare SD directly at 800-304-3064 or by visiting their website at www.BioCareSD.com.

Information about BIVIGAM® for healthcare professionals, patients with primary immune deficiency disease and their healthcare partners can be found at: www.bivigam.com. Through the BIVIGAM® website, physicians can access the prescription request form and request a meeting with a sales professional. Any medical or scientific questions regarding BIVIGAM®, or any other products produced by ADMA Biologics, should be directed to our Medical Affairs Department at medicalaffairs@admabio.com or 800-458-4244, prompt 2.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is a vertically integrated commercial biopharmaceutical company that manufactures and markets three United States Food and Drug Administration ("FDA") approved plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases. ADMA's mission is to manufacture, market and develop 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 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 BioCare SD

Based in Phoenix, Arizona, BioCare SD has been devoted to delivering specialty and therapeutic biological products to our customers since 1982. BioCare SD is committed to being the industry's most trusted specialty distributor by providing customer-oriented solutions, unmatched service levels, and a unique distribution network to ensure the highest quality in patient care. The BioCare SD customer support team and local, field-based account management teams are available 24 hours a day, 7 days a week, 365 days a year by calling 800-304-3064. For more information, please visit www.BioCareSD.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 Primary Humoral Immunodeficiency ("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") acquisition in June 2017 and resumed the production of BIVIGAM® during the fourth quarter of 2017. Based on ADMA's optimized IVIG manufacturing process, the FDA approved a Prior Approval Supplement to amend the Biologics License Application for the product on May 9, 2019, allowing the Company to resume supplying BIVIGAM® to the U.S. market. The FDA completed the license transfer for BIVIGAM® to ADMA on July 2, 2019. BIVIGAM® was reintroduced to the US market on August 22, 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.

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 such words as "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 ability to operate in accordance with FDA quality and compliance, regulations and expectations; our ability to provide a continuous supply of BIVIGAM® to PI patients; our ability to successfully pursue commercialization and prelaunch activities for our products; and 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. 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. 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 |