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): February 11, 2020

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):

☐ 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 Global 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 February 11, 2020, ADMA Biologics, Inc. issued a press release entitled "ADMA Biologics Receives BioNJ 2020 Innovator Award for ASCENIV™." 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 February 11, 2020, entitled "ADMA Biologics Receives BioNJ 2020 Innovator Award for ASCENIV™."

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.

February 11, 2020

ADMA Biologics, Inc.

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

ADMA Biologics Receives BioNJ 2020 Innovator Award for ASCENIV™

RAMSEY, NJ and BOCA RATON, FL, February 11, 2020 -- ADMA Biologics, Inc. (Nasdaq: ADMA), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and for the prevention of certain infectious diseases, today announced that it was awarded the BioNJ 2020 Innovator Award in recognition of the development and approval of ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) by the U.S. Food and Drug Administration (FDA) in 2019.

“We are honored to be recognized by BioNJ with this prestigious award,” said Adam Grossman, President and Chief Executive Officer of ADMA. “The robust life sciences community in New Jersey provides ADMA with talented and dedicated healthcare professionals that are contributing to the launch and commercialization of ASCENIV, our novel, proprietary immune globulin product, which we believe can help appropriate patients in the U.S.”

“The purpose of the BioNJ Innovator Award is to celebrate the dominant role New Jersey plays in the healthcare landscape and to highlight the vision and innovation contributed by these recipients,” said Debbie Hart, President and Chief Executive Officer of BioNJ. “We are delighted to present ADMA with the 2020 Innovator Award for its success in bringing ASCENIV to market to help immune deficient patients.”

About Primary Humoral Immunodeficiency

Primary humoral immunodeficiency (PI), also known as primary immune deficiency disease (PIDD), 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 are present at birth or in early childhood and 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 are more likely to suffer complications from these infections compared to individuals with a normal functioning immune system. 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. Initially thought to be very rare, it is now estimated that the prevalence of PI in the U.S. is 1 in 1,200, which translates to approximately 250,000 people.

About ASCENIV™ (Formerly RI-002)

ASCENIV (immune globulin intravenous, human – slra 10% liquid) is a plasma-derived, polyclonal, intravenous immune globulin (IVIG). ASCENIV was approved by the FDA on April 1, 2019 and is indicated for the treatment of primary humoral immunodeficiency (PI), also known as primary immune deficiency disease (PIDD), in adults and adolescents (12 to 17 years of age). ASCENIV is manufactured using ADMA's unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and plasma from donors tested using the Company's proprietary microneutralization assay. ASCENIV contains naturally occurring polyclonal antibodies, which 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 is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886.

Indication

ASCENIV (immune globulin intravenous, human – slra) is a 10% immune globulin liquid for intravenous injection, indicated for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age). PI includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies (SCID).

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

Thrombosis may occur with immune globulin (IGIV) products, including ASCENIV. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known 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. ASCENIV does not contain sucrose.

For patients at risk of thrombosis, renal dysfunction or renal failure, administer ASCENIV 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.

For additional safety information about ASCENIV, please see full Prescribing Information.

Contraindications

ASCENIV is contraindicated in:

•Patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin.

•IgA-deficiency patients with antibodies to IgA and a history of hypersensitivity.

Warnings and Precautions

Severe hypersensitivity reactions may occur with IGIV products, including ASCENIV. In case of hypersensitivity, discontinue ASCENIV infusion immediately and institute appropriate treatment. Patients with known antibodies to IgA may have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions.

Thrombosis may occur following treatment with immunoglobulin products and in the absence of known risk factors. Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity and ensure adequate hydration before administration. For patients at risk of thrombosis, administer ASCENIV at the minimum dose and infusion rate practicable. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Acute renal dysfunction/failure, osmotic nephrosis, and death may occur upon use of human IGIV products. Ensure that patients are not volume depleted before administering ASCENIV. Periodic monitoring of renal function and urine output is particularly important in patients judged to be at increased risk of developing acute renal failure. Assess renal function, including measurement of blood urea nitrogen (BUN) and serum creatinine, before the initial infusion of ASCENIV and at appropriate intervals thereafter. Discontinue ASCENIV if renal function deteriorates. In at risk patients, administer ASCENIV at the minimum infusion rate practicable.

Hyperproteinemia, increased serum viscosity, and hyponatremia or pseudohyponatremia may occur in patients receiving IGIV treatment, including ASCENIV. It is critical to clinically distinguish true hyponatremia from a pseudohyponatremia that is associated with or causally related to hyperproteinemia. Treatment aimed at decreasing serum free water in patients with pseudohyponatremia may lead to volume depletion, a further increase in serum viscosity, and a possible predisposition to thrombotic events.

Aseptic meningitis syndrome (AMS) may occur with IGIV treatments, including ASCENIV. AMS usually begins within several hours to 2 days following IGIV treatment. AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV. Conduct a thorough neurological examination on patients exhibiting signs and symptoms of AMS, including cerebrospinal fluid (CSF) studies, to rule out other causes of meningitis.

IGIV products, including ASCENIV, may contain blood group antibodies that can act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin reaction and hemolysis. Monitor patients for clinical signs and symptoms of hemolysis, including appropriate confirmatory laboratory testing.

Non-cardiogenic pulmonary edema may occur with IV administered IG. Monitor patients for pulmonary adverse reactions. If suspected, perform appropriate tests for presence of anti-neutrophil in both product and patient serum. May be managed using oxygen therapy with adequate ventilatory support.

Because ASCENIV is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. All infections suspected by a physician to possibly have been transmitted by this product should be reported to ADMA Biologics at **(1-800-458-4244)**.

After infusion of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation. Passive transmission of antibodies to erythrocyte antigens (e.g., A, B, and D) may cause a positive direct or indirect antiglobulin (Coombs') test.

Adverse Reactions

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.

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

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and others at risk for certain infectious diseases. ADMA currently 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: ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) for the treatment of primary humoral immunodeficiency (PI); BIVIGAM® (immune globulin intravenous, human) for the treatment of PI; and NABI-HB® (hepatitis B immune globulin, human) to provide enhanced immunity against the hepatitis B virus. ADMA's mission is to manufacture, market and develop specialty 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, 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.

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 about the launch and commercialization of ASCENIV and its ability to help appropriate patients in the U.S. 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:

Sam Martin

Managing Director, Argot Partners | 212-600-1902 | sam@argotpartners.com