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 15, 2019

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):

o 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))

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 Capital Market

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.

ADMA Biologics, Inc., a Delaware corporation (the "Company"), is filing this Current Report on Form 8-K under Item 8.01 to update its prior disclosure in the Business section of its Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on March 13, 2019.

Specifically, under "Business The Plasma Industry Primary Immunodeficiency Disease", the Company has updated and restated the disclosure as follows:

"**Primary Immunodeficiency Disease**

PIDD is a class of hereditary disorders characterized by defects in the immune system, due to either a lack of necessary antibodies or a failure of these antibodies to function properly. According to the World Health Organization, there are over 150 different presentations of PIDD. As patients suffering from PIDD lack a properly functioning immune system, they typically receive monthly, outpatient infusions of IVIG therapy. Without this exogenous antibody immune support, these patients would be susceptible to a wide variety of infectious diseases. PIDD has an estimated prevalence of 1:1,200 in the U.S., or approximately 250,000 people. Of these 250,000 people diagnosed with PIDD in the U.S., approximately 125,000 receive monthly infusions of IVIG.

As most patients with PIDD present with infections, the differential diagnosis and initial investigations for an underlying immune defect are typically guided by the clinical presentation. In subjects with PIDD, individual infections are not necessarily more severe than those that occur in a normal host. Rather, the clinical features suggestive of an immune defect may be the recurring and/or chronic nature of infections with common pathogens that may result in end organ damage, such as bronchiectasis. In addition, subjects with PIDD will often respond poorly to standard antimicrobial therapy or they may have repeated infections with the same pathogen. The virulence of the infecting organism should also be considered, and a subject's immune competence should be questioned when invasive infections are caused by low virulence or opportunistic pathogens. For example, infection with the opportunistic pathogens Pneumocystis jiroveci (previously Pneumocystis carinii) or atypical mycobacteria should prompt an investigation for underlying immunodeficiency. Typical clinical presentations for subjects with PIDD are:

- antibody deficiency and recurrent bacterial infections;
- T-lymphocyte deficiency and opportunistic infections;
- other lymphocyte defects causing opportunistic infections;
- neutrophil defects causing immunodeficiency; and
- complement deficiencies.

PIDD can present at any age from birth to adulthood, posing a considerable challenge for the practicing physician to know when and how to evaluate a subject for a possible immune defect. Subjects with marked antibody deficiencies are generally dependent on IVIG therapy for survival. Benefits of adequate IVIG therapy in subjects not able to produce antibodies normally include a reduction of the severity and frequency of infections, prevention of chronic lung disease and prevention of enteroviral meningoencephalitis. Several immune globulin products have already been approved by the FDA.

ASCENIV®, formerly referred to as RI-002, contains polyclonal antibodies against various infectious agents, such as streptococcus pneumoniae, H. influenza type B, CMV, measles and tetanus, including standardized antibodies against RSV. RSV is a common respiratory virus that often presents during the winter months. Nearly all children will have been infected with RSV by three years of age; however, the immune systems of most healthy children prevent significant morbidity and mortality. Conversely, in patients who are immune-compromised, such as those with PIDD or who have undergone a hematopoietic stem cell or solid organ transplant and may be on immunosuppressive drugs or chemotherapy, RSV infection can be associated with significant morbidity and mortality. Immune-compromised patients historically have a 5% to 15% rate of RSV infection, and, if left untreated, lower respiratory tract RSV infections in immune-compromised patients can result in a mortality rate of 43% of infected patients."

Additionally, under “Business Immune Globulins”, the Company has updated and restated the disclosure as follows:

“***Immune Globulins***

In June 2008, the FDA published the FDA Guidance for Industry outlining the regulatory pathway for the approval of IVIG for the treatment of PIDD *(Guidance for Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency)*.

Immune globulins can be administered in three ways: intramuscularly, intravenously or subcutaneously. IVIG principally contains antibodies and, as such, provides passive immunization for individuals who are immune-deficient or who have been exposed to various infectious agents. IVIG is used therapeutically in a variety of immunological diseases/deficiencies, such as PIDD, idiopathic thrombocytopenic purpura, Guillain-Barré syndrome, Kawasaki disease, bone marrow transplant, and chronic inflammatory demyelinating polyneuropathy. We are aware that other companies are also evaluating IVIG in a clinical trial for the treatment of Alzheimer’s disease. Additionally, IVIG is also used as therapy in a variety of other diseases that do not involve primary or secondary immune deficiencies, such as multiple sclerosis, skin disease, and asthma. These latter uses are referred to as “off-label” or evidence-based uses because the FDA has not approved their use in these indications and promotion of such uses is not permitted by FDA unless a BLA or BLA supplement with additional data is approved. Among the 14 current FDA-approved IVIG products, there are only six labeled indications approved by the FDA. However, medical literature identifies at least 150 evidence-based uses for IVIG, of which approximately 60 are currently included on lists of reimbursable uses by Medicare and other healthcare plans. This provides opportunities for new product development and submissions.

There are two types of immune globulins; standard and hyperimmune. The difference between standard immune globulins and hyperimmune globulins is that the latter are manufactured using plasma obtained from donors who have elevated amounts (high-titers) of specific antibodies. These high-titer products can be used to treat and prevent diseases that present those specific antigens that are reactive with the high-titer antibodies. Hyperimmune products currently available include Hepatitis B, tetanus, rabies, CMV and RhoD immune globulins.

As reported in industry journals, the U.S. sales of immune and hyperimmune globulin products for all its uses were reported to be approximately $6.2 billion in 2017, and in 2016 industry journals reported that the worldwide market for plasma-derived therapeutic drug products was approximately $22 billion. IVIG products are used to treat primary immune deficiencies, certain autoimmune diseases, and other illnesses for immune-compromised patients and certain neuropathy indications. New research and data, additional labeled indications, an aging population and emerging countries with new markets are all adding to the worldwide demand and growth of IVIG utilization.”

Furthermore, under “Business Intellectual Property”, the Company has updated and restated the disclosure as follows:

“***Intellectual Property***

During the second quarter of 2015, U.S. Pat. App. Serial No. 14/592,721, entitled ‘Compositions and Methods for the Treatment of Immunodeficiency’, encompassing ASCENIV®, was allowed and issued August 18, 2015 as U.S. Patent No. 9,107,906. The ‘906 patent has a term at least through January 2035 and covers methods of producing pooled plasma compositions, as well as immunoglobulin prepared therefrom, that contain a standardized, elevated titer of RSV neutralizing antibodies as well as elevated levels of antibodies specific for one or more other respiratory pathogens. Our proprietary methods allow us to effectively identify and isolate donor plasma with high-titer RSV neutralizing antibodies and to standardize ASCENIV®’s antibody profile, which we believe may enable us to garner a premium price.

During the third quarter of 2017, U.S. Pat. App. Serial No. 14/790,872, entitled ‘Compositions and Methods for the Treatment of Immunodeficiency’, encompassing immunotherapeutic methods of using immune globulin compositions proprietary to us, was allowed and issued July 25, 2017 as U.S. Patent No. 9,714,283. The ‘283 patent has a term at least through January 2035.

In November 2017, U.S. Pat. App. Serial No. 14/592,727, related to immune globulin compositions containing elevated, neutralizing antibody titers to RSV, as well as elevated antibody titers to other respiratory pathogens, was allowed and issued as U.S. Patent No. 9,815,886. The term of the issued patent extends to January 2035.

In May 2018, U.S. Patent No. 9,969,793 was issued covering methods of treating respiratory infections. The newly issued patent encompasses methods of treating upper and lower respiratory infections, including those caused by RSV, other viruses as well as bacteria utilizing ASCENIV®, 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.

During the first quarter of 2019, U.S. Pat. App. Serial No. 14/790,872, entitled ‘Compositions and Methods for the Treatment of Immunodeficiency’, encompassing immunotherapeutic methods of using immune globulin compositions proprietary to us, was allowed and issued July 25, 2017 as U.S. Patent No. 9,714,283. The ‘283 patent has a term at least through January 2035.

On January 24, 2019, the U.S. Patent and Trademark Office issued a Notice of Allowance for U.S. Patent Application Serial No. 15/460,147 related to methods of treatment and prevention of *S. pneumonia* infection. The allowed 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-*S pneumococcal* immune globulin containing elevated opsonic antibodies to a plurality of *S. pneumonia* serotypes, hyperimmune anti-*S pneumococcal* immune globulin so prepared and methods of treating *S. pneumonia* infection and methods of providing immunotherapy using the hyperimmune anti-*S pneumococcal* immune globulin. This allowed Application is expected to issue as a patent in March 2019. The term of the patent, once issued, is expected to extend to March 2037.

We also rely on a combination of patents, trademarks, trade secrets and nondisclosure and non-competition agreements to protect our proprietary intellectual property and will continue to do so. We also seek to enhance and ensure our competitive position through a variety of means, including our unique and proprietary plasma donor selection criteria, our proprietary formulation methodology for plasma pooling and the proprietary reagents, controls, testing standards, standard operating procedures and methods we use in our anti-RSV microneutralization assay. While we intend to defend against threats to our intellectual property, litigation can be costly and there can be no assurance that our patent will be enforced or that our trade secret policies and practices or other agreements will adequately protect our intellectual property. We seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. These processes, systems, and/or security measures may be breached, and we may not have adequate remedies as a result of any such breaches. Third parties may also own or could obtain patents that may require us to negotiate licenses to conduct our business, and there can be no assurance that the required licenses would be available on reasonable terms or at all.

In addition, our trade secrets may otherwise become known or be independently discovered by competitors. We also seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and contractors. Although we rely, in part, on confidentiality, nondisclosure and non-competition agreements with employees, consultants and other parties with access to our proprietary information to protect our trade secrets, proprietary technology, processes and other proprietary rights, there can be no assurance that these agreements or any other security measures related to such trade secrets, proprietary technology, processes and proprietary rights will be adequate, will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. We have filed for other provisional patent applications with the U.S. which are pending related to expanded hyperimmune globulin products.

We currently hold multiple trademarks, including but not limited to *BIVIGAM* and *Nabi-HB*. We have spent considerable resources registering the trademarks and building brand awareness and equity of the ADMA Biologics trade name, which has been used in commerce since 2006. We expect to maintain and defend our various trademarks to the fullest extent possible."

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 15, 2019

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer