

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 16, 2019

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 April 17, 2019, ADMA Biologics, Inc., a Delaware corporation (the “Company”), announced that the United States Patent and Trademark Office issued to the Company U.S. Patent No. 10,259,865 related to methods of treatment and prevention of *S. pneumonia* infection. The patent claims encompass methods of preparing immune globulin via harvesting plasma from *S. pneumonia* vaccinated, healthy adult human donors and pooling the harvested plasma as the source for manufacturing a hyperimmune anti-*pneumococcal* immune globulin containing elevated opsonic antibodies to a plurality of *S. pneumonia* serotypes. The issued claims also encompass hyperimmune anti-*pneumococcal* immune globulin so prepared, methods of treating *S. pneumonia* infection and methods of providing immunotherapy using the hyperimmune anti-*pneumococcal* immune globulin.

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

Item 9.01 Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>ADMA Biologics, Inc. Press Release, dated April 17, 2019.</u>

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 17, 2019

ADMA Biologics, Inc.

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Executive Vice President and Chief
Financial Officer



ADMA Biologics Granted U.S. Patent for Treatment and Prevention of Pneumococcal Infections

Fifth Patent Issued to the Company in the U.S. Provides Coverage for Expanding the Company's Hyperimmune IVIG Portfolio Through 2037

RAMSEY, N.J. and BOCA RATON, FL., April 17, 2019 - 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. 10,259,865 related to methods of treatment and prevention of *S. pneumonia* infection. The patent claims encompass methods of preparing immune globulin via harvesting plasma from *S. pneumonia* vaccinated, healthy adult human donors and pooling the harvested plasma as the source for manufacturing a hyperimmune anti-*pneumococcal* immune globulin containing elevated opsonic antibodies to a plurality of *S. pneumonia* serotypes. The issued claims also encompass hyperimmune anti-*pneumococcal* immune globulin so prepared, methods of treating *S. pneumonia* infection and methods of providing immunotherapy using the hyperimmune anti-*pneumococcal* immune globulin.

This patent will enable ADMA to protect its proprietary rights and at the same time attract collaborators interested in the development, marketing and commercialization of a much needed therapeutic for the treatment and prevention of infection in immune compromised, immunodeficient, and elderly patients who are poorly responsive to available *S. pneumonia* vaccines. The term of the patent extends to March 2037.

"We are very pleased to have another patent issued to add to our intellectual property estate for novel, differentiated hyperimmune globulins as we look to develop, manufacture and commercialize immune globulin therapies to treat and prevent serious infections in the immune compromised, immunodeficient, and elderly patients," stated Adam Grossman, President and CEO of ADMA.

Mr. Grossman concluded, "This will be the first patent to issue in ADMA's immune globulin program tailored specifically to anti-*pneumococcal* hyperimmune globulin compositions and treatment modalities. As stated in the National Foundation for Infection Diseases, it is estimated that about one million U.S. adults get pneumococcal pneumonia each year and as many as 400,000 hospitalizations from pneumococcal pneumonia occur annually in the U.S. and about 5-7% of those who are hospitalized from it will die despite the widespread use of multiple vaccines for disease prevention, as stated in the National Foundation for Infectious Diseases. With large pharmaceutical companies developing vaccines for *S. pneumonia*, we believe our proprietary technology creates unique collaboration opportunities for ADMA with developers of these vaccines."

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease (“PI”) 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, 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 Primary Immune Deficiency Disease (“PI”)

PI is a class of inherited genetic disorders that causes an individual to have a deficient or absent immune system. According to the World Health Organization, there are approximately 350 different genetic mutations encompassing PI. Some disorders present at birth or in early childhood, the disorders can affect anyone regardless of age or gender. Some affect a single part of the immune system, others may affect one or more components of the system. PI patients are vulnerable to infections and more likely to suffer complications from these infections as compared to individuals with a normal functioning immune system. The infections may occur in any part of the body. Because patients suffering from PI lack a properly functioning immune system, they typically receive monthly treatment with polyclonal immune globulin products. Without this exogenous antibody replacement, these patients would remain vulnerable to persistent and chronic infections. PI has an estimated prevalence of 1:1,200 in the United States, or approximately 250,000 people in the U.S.

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, product expansions into new fields of use, indications and product candidates, and the labeling or nature of any such approvals, our ability to successfully pursue commercialization and prelaunch activities for our products, the potential of our specialty plasma-based biologics products and product candidates 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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