

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): May 16, 2018

ADMA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-36728

(Commission
File Number)

56-2590442

(IRS Employer
Identification No.)

465 State Route 17, Ramsey, New Jersey

(Address of principal executive offices)

07446

(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.

Item 8.01 Other Events.

On May 16, 2018, ADMA Biologics, Inc. (the “Company”) issued a press release announcing the issuance by the United States Patent and Trademark Office (USPTO) of a new Company patent encompassing methods of treating upper and lower respiratory infections, including those caused by Respiratory Syncytial Virus (RSV), other viruses and bacteria utilizing the Company’s investigational drug RI-002 that contains elevated, neutralizing antibody titers to RSV as well as elevated antibody titers to other respiratory pathogens, such as influenza virus, coronavirus, parainfluenza virus and metapneumovirus.

The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	ADMA Biologics, Inc. Press Release, dated May 16, 2018.

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.

May 16, 2018

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Vice President and Chief Financial Officer



ADMA Biologics Granted U.S. Patent for Treating Respiratory Infections

Fourth Patent Issued to the Company in the U.S. Provides Coverage for RI-002 Through 2035

RAMSEY, N.J. and BOCA RATON, FL., May 16, 2018 - ADMA Biologics, Inc. (NASDAQ: ADMA) (“ADMA” or the “Company”) today announced that the United States Patent and Trademark Office issued to the Company U.S. Patent No. 9,969,793 covering methods of treating respiratory infections. The newly issued patent encompasses methods of treating upper and lower respiratory infections, including those caused by Respiratory Syncytial Virus (“RSV”), other viruses, as well as bacteria utilizing ADMA’s investigational drug RI-002 that contains elevated, neutralizing antibody titers to RSV as well as elevated antibody titers to other respiratory pathogens, such as influenza virus, coronavirus, parainfluenza virus, and metapneumovirus. The term of the issued patent extends to January 2035.

“The addition of this patent to ADMA’s immunoglobulin portfolio provides unique coverage for the therapeutic treatment of respiratory infections using our investigational drug RI-002,” stated Adam Grossman, President and CEO of ADMA.

“This patent is the first of its kind for use of a polyclonal immunoglobulin preparation for treatment of respiratory infection and, in conjunction with three previously issued patents to ADMA, further protects our proprietary immune globulin technology for the prevention and treatment of infection. ADMA will continue to pursue additional U.S. and international patents.”

Mr. Grossman continued, “ADMA remains committed to providing new avenues for treating patients at risk for or suffering from infection, including respiratory infections, while concurrently meeting or exceeding the high regulatory standards set by the United States Food and Drug Administration for immune globulin products. While the patent encompasses the therapeutic treatment of respiratory infection in any type of patient, the immune compromised and immunodeficient patient populations remain a top priority for our Company and the medical community at large.”

About ADMA Biologics, Inc. (ADMA)

ADMA is a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease (“PIDD”) and the prevention and treatment of certain infectious diseases. ADMA’s mission is to develop and commercialize plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases. The target patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disease, 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 and 9,969,793 related to certain aspects of its lead product candidate, RI-002. For more information, please visit www.admabiologics.com.

About RI-002

ADMA's lead product candidate, RI-002, is a specialty plasma-derived, polyclonal, intravenous immune globulin ("IGIV") derived from human plasma containing naturally occurring polyclonal antibodies (e.g., *Streptococcus pneumoniae*, H. influenza type B, cytomegalovirus, measles, tetanus, etc.) as well as plasma from donors tested to have high levels of neutralizing antibodies to RSV. ADMA is pursuing an indication for the use of this specialty IGIV product for treatment of patients diagnosed with PIDD. Polyclonal antibodies are the primary active component of IGIV products. Polyclonal antibodies are proteins that are used by the body's immune system to neutralize microbes, such as bacteria and viruses. Data review indicates that the polyclonal antibodies present in RI-002 support its ability to prevent infections in immune-compromised patients.

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 the words "estimate," "project," "intend," "forecast," "target," "anticipate," "plan," "planning," "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 concerning our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products, the safety, efficacy and expected timing of, and our ability to, obtain and maintain regulatory approvals of our current products and product candidates, and the labeling or nature of any such approvals, the success of our work with our third party vendors and the U.S. Food and Drug Administration (the "FDA") in furtherance of and progress towards an approval of our Biologics License Application for specialty plasma-based biologics and the ability of such third parties to respond adequately or in a timely manner to the issues raised by the FDA, our ability to successfully pursue commercialization and prelaunch activities, the timeframe within which we may receive approval from the FDA for specialty plasma-based biologics, if at all, the potential of our specialty plasma-based biologics to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease or other indications, our ability to realize increased prices for plasma growth in the plasma collection industry and our expectations for future capital requirements. Actual events or results may differ materially from those described in this document 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. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by ADMA or any other person that the objectives and plans of ADMA will be achieved in any specified time frame, if at all. 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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