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): July 20, 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):

☐ 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 July 20, 2021, ADMA Biologics, Inc. (the "Company") issued a press release announcing that the United States Food and Drug Administration ("FDA") recently completed a Pre-Approval Inspection ("PAI") of the Boca Raton, FL manufacturing facility related to the Company's application for its VanRx SA25 Workcell aseptic fill-finish machine ("VanRx"). The PAI successfully concluded with the FDA issuing zero Form 483 observations in the FDA's determination that the Company's Boca Raton, FL manufacturing facility continues to operate in compliance with the principles and guidelines of Good Manufacturing Practices standards. A full copy of the press release it attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	ADMA Biologics, Inc. Press Release, dated July 20, 2021

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.

July 20, 2021

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

Exhibit 99.1

ADMA Biologics Announces Successful Completion of FDA Pre-Approval Manufacturing Facility Inspection

Approval for VanRx Fill-Finish Machine Expected in the Second Half of 2021

All Supply Chain Robustness Initiatives Remain on Schedule

RAMSEY, NJ and BOCA RATON, FL – July 20, 2021 – ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA"), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics, announced the United States Food and Drug Administration ("FDA") recently completed a Pre-Approval Inspection ("PAI") of the Boca Raton, FL manufacturing facility related to ADMA's application for its VanRx SA25 Workcell aseptic fill-finish machine ("VanRx"). The PAI successfully concluded with the FDA issuing zero Form 483 observations in the Agency's determination that the Company's Boca Raton, FL facility continues to operate in compliance with the principles and guidelines of Good Manufacturing Practices ("GMP") standards. The FDA's review of ADMA's VanRx regulatory filing remains ongoing, with anticipated regulatory approval in the second half of 2021.

"Through pandemic-related challenges, the successful completion of the FDA's PAI for the VanRx demonstrates our continued adherence to GMP standards and speaks to our organization's continued ability to deliver on regulatory commitments through unprecedented and challenging operating conditions," said Adam Grossman, President and Chief Executive Officer of ADMA. "With this favorable inspection outcome, we are anticipating receiving approval for the VanRx in the second half of 2021. We would like to thank the FDA for its focused engagement and collaboration in working with ADMA to meet the growing demands of the U.S. immune compromised patient community that relies on plasma-derived immune globulin products for their treatment."

"The anticipated VanRx approval will provide ADMA with internal fill-finish production capabilities for its commercial products, which is expected to translate into greater patient supply consistency, significant gross margin efficiencies, improved visibility of commercial product lot releases and, consequently, more predictable near-term revenue results. Additionally, the expected approval will enable ADMA to onboard third-party fill-finish contracts as a new and accretive revenue source. The COVID-19 pandemic has illuminated the importance and the scarcity value associated with fill-finish manufacturing capabilities and, once approved, we plan to update the market as we explore these potential new business opportunities in the periods ahead," concluded Mr. Grossman.

The VanRx fill-finish machine utilizes a state-of-the-art closed isolator design, allowing for the removal of human interventions and providing safe drug products for patients. The VanRx machine has the capability of rapidly switching between different container and closure formats, enabling aseptic filling in a variety of different fill volumes and presentation sizes. The combination of the recently FDA-approved increased BIVIGAM® manufacturing production scale as well as the enhanced vertical integration that will result from the anticipated approval of the VanRx machine will allow ADMA to bring its products to market faster, improve gross margins and substantially increase ADMA's end-to-end control over its critical manufacturing process.

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-licensed 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.

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. ("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; the expected timing of FDA's approval of ADMA's VanRx regulatory filing; and the expected commercial, financial and other business benefits in the event of VanRx regulatory 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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