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): January 26, 2021

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 Global Market
Preferred Stock Purchase Rights	—	Nasdaq Global Market

Item 8.01 Other Events.

On January 26, 2021, ADMA Biologics, Inc. issued a press release announcing that the Centers for Medicare and Medicaid Services (CMS) has issued a permanent, product-specific J-code for ASCENIV™. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company, dated January 26, 2021
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.

January 26, 2021

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics Receives Unique Permanent J-Code for ASCENIV™

RAMSEY, N.J. and BOCA RATON, FL., January 26, 2021 – ADMA Biologics, Inc. (Nasdaq: ADMA), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics, today announced that the Centers for Medicare and Medicaid Services (CMS) has issued a permanent, product-specific J-code for ASCENIV™. Under the Healthcare Common Procedure Coding System (HCPCS), the J-code (J1554) will become effective April 1, 2021 and will replace the currently issued C-code for ASCENIV (C9072), which can continue to be utilized in the interim for reimbursement purposes. The Company will retain transitional pass-through status granted for ASCENIV from CMS.

“The issuance of this product-specific J-code by CMS for ASCENIV is a significant milestone in the product’s commercial launch. This J-code will provide for a streamlined and permanent reimbursement process in all outpatient treatment settings,” said Adam Grossman, President and Chief Executive Officer of ADMA. “The J-code implementation will accelerate and expand patient access to ASCENIV, and as a result, increases our confidence in the ongoing commercial roll-out, in addition to the product’s potential contribution to our overall 2024 revenue target of $250 million or more.”

Permanent J-codes are used by commercial insurers and government payers to standardize claims submissions and reimbursements for medications, such as ASCENIV, that are administered by a healthcare professional in an outpatient setting. While not a guarantee of payment, these codes enable timely claims adjudication and processing, and consequently facilitate a simplified pathway to prescription, administration and ultimately patient utilization.

About ASCENIV™

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 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.

About ADMA Biologics, Inc.

ADMA Biologics is an end-to-end American 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 a portion of 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 related to certain aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the anticipated benefits and expected consequences of the rights plan that ADMA has adopted. Such statements are identified by use of the words "anticipates," "believes," "estimates," "expects," "intends," "plans," "predicts," "projects," "should," and similar expressions. Any forward-looking statements contained herein are based on current expectations, but are subject to risks and uncertainties that could cause actual results to differ materially from those indicated, including, but not limited to, the effectiveness of the rights plan in providing the Board of Directors with time to make informed decisions that are in the best long-term interests of ADMA and its stockholders, and other risk factors discussed from time to time in our filings with the SEC, including those factors discussed under the caption "Risk Factors" in our most recent annual report on Form 10-K, filed with the SEC on March 13, 2020, and in subsequent reports filed with or furnished to the SEC. ADMA assumes no obligation and does not intend to update these forward-looking statements, except as required by law, to reflect events or circumstances occurring after today's date.

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