ADMA BIOLOGICS, INC.
Form 10-K
March 29, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2017

¨ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 001-36728

ADMA BIOLOGICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**56-2590442**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. 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**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common stock, par value $0.0001 per share	**NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

¨ Large Accelerated Filer ¨ Accelerated Filer ¨ Non-accelerated Filer x Smaller Reporting Company x 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 ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates was $25,433,363 as of June 30, 2017 (the last business day of the registrant's most recently completed second fiscal quarter), based on a total of 6,873,882 shares of common stock held by non-affiliates and a closing price of $3.70 as reported on the Nasdaq Capital Market on June 30, 2017.

As of March 9, 2018, there were 45,317,244 shares of the issuer's common stock outstanding, comprised of 36,726,084 shares of voting common stock and 8,591,160 shares of non-voting common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the ADMA Biologics, Inc. definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year are incorporated by reference into Part III of this Annual Report on Form 10-K and certain documents are incorporated by reference into Part IV.

ADMA BIOLOGICS, INC.

Table of Contents

Special Note Regarding Forward-Looking Statements

Some of the information in this Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. These statements include, among others, statements about:

- our ability to successfully leverage the anticipated benefits and synergies from our June 6, 2017 acquisition of certain assets of Biotest Pharmaceuticals Corporation (the "Biotest Transaction"), including optimization of the combined businesses, operations and products and services, including the nature, strategy and focus of the combined company and the management and governance structure of the combined company;

- our ability to resume the manufacturing and commercialization of Bivigam once the deficiencies identified in a November 2014 warning letter (the "Warning Letter") with respect to the outstanding issues at the plasma fractionation facility in Boca Raton, FL acquired in the Biotest Transaction have been resolved by us to the satisfaction of the U.S. Food and Drug Administration (the "FDA"), as well as a positive review of the optimized manufacturing process under a Prior Approval Supplement by the FDA;

- our ability to successfully resubmit to the FDA our Biologics License Application (the "BLA") for our lead pipeline product candidate, RI-002 ("RI-002"), once the deficiencies identified in the Complete Response Letter we received in July 2016 reaffirming the issues set forth in the Warning Letter have been resolved by us and/or our third-party vendors to the satisfaction of the FDA, and other requests for information included therein have been provided by us;

- our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products and the success of such efforts;

- the safety, efficacy and expected timing of and our ability to obtain and maintain regulatory approvals for our current products and product candidates, including the timeframe within which we may receive approval from the FDA, if at all, of our BLA resubmission for RI-002 and the labeling or nature of any such approvals;

- the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals;

- our dependence upon our third-party and related-party customers and vendors and their compliance with regulatory bodies;

- our ability to obtain adequate quantities of FDA-approved plasma with proper specifications;

- our plans to increase our supplies of plasma;

- the potential indications for our product candidates;

- potential investigational new product applications;

- the acceptability of any of our products, including RI-002, for any purpose by physicians, patients or payers;

- concurrence by the FDA with our conclusions and the satisfaction by us of its guidance;

- the comparability of results of our immune globulin products to other comparably run Intravenous Immune Globulin trials;

- the potential of RI-002 and Bivigam to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease;

- our ability to market and promote Nabi-HB in a highly competitive environment and to generate meaningful revenues from this product;

1

Table of Contents

- our intellectual property position and the defense thereof, including our expectations regarding the scope of patent protection with respect to RI-002 or other future pipeline product candidates;
- our manufacturing capabilities, third-party contractor capabilities and strategy;
- our plans related to manufacturing, supply and other collaborative agreements;
- our estimates regarding expenses, capital requirements and the need for additional financing;
- possible or likely reimbursement levels for our currently marketed products and, if any, if and when RI-002 is approved for marketing;
- estimates regarding market size, projected growth and sales for our existing products as well as our expectations of market acceptance of RI-002;
- future economic conditions or performance; and
- expectations for future capital requirements.

These statements may be found under the "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" sections of this Annual Report on Form 10-K. Forward-looking statements typically are identified by the use of terms such as "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should" or "will" or the negative thereof or other variations thereof or comp terminology. You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to the factors referenced above.

In addition to the foregoing, you should also consider carefully the statements under the section entitled "Risk Factors" and other sections of this Annual Report on Form 10-K, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements. We undertake no obligation to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

This Annual Report on Form 10-K includes our trademarks, trade names and service marks, such as "Nabi-HB®" and "Bivigam®" which are protected under applicable intellectual property laws and are the property of ADMA Biologics, Inc., or its subsidiaries. Solely for convenience, trademarks, trade names and service marks referred to in this Annual Report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

2

Table of Contents

PART I

Item 1. Business

Unless the context otherwise requires, references in this Business section to "ADMA," "ADMA Biologics," the "Company," "we," "us" and "our" refer to ADMA Biologics, Inc., a Delaware corporation, as well as its wholly-owned and indirectly owned subsidiaries, ADMA Plasma Biologics, Inc., a Delaware corporation, ADMA Bio Centers Georgia Inc., a Delaware corporation ("ADMA BioCenters") and ADMA BioManufacturing, LLC, a Delaware limited liability company ("ADMA BioManufacturing").

Overview

We are a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies 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. We currently have two marketed products: Nabi-HB, indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen ("HBsAg"); and Bivigam, indicated for the treatment of primary humoral immunodeficiency. We are also developing a pipeline of plasma-derived therapeutics, including our lead pipeline product candidate, RI-002, for the treatment of Primary Immune Deficiency Disease ("PIDD"). Our products and product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients with or at risk for certain infectious diseases. Through ADMA BioCenters, we operate two United States Food and Drug Administration (the "FDA")-licensed, German Health Authority ("GHA") and Korean Ministry of Food and Drug Safety ("KMFDS")-certified source plasma collection facilities located in the U.S., which provide us with a portion of our blood plasma for the manufacture of our products and product candidates. 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' facilities that is not used to manufacture our products or product candidates is sold to third-party customers in the U.S., in other locations where we are approved globally under supply agreements or in the open "spot" market.

On June 6, 2017, we completed the acquisition of certain assets (the "Biotest Assets") of the Therapy Business Unit ("BTBU") of Biotest Pharmaceuticals Corporation ("BPC" and, together with Biotest AG, "Biotest"), which include two FDA-licensed products, Nabi-HB (Hepatitis B Immune Globulin, Human) and Bivigam (Immune Globulin Intravenous, Human) and a plasma fractionation facility located in Boca Raton, FL (the "Boca Facility") (the "Biotest Transaction"). The Boca Facility is FDA-licensed and certified by the GHA. In addition to the manufacture and sale of Nabi-HB and Bivigam, we also provide contract manufacturing services for certain historical clients, including the

sale of intermediate by-products. Immediately following the acquisition, the Biotest Assets were contributed into ADMA BioManufacturing.

Concurrent with the closing of the Biotest Transaction, Biotest committed to an aggregate of $40.0 million of funding for us. Upon the closing of the Biotest Transaction, we received $27.5 million from Biotest, comprised of $12.5 million in cash from BPC and a $15.0 million subordinated note at 6% interest payable to BPC with a maturity of five years. At the closing of the Biotest Transaction, we delivered to BPC an aggregate equity interest equal to 50%, less one share, of our then-issued and outstanding capital stock comprised of 25%, or 4,295,580 shares, of our voting common stock, $0.0001 par value per share ("Common Stock"), and 8,591,160 shares in the form of our non-voting common stock, $0.0001 par value per share ("Non-Voting Common Stock") (calculated as of immediately following the closing and on a post-closing issuance basis). The Non-Voting Common Stock is convertible into our Common Stock upon the occurrence of certain specified events. Biotest also participated in our November 2017 follow-on equity offering by investing $12.5 million of the $42.0 million of total gross proceeds from the offering (see "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this Annual Report).

As part of the purchase price to acquire the Biotest Assets, we agreed to transfer ownership of two of our plasma collection facilities to BPC on January 1, 2019. We completed the construction of our third plasma collection facility, filed our Biologics License Application with the FDA and initiated collections for this facility in December 2017. We anticipate FDA approval of our third plasma collection facility to occur during the second half of 2018

Table of Contents

Our Marketed Products

Nabi-HB

Nabi-HB is a hyperimmune globulin that is rich in antibodies to the Hepatitis B virus. Nabi-HB is a purified human polyclonal antibody product collected from plasma donors who have been previously vaccinated with a Hepatitis B vaccine. Nabi-HB is indicated for the treatment of acute exposure to blood containing HBsAg, prenatal exposure to infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection. Hepatitis B is a potentially life-threatening liver infection caused by the Hepatitis B virus. It is a major global health problem. It can cause chronic infection and puts people at high risk of death from cirrhosis and liver cancer. Nabi-HB has a well-documented record of long-term safety and effectiveness since its initial market introduction. FDA approval for Nabi-HB was received on March 24, 1999. Biotest acquired Nabi-HB from Nabi Biopharmaceuticals in 2007. Production of Nabi-HB at the Boca Facility has continued under our leadership since the third quarter of 2017. Subsequent to the end of 2017, we received authorization from the FDA for the release of our first commercial batch of Nabi-HB for commercial distribution in the U.S.

Bivigam

Bivigam is an intravenous immune globulin indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These primary immunodeficiencies (“PIs” are a group of genetic disorders. Initially thought to be very rare, it is now believed that as many as one in every 1,200-2,000 people has some form of PI. 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 Immunoglobulin (“IgG”) antibodies. Antibodies are proteins in the human immune system that work to defend against disease. FDA approval for Bivigam was received on December 19, 2012, and sales commenced in the first quarter of 2013. In December 2016, BPC temporarily suspended the commercial production of Bivigam in order to focus on the completion of planned improvements to the manufacturing process. We resumed production of Bivigam utilizing our optimized intravenous immunoglobulin (“IVIG”) manufacturing process with two conformance lots in the fourth quarter of 2017 and a third conformance lot in the first quarter of 2018. Subsequent to the end of 2017, we qualified and filled these Bivigam conformance batches and the product is on stability. We expect to file a Prior Approval Supplement (the “PAS”) with the FDA during the first half of 2018 and are seeking FDA clearance which would enable us to relaunch this product during the second half of 2018.

Our Lead Pipeline Product Candidate – RI-002

We are currently developing our lead pipeline product candidate, RI-002, for the treatment of PIDD and have completed a pivotal Phase III clinical trial, which met the primary endpoint of no Serious Bacterial Infections ("SBIs") reported. Secondary efficacy endpoints further demonstrated the benefits of RI-002 in the low incidence of infection, therapeutic antibiotic use, days missed from work/school/daycare and unscheduled medical visits and hospitalizations. RI-002 is derived from human plasma blended from normal donors and from donors tested to have high levels of neutralizing titers to Respiratory Syncytial Virus ("RSV"). RI-002 is manufactured using a process known as fractionation, which purifies human IgG from this blended plasma pool resulting in a final IVIG product enriched with naturally occurring polyclonal anti-pathogen antibodies (such as streptococcus pneumonia, H. influenza type B, Cytomegalovirus ("CMV"), measles and tetanus). We use our proprietary RSV microneutralization assay to test for standardized levels of neutralizing antibodies to RSV in the final drug product.

Prior to the closing of the Biotest Transaction, BTBU was our third-party manufacturer for RI-002. In the third quarter of 2015, the FDA accepted for review our Biologics License Application for RI-002 (the "BLA") for the treatment of PIDD. In July 2016, the FDA issued a Complete Response Letter (the "CRL"). The CRL reaffirmed the issues set forth in a November 2014 warning letter (the "Warning Letter") that had been issued by the FDA to Biotest related to certain issues identified at the Boca Facility, but did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in our BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002. The FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies related to Chemistry, Manufacturing and Controls ("CMC") and Good Manufacturing Practices ("GMP") at the Boca Facility and at certain of our third-party vendors, and requested documentation of corrections for a number of these issues. The FDA indicated in the CRL that it cannot grant final approval of our BLA until, among other things, these deficiencies are resolved. Following the completion of the Biotest Transaction, we now have control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility, and our highest priority is to remediate the outstanding compliance issues that were identified at the Boca Facility in the Warning Letter. We have been working with a consulting firm consisting of quality management systems and biologics production subject matter experts in preparation for a re-inspection by the FDA in order to improve the FDA inspection classification relative to the Warning Letter compliance issues as indicated in the CRL. We believe that we have been inspection-ready since the end of 2017. Once the Warning Letter status is improved following the FDA inspection, we anticipate that we will be in a position to refile our BLA for RI-002 in the second half of 2018. Subsequent to the end of 2017, we produced three conformance lots using the optimized IVIG manufacturing process, and these batches are expected to be filled and finished during the second quarter of 2018 and will then be placed on stability.

Table of Contents

Evaluation of RI-002 in PIDD Patients

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. 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. It is estimated that there are about 250,000 diagnosed PIDD patients in the U.S., approximately half of whom are treated with IVIG regularly. In the U.S., sales of immune globulin products for all its uses were reported to be approximately $4.8 billion in 2014.

The RI-002 pivotal Phase III clinical 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 nine treatment centers in the U.S. 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 ("PK") data collection points including antibody titers for certain agents, including RSV antibody levels at various time points after infusion.

RI-002 demonstrated positive results in the Phase III study in patients with PIDD, meeting its primary endpoint of no SBIs reported. RI-002 was administered in a total of 793 infusions with zero serious adverse events to 59 patients in nine treatment centers throughout the U.S. These results, included in our BLA, more than meet the requirement specified by FDA guidance of ≤ 1 SBI per patient-year.

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 93 days, or 1.66 days per patient per year lost from work or school due to infection; one hospitalization due to an infection 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 immunoglobulins.

Rationale for the Potential Evaluation of RI-002 in RSV Infected Patients

RSV is a common virus that ordinarily leads to mild, cold-like symptoms in healthy adults and children. In high-risk groups, such as the PIDD population and the other immune-compromised populations, RSV can lead to a more serious

infection and may even cause death. The polyclonal antibodies which are present in RI-002 are expected to prevent infections in immune-compromised patients.

We previously conducted a randomized, double-blind, placebo-controlled Phase II clinical trial to evaluate RI-001, RI-002's predecessor product candidate, in immune-compromised, RSV-infected patients. This trial was conducted with 21 patients in the U.S., Canada, Australia, and New Zealand. The Phase II dose-ranging trial demonstrated a statistically significant improvement in the change from baseline RSV titers to day 18 in the high dose and low dose treatment groups when compared with placebo (p=0.0043 and p=0.0268, respectively). The mean fold increase for high dose was 9.24 (95% CI 4.07, 21.02) and the observed mean fold increase for low dose was 4.85 (95% CI 2.22, 10.59). The mean fold change for placebo treated patients was 1.42 (95% CI 0.64, 3.17). In addition, more patients in the high dose (85.7%) and low dose (42.9%) groups experienced greater than a four-fold increase from baseline to day 18 in RSV titer levels compared to placebo (0%). There were no serious drug-related adverse events reported during the trial.

Table of Contents

From April 2009 through February 2011, RI-001 was also administered to 15 compassionate use patients where physicians requested access to the product for treating their patients with documented lower respiratory tract RSV infections due to the fact that these patients had failed conventional therapeutic interventions. Serum samples were obtained from 13 patients. Samples showed that patients demonstrated a four-fold or greater rise in RSV antibody titers from baseline. Serum samples were not obtained from two patients that received Palivizumab. All 11 surviving patients received RI-001 within an average of 4.4 days after the onset of the diagnosis of RSV. The drug was well-tolerated in all 15 patients and there were no reports of serious adverse events attributable to RI-001. Data from our Phase II clinical trial, compassionate use experience and data obtained from the evaluation of RI-002 in the infected cotton rat animal model has been presented at various conferences the past several years.

Based on these results, we intend to evaluate RI-002 for the treatment of RSV patients following FDA approval, if received, for treatment of PIDD.

Manufacturing and Supply of Our Products

In order to produce plasma-derived immunoglobulin products, raw material plasma is collected from human donors and then manufactured into specialized products. Historically, plasma for our products and product candidates has been collected from healthy donors at FDA-licensed plasma donation centers. Source plasma is collected at any one of over 400 FDA-licensed donation centers located throughout the U.S., using a process called automated plasmapheresis. This sterile, self-contained, automated process separates red blood cells and other cellular components in the blood, which are then returned to the donor. Source plasma obtained by plasmapheresis is tested and must be negative for antibodies to human immunodeficiency virus types 1 and 2 (HIV-1/2), HBsAg and Hepatitis C virus (“HCV”), using FDA-licensed serological test procedures.

After receipt of the source plasma, the frozen plasma is thawed and pooled and goes through the fractionation process. This process is referred to as the Cohn method or cold ethanol method of fractionation. During cold ethanol fractionation, classes of proteins are precipitated and removed by centrifugation or filtration. The fractionation process includes the following steps; precipitation and absorption, depth filtration, centrifugation and chromatography. Because of the human origin of the raw material and the thousands of donations required in the fractionation process, the major risk associated to plasma products is the transmission of blood-borne infectious pathogens. These purification processes have the potential to reduce the viral load. The manufacturing process also utilizes a multistep viral removal/inactivation system, which further increases the safety of the products. The following manufacturing processes have been validated for their capability to eliminate or inactivate viruses: precipitation during cold ethanol fractionation, solvent/detergent treatment, and nanofiltration. Incorporation of these processes in the manufacturing process ensures that the Company’s products comply with the requirements of the FDA and are safe and efficacious.

Sales and Commercialization of Our Products

Historically, Nabi-HB has been sold through independent distributors, drug wholesalers acting as sales agents, specialty pharmacies and other alternate site providers. In the U.S., third-party drug wholesalers ship a significant portion of Nabi-HB through their distribution centers. These centers are generally stocked with adequate inventories to facilitate prompt customer service. Sales and distribution methods include frequent contact by sales and customer service representatives, automated communications via various electronic purchasing systems, circulation of catalogs and merchandising bulletins, direct-mail campaigns, trade publication presence and advertising.

While we have been working towards remediating the Warning Letter and other CMC and GMP inspection deficiencies and eventually refiling our BLA resubmission for RI-002, we expect to continue our commercialization efforts for our approved products and plan to bolster these initiatives by hiring a small, specialty sales force to market Nabi-HB, Bivigam upon its relaunch and, upon approval by the FDA, RI-002 to hospitals, physician offices/clinics, and other specialty treatment organizations. We also anticipate staffing our company with additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, third-party 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.

Table of Contents

Pharmaceutical Pricing and Reimbursement of Our Products

All sales of Nabi-HB, Bivigam and, if and when approved by the FDA, RI-002 in the U.S. depend in part upon the availability of reimbursement from third-party payers. Third-party payers include government health programs, managed care providers, private health insurers and other organizations. Nabi-HB and Bivigam are reimbursed or purchased under several government programs, including Medicaid, Medicare Parts B and D, the 340B/Public Health Service program, and pursuant to an existing contract with the Department of Veterans Affairs. Medicaid is a joint state and federal government health plan that provides covered outpatient prescription drugs for low-income individuals. Under Medicaid, drug manufacturers pay rebates to the states based on utilization data provided by the states.

Plasma Collection Facilities

ADMA BioCenters operates FDA-licensed, GHA and KMFDS certified source plasma collection facilities located in the U.S. which provide us with a portion of our blood plasma for the manufacture of our products and product candidates. 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' facilities that is not used to manufacture our products or product candidates are sold to third-party customers in the U.S. and other locations where we are approved globally under supply agreements or in the open "spot" market.

As part of the purchase price to acquire the Biotest Assets, we agreed to transfer ownership of two of our plasma collection facilities to BPC on January 1, 2019. We completed the construction of our third plasma collection facility, filed our Biologics License Application with the FDA and initiated collections for this facility in December 2017. We anticipate FDA approval of our third plasma collection facility to occur during the second half of 2018.

Leadership

The founders of ADMA have several decades of combined experience marketing and distributing blood plasma products and devices. With our executive team, members of our Board of Directors (the “Board”) and our commercial team, we collectively possess a significant level of deep medical, technical, development and commercial experience in the biologics and pharmaceutical industries.

Our Strategy

Our goal is to be a leader in developing, manufacturing and commercializing specialized, targeted, plasma-derived therapeutics that are intended to extend and enhance the lives of individuals who are naturally or medically immune-compromised. The key elements of our strategy for achieving this goal are as follows:

- **Remediate the outstanding compliance deficiencies identified by the FDA in the CRL and Warning Letter at the Boca Facility**. Following the completion of the Biotest Transaction, we now have control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility. Our highest priority has been to remediate the outstanding compliance issues at the Boca Facility while owned and operated by Biotest that were identified by the FDA in the CRL and the Warning Letter. We engaged a leading consulting firm with extensive experience in remediating compliance and inspection issues related to quality management systems that manages a robust team of subject matter experts in plasma derived products and biologic drugs to assist us in addressing all identified CMC and current good manufacturing practice ("cGMP") issues and deficiencies. We believe that we have been inspection-ready since the end of 2017 and expect to have the FDA inspection classification relative to the Warning Letter improved after the next inspection by the FDA.

Table of Contents

- **Increase marketing efforts around Nabi-HB and relaunch Bivigam.** We plan to increase our marketing efforts and attend relevant medical conferences during 2018, raising awareness of the risks associated with Hepatitis B and the benefits and efficacy of Nabi-HB. Similarly, we plan to relaunch Bivigam following the submission and review by the FDA of the PAS, which will detail our optimized Bivigam manufacturing process.

- **Obtain FDA approval of RI-002 as a treatment for PIDD**. In the third quarter of 2015, the FDA accepted for review our BLA for the treatment of PIDD. In July 2016, the FDA issued the CRL. The CRL did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in our BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002. In connection with our remediation efforts at the Boca Facility, we anticipate that we will be in a position to refile our BLA for RI-002 in the second half of 2018.

- **Commercialize RI-002 as a treatment for PIDD**. We plan to enhance our recruiting initiatives and expand our existing specialty commercial sales force to market RI-002 to hospitals, physician offices/clinics, and other specialty treatment and infusion center organizations. We also anticipate staffing our company with additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, third-party reimbursement, inventory and logistics, human resources, and financial and operational management. We may also use a network of national distributors to fulfill orders for RI-002.

- **Expand RI-002's FDA-approved uses**. If RI-002 is approved by the FDA as a treatment for PIDD, we plan to evaluate the clinical and regulatory paths to grow the RI-002 franchise through expanded FDA-approved uses. We believe that there may be patient populations beyond PIDD that would derive clinical benefit from RI-002, some of which may be eligible for orphan status. We plan to leverage our previously conducted randomized, double-blind, placebo-controlled Phase II clinical trial evaluating RI-001, RI-002's predecessor product candidate, in immune-compromised, RSV-infected patients to explore RI-002 for the treatment of RSV.

- **Expand our pipeline with additional plasma-derived therapeutics**. Our core competency is in the development, manufacturing, testing and commercialization of plasma-derived therapeutics. We believe there are a number of under-addressed medical conditions for which plasma-derived therapeutics may be beneficial. Utilizing our intellectual property patents, which include our proprietary testing assay and other standardization methods and technologies, we have identified potential new product candidates that we may advance into preclinical activities in the near term.

- **Develop and expand ADMA BioCenters**. In order to maintain partial control of our raw material supply as well as generate revenues through additional sources, we operate ADMA BioCenters, a subsidiary that manages plasma collection facilities in the U.S. These facilities hold FDA licenses, along with GHA and KMFDS certifications. Under the FDA licenses, ADMA BioCenters may collect normal source plasma and high-titer RSV plasma, with a portion of the plasma being sold to third-party buyers. We also plan to grow through the creation and licensing of additional ADMA BioCenters facilities in various regions of the U.S., including the recent construction of our third facility for which we filed our BLA with the FDA in December 2017. Additional ADMA BioCenters may allow us to cost-effectively secure additional plasma for our product manufacturing, and potentially increase revenues through the collection and sale of normal source plasma and other hyperimmune plasma to third parties.

The Plasma Industry

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 and it is estimated that over 300,000 patients worldwide receive monthly IVIG infusions for PIDD.

Table of Contents

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.

RI-002, our IVIG product candidate, 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 up to 40% of infected patients. In hematopoietic stem cell transplant ("HSCT") patients, a subset of the immune-compromised patient population with approximately 25,000 transplants being performed annually in the U.S., it is estimated that about 25% of patients treated with the current standard of care (aerosolized Ribavirin) will progress to Lower Respiratory Tract Infection ("LRTI") while 41% of patients untreated with the current standard of care will progress to LRTI.

Plasma - Background, Composition and Manufacturing

Human blood contains a number of components including:

- Red blood cells – Used to carry oxygen from the lungs to the body;
- White blood cells – Used by the immune system to fight infection;
- Platelets – Used for blood clotting; and
- Plasma – Used to carry the aforementioned components throughout the body and provide support in clotting and immunity.

9

Table of Contents

Plasma is the most abundant blood component, representing approximately 55% of total blood volume. Plasma, which is 90% water, is rich in proteins used by the human body for blood clotting and fighting infection. These proteins account for approximately 7% of plasma's volume. As plasma contains these valuable proteins, plasma collection and the manufacturing of human plasma-derived therapeutics provide therapeutic benefits for ill patients.

In order to produce plasma-derived therapeutics that can be administered to ill patients, raw material plasma must be collected from human donors and then manufactured into specialized products. Plasma is collected from healthy donors at FDA-licensed plasma donation centers. To ensure safety of the collected plasma, all plasma donations are tested using FDA-approved methods of Nucleic Acid Testing for various infectious diseases, such as HIV or HCV.

Plasma is collected using a process called "plasmapheresis." During plasmapheresis, a donor's blood is drawn into a specialized medical device that separates the plasma component through centrifugation, and then returns the other blood components back into the donor's bloodstream. Plasmapheresis is performed utilizing an FDA-approved, automated device with a sterile, self-contained collection kit. The plasma that is collected is known as "normal source plasma." There are over 500 plasma donation centers in the U.S. As noted in a variety of plasma industry trade reports and related conferences, approximately 35 million liters of source plasma were collected in the U.S. in 2015. In the U.S., a donor may donate plasma a maximum of two times during any seven-day period, with at least two days in between donations. Plasma donation centers in the U.S. typically pay donors $25 to $50 per donation and some donors with rare or high antibody levels can be paid more.

In order to isolate the desired therapeutic elements in normal source plasma, it must initially undergo a manufacturing process known as "fractionation." The process of fractionation was invented in the 1940's by E.J. Cohn and is referred to as the Cohn method or cold ethanol fractionation. First, the source plasma undergoes a process called pooling, in which the individual plasma donations are combined into a pooling tank. Second, the Cohn fractionation method, which is a combination of time, temperature, pH, alcohol concentration and centrifugation, is used to separate the desired plasma protein components, or "fractions." After fractionation, the separated proteins are then re-suspended and are treated with a solvent detergent treatment process for viral inactivation. Next, other forms of filtration, such as nanofiltration, are performed as an additional viral removal and viral reduction step. Finally, with the various components separated and purified, the bulk product is formulated and filled into final, finished vials. During these various steps of manufacturing, each lot is reviewed and tested for potency and purity prior to being approved for release.

The proteins in human plasma fall into four categories: albumin (60% of protein volume), immune globulins (15% of protein volume), coagulation factors (1% of protein volume), and other proteins (24% of protein volume) such as alpha-1 proteinase inhibitor, C1 esterase inhibitor, fibrin sealants and fibrinogen. Many of the other proteins in plasma have yet to be developed into commercial therapies. In the U.S., not only are the plasma collection centers subject to FDA licensure, but each plasma protein product that is derived and fractionated from plasma must undergo an approval process with FDA's Center for Biologics Evaluation and Research.

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 various IVIG products, there are only 14 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.

Table of Contents

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 of 2014, the worldwide market for plasma-derived therapeutic drug products was approximately $15 billion and the U.S. market for all plasma-derived products was approximately $7.8 billion. IVIG products accounted for approximately $4.8 billion of sales in the U.S. in 2014. 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 growth of IVIG utilization.

Manufacturing and Supply

In order to produce plasma-derived therapeutics that can be administered to patients, raw material plasma is collected from healthy donors at plasma collection facilities licensed by the FDA. ADMA BioCenters operates FDA-licensed, GHA and KMFDS certified source plasma collection facilities located in the U.S. which provide us with a portion of our blood plasma for the manufacture of our current products and product candidates. 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' facilities that is not used for the manufacture of our current products and product candidates is sold to third-party customers in the U.S., and other locations where we are approved globally under supply agreements or in the open "spot" market.

On June 6, 2017, we and BPC entered into a Termination Agreement with respect to the Manufacturing Supply and License Agreement and Master Services Agreement, which included, effective as of January 21, 2017, a mutual release with respect to any claims relating to or arising from any breach or default under the existing Manufacturing Supply and License Agreement and Master Services Agreement between ADMA BioManufacturing and BPC. Under our Manufacturing, Supply and License Agreement with BPC, we had agreed to purchase exclusively from BPC our worldwide requirements of RSV immune globulin manufactured from human plasma containing RSV antibodies. The term of the agreement was for a period of ten years from January 1, 2013, renewable for two additional five year periods at the agreement of both parties. We were obligated under this agreement to purchase a minimum of at least one lot of product during each calendar year after the finished product is approved by the FDA. This number was subject to increase at our option. As consideration for BPC’s obligations under the agreement, we were obligated to pay a dollar amount per lot of RSV immune globulin manufactured from human plasma containing RSV antibodies, as well as a percentage royalty on the sales thereof and of RI-002, up to a specified cumulative maximum amount.

Pursuant to the terms of a Plasma Purchase Agreement with BPC, we have agreed to purchase from BPC an annual minimum volume of source plasma containing antibodies to RSV to be used in the manufacture of RI-002. We must purchase a to-be-determined and agreed upon annual minimum volume from BPC, but may also collect high-titer RSV plasma from up to five wholly-owned ADMA BioCenters. During 2015, BPC and ADMA amended its plasma supply agreement to allow ADMA the ability to collect its raw material RSV high-titer plasma from other third-party collection organizations, thus allowing ADMA to expand its reach for raw material supply as we approach commercialization for RI-002. Unless terminated earlier, the agreement expires in November 2021, after which it may be renewed for two additional five-year periods if agreed to by the parties. Either party may terminate the agreement if the other party fails to remedy any material default in the performance of any material condition or obligation under the agreement following notice. Either party may also terminate the agreement, after providing written notice, if a proceeding under any bankruptcy, reorganization, arrangement of debts, insolvency or receivership law is filed by or against the other party, and is not dismissed or stayed, or a receiver or trustee is appointed for all or a substantial portion of the assets of the other party, or the other party makes an assignment for the benefit of its creditors or becomes insolvent. We may also terminate the agreement upon written notice if the clinical development of our product candidate is halted or terminated, whether by the FDA, a Data Safety Monitoring Board, or any other regulatory authority. Upon termination of the agreement, we must pay for any source plasma already delivered to us and for any source plasma collected under the terms of the agreement. As part of the closing of the Biotest Transaction, we amended the Plasma Purchase Agreement to extend BPC’s annual minimum purchase requirements of plasma containing antibodies to RSV for ten years through the closing date of the Biotest Transaction.

Table of Contents

On June 22, 2012, we entered into a Plasma Supply Agreement with BPC for the purchase of normal sourc