ADMA BIOLOGICS, INC.
Form 8-K
April 27, 2016

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 27, 2016

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))

Item 8.01 Other Events

Public Offering Announcement

On April 27, 2016, ADMA Biologics, Inc. (the "Company") issued a press release announcing that it intends to commence an underwritten public offering of shares of its common stock. Raymond James will act as book-running manager for the proposed offering. The Company intends to grant the underwriters a 30-day option to purchase up to an additional 15 percent of the amount sold to cover over-allotments, if any. A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report.

Updated Business Description and Risk Factors

On April 27, 2016, the Company filed with the Securities and Exchange Commission a prospectus supplement to its Registration Statement on Form S-3 (File No. 333-200638), which included an updated business description and two modified factors, each as set forth below.

All references below to "ADMA Biologics," "ADMA," the "Company," "we," "us," "our," or similar references refer to ADM Biologics, Inc., except where the context otherwise requires or as otherwise indicated.

Description of Business

Our Business

ADMA Biologics is a late stage biopharmaceutical company that develops, manufactures, and intends to market specialty plasma-based biologics for the treatment and prevention of certain infectious diseases. Our targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons. Our product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients at risk of contracting infectious diseases.

Our lead product candidate, RI-002, is intended for the treatment of Primary Immune Deficiency Disease, or PIDD, and has completed a pivotal Phase III clinical study. In the third quarter of 2015, the U.S. Food and Drug Administration, or FDA, accepted for review, a Biologics License Application, or BLA, for RI-002 for the treatment of PIDD. The FDA could approve this BLA within approximately one year of its filing, in which case potential first commercial sales could occur as early as the fourth quarter of 2016. During the first half of 2016, we had mid-cycle and late-cycle communications with the FDA regarding our BLA application. We continue to interact with the FDA in the normal course of business relating to their review of our BLA for RI-002.

As part of our currently ongoing commercialization efforts, we plan to increase our initiatives by hiring a small, specialty sales force to market RI-002 to hospitals, physician offices/clinics, and other specialty treatment organizations. We anticipate staffing our company with additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, reimbursement, inventory and logistics, human resources, and financial and operational management. If and when we receive FDA approval, we may also use a network of national distributors to assist with order fulfillment for RI-002 for use by healthcare professionals and hospitals.

RI-002 achieved positive data in its clinical trials. RI-002 has been administered for a total of 793 infusions with zero serious adverse events to 59 patients in 9 treatment centers throughout the United States in a pivotal Phase III clinical trial. RI-002 is an injectable immune globulin derived from human plasma, enriched with standardized high levels of naturally occurring polyclonal antibodies (e.g., streptococcus pneumoniae, H. influenza type B, CMV, measles, tetanus, etc.) as well as high levels of antibodies targeted to Respiratory Syncytial Virus, or RSV. Our patented,

microneutralization assay allows us to standardize RI-002's potency by effectively identifying and isolating hyperimmune donor plasma with high-titer RSV antibodies, thereby allowing us to differentiate our immune globulin and may potentially garner a premium price.

PIDD, a genetic disorder that causes a deficient or absent immune system, is caused by hereditary or genetic defects and can affect anyone regardless of age or gender. PIDD patients are more vulnerable to infections and more likely to suffer complications from these infections. Intravenous immune globulin, or IVIG, is a plasma derived product that is used to prevent serious infections in patients with PIDD. It is comprised of polyclonal antibodies, which are proteins produced by B-cells that are used by the body's immune system to neutralize foreign objects such as bacteria and viruses. RI-002, a specialty IVIG with standardized levels of high-titer RSV antibodies, is intended to prevent infections in PIDD patients. The polyclonal antibodies which are present in RI-002 are expected to prevent infections in immune-compromised patients. It is estimated that there are about 250,000 diagnosed PIDD patients in the United States, approximately half of whom are treated with IVIG regularly. In the United States, sales of immune globulin products for all its uses were reported to be approximately $4.8 billion in 2014. Since the introduction of IVIG therapy, the incidence of infections in IVIG-treated patients has dropped significantly.

On December 3, 2014, we announced that RI-002 demonstrated positive Phase III results and successfully achieved its primary endpoint, and that the treatment with RI-002 resulted in no Serious Bacterial Infections, or SBIs, observed in study subjects during the trial. On February 22, 2015, at the 2015 American Academy of Allergy Asthma & Immunology Annual Meeting, scientific investigators reported on the secondary outcomes that included: a total of 1.66 days per patient per year lost from work or school due to infection; one hospitalization due to a non-serious infection, unrelated to RI-002, of only five days duration in the entire study; and IgG trough levels above those required by the FDA for IVIG products. Additionally, there was a marked increase in all of the measured specific anti-pathogen antibodies in PK subjects (n=31). The mean of maximum fold increases in specific antibody levels after infusion of RI-002 ranged from 1.9 fold (S. pneumonia type 19A) to 5.3 fold (RSV), which were statistically significant fold increases from the pathogen's specific measured baselines.

The safety profile of RI-002 is comparable to that of other immune globulins. These secondary outcome results follow the prior announcement that the trial achieved its primary endpoint with zero reported acute or SBI in the course of the trial.

The trial was conducted as a single arm study in which patients were treated approximately once per month for a period of 12 months plus 90 days for follow up. Fifty-nine patients were enrolled in 9 treatment centers in the United States. The pivotal Phase III primary endpoint followed published FDA industry guidance, which provides for a reduction in the incidence of serious infections to less than one per year in each subject receiving IVIG. The secondary outcome was safety and included other pharmacokinetic, or PK, data collection points including antibody titers for certain agents, including RSV antibody levels at various time points after infusion. Following the FDA's published “Guidance for Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as a Replacement Therapy for Primary Humoral Immunodeficiency,” or FDA Guidance for Industry, for our protocol, should provide that a successful single Phase III trial and BLA submission, should lead to FDA approval.

RI-002’s predecessor product candidate, RI-001 was the subject of a Phase II randomized, double-blind, placebo-controlled human clinical trial in RSV-infected, immune-compromised patients. In that trial, RI-001 treated patients demonstrated a statistically significant rise in anti-RSV titers compared to patients receiving placebo. RI-002 is an improved formulation of our prior product candidate RI-001. RI-002 is manufactured using the same FDA-approved contract manufacturing facility as its predecessor. To date, RI-002 has demonstrated improved production yields, an improved stability profile and comparable anti-RSV antibody titer potency levels relative to the prior formulation.

We operate two FDA-licensed, German Health Authority, or GHA, and Korean Ministry of Food and Safety, or MFDS, certified source plasma collection facilities at our ADMA BioCenters located in Norcross, Georgia and Marietta, Georgia, which provide us with a portion of our blood plasma for the manufacture of RI-002. During the

third quarter of 2014, we completed the expansion of our Norcross, Georgia ADMA BioCenters facility by securing additional rented space to increase our donor and collection screening areas to meet an increase in market demand for source plasma. In 2014, we entered into another lease for a second plasma collection center in Marietta, Georgia, and we completed construction of this new facility during the fourth quarter of 2014. In November 2014, we announced the opening of our second plasma collection center in Marietta, Georgia. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase, and market conditions at the time of sale. Plasma collected from ADMA BioCenters' two Georgia facilities that is not used for making RI-002 is sold to third party customers in the United States, and other locations where we are approved globally under supply agreements or in the open "spot" market. We have entered into long term manufacturing and licensing agreements with Biotest AG and their United States subsidiary, Biotest Pharmaceuticals, Inc., together referred to as Biotest, that provide for the exclusive manufacture of RI-002. At the same time, we granted Biotest an exclusive, royalty-bearing license to market and sell RSV antibody-enriched IVIG in Europe and in other selected territories in North Africa and the Middle East.

The founders of ADMA have combined greater than 60 years of experience marketing and distributing blood plasma products and devices. With our executive team, members of the board of directors and our commercial team, we collectively possess over 200 years of deep medical, technical, development and commercial experience in the biologics and pharmaceutical industry.

Our mission is to develop and commercialize plasma-derived, human immune globulins targeted to niche immune-compromised patient populations. We intend to accomplish our mission by achieving the following:

- obtain FDA approval to manufacture and market RI-002 for the treatment of patients with PIDD;
- establish a specialty sales force to commercialize RI-002;
- explore other possible indications (e.g., label expansion) for RI-002;
- develop additional plasma-derived products for the treatment and/or prevention of infectious diseases in immune-compromised patient populations; and
- expand our network of ADMA BioCenters facilities, both to maintain control of a portion of our raw material supply and to generate additional revenue through the collection and sale of source plasma to third party customers.

Proposed Expansion of Availability under Senior Loan Agreement

We have also recently obtained from our senior lender, Oxford Finance LLC, a proposal to enter into an amendment to our existing senior loan and security agreement pursuant to which the total term loan amount may be increased to an aggregate of $25.0 million, consisting of our existing loan balance of $16.0 million plus $9.0 million of additional availability in tranches of $4.0 million and $5.0 million, respectively. Following Oxford's completion of confirmatory due diligence and the execution of an amendment to our loan and security agreement consistent with this proposal: (i) the new tranche of $4.0 million would become available within 30 days after consummation of an equity raise on or before May 31, 2016 generating at least $10.0 million in gross proceeds, and (ii) the second tranche of $5.0 million would become available to us within 30 days of our BLA approval for RI-002, provided that such approval is received on or before January 31, 2017.

Risk Factors

Relying exclusively on third-parties to manufacture and commercialize our product candidates exposes us to risks that may delay testing, development, regulatory approval, commercialization and overall manufacturing of our product candidates.

We lack the internal resources to manufacture RI-002. Although we have agreements pertaining to the manufacture, testing, supply, storage and distribution of RI-002, upon commercialization, it is possible that our manufacturing requirements may exceed the available supply allotments under our existing agreements. We rely on one third-party contractor to manufacture RI-002. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement manufacturer. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our

products after receipt of FDA approval, if any;

- third-party manufacturers might be unable to manufacture our products in the volume and of the quality required to meet our clinical and commercial needs, if any;

- contract manufacturers may not perform as agreed, and operate their business independently from us. Contract manufacturers are directly responsible for their own FDA cGMP interactions and we may not be privy to all ongoing discussions and information concerning products or process unrelated to our products or product candidates or us. Additionally, contract manufacturers may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products;

- product manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign requirements. We do not have control over third-party manufacturers' compliance with these regulations and requirements and our manufacturers may be found to be in noncompliance with certain regulations or requirements, which may impact our ability to manufacture our drug product candidates and may impact the regulatory status of us and our product candidates; and

- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation. We may be required to pay fees or other costs for access to such improvements and additional clinical trials or other studies may be required.

Each of these risks could delay the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues. Our contract manufacturer announced in November 2014 that it received a warning letter from the FDA relating to an inspection at its Boca Raton, Florida location, which, we are informed, does not prevent the manufacturing or distribution of any of our contract manufacturer’s commercial products. Failure to resolve any outstanding issues or any administrative actions or changes taken by FDA toward our contract manufacturers, vendors or us, could impact our ability to receive approval, including the timing thereof, for RI-002, disrupt our business operations and the timing of our commercialization efforts, and may have a material adverse effect on our financial condition and operating results.

Currently, our only viable product candidate is RI-002. If we do not obtain the necessary U.S. or worldwide regulatory approvals to commercialize RI-002, we will not be able to sell RI-002.

At the present time, our entire focus is obtaining regulatory approval for RI-002, our only product candidate. If we cannot obtain regulatory approval for RI-002, our only source of revenue will be plasma collection and sales. We cannot assure you that we will receive the approvals necessary to commercialize RI-002 or any other product candidate we may acquire or develop in the future. In order to obtain FDA approval of RI-002 or any other biological product candidate requiring FDA approval, our clinical development must demonstrate that the product candidate is safe for humans and effective for its intended use, that the product can be manufactured in accordance with FDA requirements, and we must submit a BLA demonstrating the product’s safety, purity, and potency. To attain required FDA approval of any other product candidate generally requires significant research and testing, referred to as preclinical studies, as well as human tests, referred to as clinical trials. Satisfaction of the FDA's regulatory

requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in products that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the product approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review as well as any administrative actions or changes by the FDA that occur with any of our third party contract manufacturing vendors, or us. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidate;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject our BLA. In addition, the FDA could require that we conduct further studies with more subjects. We may never obtain regulatory approval for RI-002 or any other potential product candidate. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without a saleable product beyond the plasma collected by ADMA BioCenters, and therefore without any source of additional revenues if and until another product candidate can be developed and commercialized. There is no guarantee that we will ever be able to develop or acquire another product candidate. In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any products. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any product candidate for sale outside the United States.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated April 27, 2016

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 27, 2016 ADMA Biologics, Inc.

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Chief Financial Officer

INDEX OF EXHIBITS

Exhibit No.	Description
99.1	Press Release, dated April 27, 2016