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): December 12, 2023

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))

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 Global Market

Item 8.01 Other Events

On December 12, 2023, ADMA Biologics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has approved the Company's supplemental Biologics License Application submitted under section 351(a) of the Public Health Service Act for BIVIGAM®. A copy of the press release is attached as Exhibit 99.1 and incorporated by reference herein.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	ADMA Biologics, Inc. Press Release, dated December 12, 2023
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

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.

December 12, 2023

ADMA Biologics, Inc.

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

Exhibit 99.1

ADMA Biologics Announces FDA Approval for BIVIGAM® in the Pediatric Patient Setting for Those 2 Years of Age and Older

Signifies the Successful Fulfillment of BIVIGAM's Post Marketing Commitments as Part of the Original BLA Approval

Expanded Label in the U.S. Now Includes Pediatric PI Patients 2 Years of Age and Older

RAMSEY, N.J. and BOCA RATON, Fla., Dec. 12, 2023-- ADMA Biologics, Inc. (Nasdaq: ADMA) ("ADMA" or the "Company"), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing, and developing specialty plasma-derived biologics, today announced the U.S. Food and Drug Administration ("FDA") has approved the Company's supplemental Biologics License Application submitted under section 351(a) of the Public Health Service Act for BIVIGAM. The FDA approval represents the final study report for the Pediatric assessment as required in the post marketing commitment. Additionally, the approval provides for a revision of BIVIGAM's prescribing information to expand the primary humoral immunodeficiency ("PI") indication to pediatric patients 2 years of age and older.

"We are pleased to announce that BIVIGAM has received FDA approval for treating PI in patients aged 2 years and older. Previously, the indication for BIVIGAM was restricted to PI patients aged 12 years and older," said Adam Grossman, President and Chief Executive Officer of ADMA. "This expanded label for BIVIGAM allows ADMA to actively address the treatment needs of younger PI patients earlier in their treatment journey. In the periods ahead, we look forward to offering BIVIGAM as an FDA-approved treatment option for these pediatric PI patients," concluded Mr. Grossman.

"We extend our gratitude to the collaborative efforts of the PI disease community, physicians, and the invaluable contribution of the children and families who played a pivotal role in advancing this clinical program," said Kaitlin Kestenberg, Senior Vice President, Compliance & Project Operations. "Enrolling and successfully completing these challenging trials is no small feat, and this approval is a testament to the commendable clinical execution and the dedication of the ADMA team."

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: BIVIGAM® (immune globulin intravenous, human) for the treatment of primary humoral immunodeficiency (PI); ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) for the treatment of PI; and NABI-HB® (hepatitis B immune globulin, human) to provide enhanced immunity against the hepatitis B virus. ADMA manufactures its immune globulin products at its FDA-licensed plasma fractionation and purification facility located in Boca Raton, Florida. Through its ADMA BioCenters subsidiary, ADMA also operates as an FDA-approved source plasma collector in the U.S., which provides its blood plasma for the manufacture of its products. 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 and European Patent No. 3375789, among others, related to certain aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

About BIVIGAM®

BIVIGAM (immune globulin intravenous, human – 10% liquid) is a plasma-derived, polyclonal, intravenous immune globulin (IVIG). BIVIGAM was approved by the FDA in May 2019 and is indicated for the treatment of primary humoral immunodeficiency (PI), including, but not limited to the following group of genetic disorders: X-linked and congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiency. 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 antibodies. 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 About BIVIGAM®

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, 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® Contraindications:

History of anaphylactic or severe systemic reactions to human immunoglobulin.

IgA deficient patients with antibodies to IgA and a history of hypersensitivity.

BIVIGAM® Warnings and Precautions:

Thrombotic events have occurred in patients receiving IGIV therapy. Monitor patients with known risk factors for thrombotic events; consider baseline assessment of blood viscosity for those at risk of hyperviscosity.

IgA deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions. Have medications such as epinephrine available immediately to treat any acute severe hypersensitivity reactions.

Monitor renal function, including blood urea nitrogen (BUN), serum creatinine, and urine output in patients at risk of developing acute renal failure.

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, especially with high doses or rapid infusion.

Hemolytic anemia 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 transfusion-related acute lung injury is suspected, test the product and patient for antineutrophil antibodies.

Because this product 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.

BIVIGAM® Adverse Reactions:

The most common adverse reactions to BIVIGAM (reported in ≥5% of clinical study subjects) were headache, fatigue, infusion site reaction, nausea, sinusitis, blood pressure increased, diarrhea, dizziness, and lethargy.

To report SUSPECTED ADVERSE REACTIONS, contact ADMA Biologics at (800) 458-4244 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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