

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): April 28, 2021

**ADMA BIOLOGICS, INC.**

(Exact name of registrant as specified in its charter)

|  |  |  |
|--|--|--|
| Delaware<br>(State or other jurisdiction<br>of incorporation)                      | 001-36728<br>(Commission<br>File Number) | 56-2590442<br>(IRS Employer<br>Identification No.) |
| 465 State Route 17, Ramsey, New Jersey<br>(Address of principal executive offices) |  | 07446<br>(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                      |
| Preferred Share Purchase Rights | -                 | Nasdaq Global Market                      |

**Item 8.01 Other Events**

On April 28, 2021, ADMA Biologics, Inc. (the “Company”) issued a press release announcing that it has received U.S. Food and Drug Administration (“FDA”) approval for its expanded manufacturing process, enabling fractionation and purification of a 4,400-liter plasma pool for the manufacture of Intravenous Immune Globulin. A copy of the Company’s press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

**Item 9.01 Exhibits.**

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u>   |
|--------------------|--|
| 99.1               | <a href="#">Press Release of the Company, dated April 28, 2021</a> |

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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.

April 28, 2021

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer



## **ADMA Biologics Receives FDA Approval for Increased IVIG Production Scale**

*ADMA Increases Total Forecasted Plant Manufacturing Capacity from 400,000 Liters up to 600,000 Liters and Increases Total Forecasted Peak Revenues in Excess of \$300 Million*

*Enhanced Gross Margins and Cost Efficiencies Expected to be Realized Beginning Late 2021 and Accelerate Throughout 2022 on Path to Profitability*

**RAMSEY, N.J. and BOCA RATON, Fla., April 28, 2021** – 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, announced that the U.S. Food and Drug Administration (“FDA”) has granted approval for the Company’s expanded manufacturing process, enabling fractionation and purification of a 4,400-liter plasma pool for the manufacture of Intravenous Immune Globulin (“IVIG”).

“The FDA approval of the 4,400-liter IVIG plasma pool production scale process is a transformative milestone for the ADMA organization and will allow the Company to produce significantly more IVIG for the U.S. market and for patients living with immune deficiencies,” said Adam Grossman, President and Chief Executive Officer of ADMA. “The expanded plasma pool production scale allows us to confidently commit to generating peak revenues in excess of \$300 million and this approval solidifies the pathway to meaningful gross margin expansion beginning potentially in the second half of 2021 and accelerating throughout 2022. In addition to the increase in ADMA’s multi-year financial guidance, the Company is reiterating its expectation for quarter-over-quarter revenue growth throughout 2021 and beyond. We commend our employees’ dedication in achieving this important manufacturing milestone and look forward to increasing our production capacity rapidly over the forward-looking quarters.”

The 4,400-liter IVIG plasma pool scale for BIVIGAM® will allow ADMA to expand its manufacturing plant’s total processing capacity from 400,000 liters to an anticipated peak throughput of up to 600,000 liters. ADMA now has FDA approval to produce BIVIGAM® at an expanded capacity with the same high quality as the previous manufacturing scale, while using the same equipment, release testing assays, disposables and labor force. The Company anticipates this will translate into meaningful gross margin improvement as production throughput flows through the standard 7 to 12-month manufacturing cycle for plasma-derived therapies. With this approval, ADMA additionally will now be able to offer BIVIGAM® in two vial sizes, both the 50 mL and 100 mL configurations.

## **About ADMA Biologics, Inc. (ADMA)**

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 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](http://www.admabiologics.com).

## **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,” “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 our production capacity; anticipated timing for reaching profitability and meaningful gross margin expansion and cost efficiencies; our anticipated revenue growth; and the amount of potential peak revenues to be generated by the Company and the related timing associated therewith. 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.

**COMPANY CONTACT:**

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