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): March 11, 2024

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 March 11, 2024, ADMA Biologics, Inc. (the "Company") issued a press release announcing the United States Food and Drug Administration's approval for the Company's supplemental Biologics License Applications for both ASCENIV and BIVIGAM to extend the approved 4-week room temperature (25°C) storage conditions during the first 24 months of shelf life, to allow for a 4-week room temperature storage at any time during the entire 36-month approved shelf life. 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 March 11, 2024
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.

March 11, 2024

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 Approvals of Extended Room Temperature Storage Conditions for ASCENIV™ & BIVIGAM®

FDA Approval Provides for Room Temperature (25°C) Storage Conditions for up to 4 Weeks at Any Point During the 36-Month Approved Shelf Life

Extends the Prior Room Temperature Storage Allowance for the Full 36-months for ASCENIV and BIVIGAM

Provides for Improved Inventory Management and Ease of Product Administration to Patients

Approval of Extended Ambient Storage Conditions for ASCENIV & BIVIGAM is Immediately Effective and Now Commercially Available to U.S. Healthcare Providers

RAMSEY, N.J. and BOCA RATON, Fla., March 11, 2024 (GLOBE NEWSWIRE) – ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA" or the "Company"), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty biologics, today announced the United States Food and Drug Administration's ("FDA") approval for its supplemental Biologics License Applications (BLAs) for both ASCENIV and BIVIGAM to extend the approved 4-week room temperature (25°C) storage conditions during the first 24 months of shelf life, to allow for a 4-week room temperature storage at any time during the entire 36-month approved shelf life. The room temperature approval applies to all existing ASCENIV and BIVIGAM lots currently in the commercial supply chain as well as to future production of ASCENIV and BIVIGAM.

"With the FDA-approved extension of room temperature storage conditions, the Company expects to reach more customers who were previously inaccessible due to limited refrigeration space and cold chain capacity constraints," said Adam Grossman, President and Chief Executive Officer of ADMA. "We believe that this added storage flexibility for both ASCENIV and BIVIGAM will meaningfully enhance our products' market offerings, enabling more versatile utilization and better inventory management for providers."

The newly approved extension of room temperature storage conditions for both ASCENIV and BIVIGAM is immediately effective, and both products are commercially available to U.S. healthcare providers and patients.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty 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 biologics, 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 holds numerous U.S. and foreign patents related to and encompassing various aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

About ASCENIV™

ASCENIV (immune globulin intravenous, human – slra 10% liquid) is a plasma-derived, polyclonal, intravenous immune globulin (IVIG). ASCENIV was approved by the United States Food and Drug Administration (FDA) in April 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 respiratory syncytial virus (RSV) plasma obtained 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. Certain data and other information about ASCENIV can be found by visiting www.asceniv.com. Information about ADMA and its products can be found on the Company's website at 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 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. and its subsidiaries (collectively, "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 "anticipate," "intend," "target," "plan," "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, the anticipated benefits and significance of the FDA's room temperature storage approval. Actual events or results may differ materially from those described in this press release 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.

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