

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): November 16, 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 November 16, 2023, ADMA Biologics, Inc. issued a press release announcing that it has received U.S. Food and Drug Administration (“FDA”) approval for its tenth ADMA BioCenters plasma collection facility located in Laurel, Maryland (the “Facility”). This plasma collection facility commenced operations and initiated source plasma collection in the first half of 2023. With the approval, the Facility is now FDA-approved to introduce into interstate commerce human source plasma for further manufacturing in the United States. A copy of the press release is attached as Exhibit 99.1 and incorporated by reference herein.

Item 9.01 Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
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99.1	ADMA Biologics, Inc. Press Release, dated November 16, 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.

November 16, 2023

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial
Officer



ADMA BioCenters Receives FDA Approval for its Tenth Plasma Collection Center, Located in Laurel, MD

FDA Approval Signifies the Accomplishment of ADMA's Corporate Goal of Plasma Supply Self-Sufficiency

RAMSEY, N.J., BOCA RATON, Fla. and Laurel, MD– Nov. 16, 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 that it has received U.S. Food and Drug Administration (“FDA”) approval for its tenth ADMA BioCenters plasma collection facility located in Laurel, Maryland. This plasma collection facility commenced operations and initiated source plasma collection in the first half of 2023. With the FDA approval announced today, this facility is now licensed to introduce into interstate commerce human source plasma for further manufacturing in the U.S.

“The successful expansion of ADMA’s plasma collection network accomplishes the Company’s goal of plasma supply self-sufficiency, supports ongoing revenue growth objectives, and further enhances ADMA’s profitability outlook. The approval is a testament to the BioCenters team’s tireless commitment, and we thank the FDA for its efforts and expeditious review of the Laurel, MD Biologics License Application (“BLA”),” said Adam Grossman, President and Chief Executive Officer of ADMA.

“This milestone achievement has been several years in the making, and we commend our dedicated staff in making this achievement possible from both a timing and budgeting standpoint. We now anticipate that our fully FDA-licensed plasma collection center network will support the rapidly growing production needs for our IG portfolio,” said Brian Lenz, Executive Vice President, Chief Financial Officer, and General Manager, ADMA BioCenters.

This new, state-of-the-art plasma collection center features automated registration, high-tech collection equipment designed to shorten the donation process, free Wi-Fi wireless network in the donor collection area, individual flat-screen TVs with cable at each donor station, and highly trained and certified staff who put donor comfort and safety first. At full capacity, the plasma center expects to maintain a staff of 50 highly trained healthcare workers. This center is approved to use the state-of-the-art Haemonetics NexSys Persona® plasma collection system.

To learn more about the ADMA BioCenters donation process, and to schedule an appointment, please visit: www.admabiocenters.com, or visit in person at 12647 Laurel Bowie Rd., Laurel, MD 20708.

About ADMA BioCenters

ADMA BioCenters is an FDA-licensed network specializing in the collection of human plasma used to make special medications for the treatment and prevention of diseases. Managed by a team of experts who have decades of experience in the specialized field of plasma collection, ADMA BioCenters provides a safe, professional and pleasant donation environment. ADMA BioCenters strictly follows FDA regulations and guidance and enforces cGMP (current good manufacturing practices) in all of its facilities. For more information about ADMA BioCenters, please visit www.admabiocenters.com.



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 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.

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, “ADMA”, “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 “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, statements about ADMA's future results of operations (including, but not limited to, revenue growth), plasma supply self-sufficiency and production needs. 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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