ADMA BIOLOGICS, INC.
Form 10-K
March 13, 2019

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, 2018

¨ 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 every Interactive Data File required to be submitted 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 x Accelerated Filer ¨ Non-accelerated Filer x Smaller Reporting Company ¨ 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 $133,158,287 as of June 30, 2018 (the last business day of the registrant's most recently completed second fiscal quarter), based on a total of 29,525,119 shares of common stock held by non-affiliates and a closing price of $4.51 as reported on the Nasdaq Capital Market on June 29, 2018.

As of March 11, 2019, there were 46,353,068 shares of the issuer's common stock outstanding.

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.

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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:

- the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals;
- 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 of BIVIGAM on a commercial scale and commercialize this product 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 and our ability to adequately address the FDA's questions and information request contained in a Complete Response Letter received by us on December 19, 2018;
- 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 Biologics License Application resubmission for RI-002 and the labeling or nature of any such 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 Nabi-HB, BIVIGAM and RI-002, for any purpose by physicians, patients or payers;

- federal, state and local regulatory and business review processes and timing by such governmental and regulatory agencies of our business and regulatory submissions;

- 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 or other immune deficiencies;

- our ability to market and promote Nabi-HB in a highly competitive environment with increasing competition from other antiviral therapies and to generate meaningful revenues from this product;

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- 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. Any forward-looking statement included or incorporated by reference in this Annual Report on Form 10-K reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions related to our operations, results of operations, industry and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements speak only as of the dates such statements are made.

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.

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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 Bio Centers") 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 the prevention and treatment 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 products with United States Food and Drug Administration (the "FDA") Biologics License Application ("BLA") approvals: Nabi-HB, which is currently marketed and commercially available and is indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen ("HBsAg"); and BIVIGAM, for which commercial distribution has been temporarily suspended since December 2016 and for which we have submitted a Prior Approval Supplement ("PAS") to the FDA to amend the approved BLA to allow for the commercial re-launch of the product, which is 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"), for which we previously submitted a BLA to the FDA and which has now been assigned a Prescription Drug User Fee Act ("PDUFA") action date of April 2, 2019. 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 Bio Centers, we operate an FDA-approved source plasma collection facility located in Kennesaw, GA, which provides us with a portion of our blood plasma for the manufacture of our products and product candidates. We intend to open additional plasma collection centers in the U.S. during the next few years. A typical plasma collection center, such as those operated by ADMA Bio Centers, 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 Bio Centers' 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 German Health Authority (the "GHA"). In addition to the manufacture and sale of Nabi-HB and the manufacture of BIVIGAM and RI-002, we also provide contract manufacturing services for certain historical clients, including the potential 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 provided us with an aggregate of $40.0 million of funding. 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 Biotest with a maturity of five years. 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 on Form 10-K).

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 then-issued and outstanding 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 (the "NV Biotest Shares") (calculated as of immediately following the closing and on a post-closing issuance basis). The NV Biotest Shares were convertible into our Common Stock upon the occurrence of certain specified events.

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On May 14, 2018, we entered into a Share Transfer, Amendment and Release Agreement with BPC, Biotest AG, Biotest US Corporation and The Biotest Divestiture Trust (the "Biotest Trust") (the "Biotest Transfer Agreement") whereby BPC transferred to us, for no cash consideration, the NV Biotest Shares. Immediately upon transfer of the NV Biotest Shares to us, the NV Biotest Shares were retired and are no longer available for issuance. The retired NV Biotest Shares comprised approximately 67% of the total common stock consideration provided to Biotest and approximately 19% of the total outstanding common stock of the Company as of May 14, 2018. In exchange for the transfer and retirement of the NV Biotest Shares, we (i) granted Biotest and its successors and assigns a release from all potential past, present and future indemnity claims arising under the Master Purchase and Sale Agreement, dated as of January 21, 2017 (the "Master Purchase Agreement"), which governs the Biotest Transaction, and (ii) relinquished our rights to, under certain circumstances, repurchase the two FDA-approved plasma collection centers which were transferred to BPC on January 1, 2019. In addition, pursuant to the Biotest Transfer Agreement, BPC waived and terminated its rights to name a director and an observer to our Board of Directors (the "Board"). As BPC has made public statements regarding the U.S. Government required divestiture of all of BPC's U.S. assets in connection with the sale of Biotest AG to CREAT Group Corporation, pursuant to the Biotest Transfer Agreement BPC transferred its remaining 10,109,534 shares of our Common Stock to the Biotest Trust on July 24, 2018, and the Biotest Trust is bound by all obligations of and has all of the remaining rights of BPC under that certain Stockholders Agreement dated as of June 6, 2017, by and between us and BPC, as amended by the Biotest Transfer Agreement (the "Stockholders Agreement").

As part of the purchase price to acquire the Biotest Assets, we transferred ownership of two of our plasma collection facilities to BPC on January 1, 2019. In October 2018, we received FDA approval for our current plasma collection facility located in Kennesaw, GA.

Our 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, a third conformance lot in the first quarter of 2018 and additional production lots in the fourth quarter of 2018. During the first half of 2018, we qualified, validated and filled the BIVIGAM conformance batches and the product is currently on stability. During the second half of 2018, we filed a PAS with the FDA for BIVIGAM to include the ADMA optimization improvements for BIVIGAM and to seek FDA authorization which would enable us to resume commercial scale manufacturing and re-launch and commercialize this product in the U.S. On December 19, 2018, we announced the receipt of a Complete Response Letter ("CRL") (the "BIVIGAM CRL") from the FDA for our PAS submission for BIVIGAM drug substance, and also announced the FDA approval of our PAS submission for BIVIGAM drug product. For clarity, drug substance is the bulk immune globulin we manufacture at the Boca Facility and drug product is the result of shipping the drug substance to our third party fill-finish provider who then fills the drug into vials and prepares the product for final release testing and potential commercial release. The BIVIGAM CRL requested certain additional information and clarifications relating to chemistry, manufacturing and control ("CMC") matters contained in our PAS submission for drug substance, including complete resolution of certain manufacturing related deviations, information pertaining to how certain in-process manufacturing samples are taken, as well as updates on certain stability data previously submitted. As the information we believed necessary to address and respond to the matters raised in the BIVIGAM CRL was readily available in our files, on January 7, 2019 we announced that our responses to the BIVIGAM CRL were submitted to the FDA for further review. Subsequent to the January 7, 2019 resubmission to the FDA, we received an information request for a limited number of questions. We believe that all requests contained in the recently received FDA information request were addressable and we have responded to the FDA. To date, we have not received a formal BIVIGAM CRL resubmission acknowledgment and we have not received formal clarity on the FDA's intended review timing. We can confirm that the FDA is actively reviewing our BIVIGAM CRL resubmission and information request responses, however we cannot provide any assurance or predict with certainty the schedule for when we will, if at all, receive authorization from the FDA with respect to our PAS for BIVIGAM.

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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, the BTBU was our third-party manufacturer for RI-002. In the third quarter of 2015, the FDA accepted for review our BLA for RI-002 (the "RI-002 BLA") for the treatment of PIDD. In July 2016, the FDA issued a CRL (the "RI-002 CRL"). The RI-002 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 RI-002 BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002. The FDA identified in the RI-002 CRL, among other things, certain outstanding inspection issues and deficiencies related to 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 RI-002 CRL that it cannot grant final approval of our RI-002 BLA until, among other things, these deficiencies are resolved. Upon the completion of the Biotest Transaction, we gained control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility. In the first quarter of 2018, we produced required conformance lots using the ADMA optimized IVIG manufacturing process, and these batches were filled and finished, have been placed on stability and are currently under FDA review. In April 2018, we completed an FDA inspection and as a result of the inspection, our Boca Facility's regulatory compliance status improved from Official Action Indicated ("OAI") to Voluntary Action Indicated ("VAI"), allowing us to submit regulatory applications to the FDA for review. Following our BLA resubmission in September 2018, in October 2018, we received a PDUFA date of April 2, 2019 for FDA action on the RI-002 BLA.

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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. 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.

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 Serious Bacterial Infections ("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.

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.

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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 600 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.

We have a PDUFA date of April 2, 2019 for RI-002 and we have been in ongoing communication with the FDA regarding the BIVIGAM PAS and the BIVIGAM CRL. We have initiated efforts to internally prepare for commercialization of our product candidates, if and when the RI-002 BLA and BIVIGAM PAS are approved, and have continued commercialization efforts to generate increased market awareness for Nabi-HB by attending and presenting at medical conferences, as well as sponsoring medical education symposiums. Upon FDA approval of either the BIVIGAM PAS or RI-002 BLA, we plan to bolster these efforts and initiatives by hiring a small, specialty sales force to market BIVIGAM upon its re-launch 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 and regional distributors to assist with order fulfillment for BIVIGAM and RI-002 for use by healthcare professionals and hospitals.

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Pharmaceutical Pricing and Reimbursement of Our Products

All sales in the U.S. of Nabi-HB, BIVIGAM and RI-002, if and when approved by the FDA, 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 Operations

ADMA Bio Centers operates an FDA-licensed source plasma collection facility located in Kennesaw, GA which provides us with a portion of our blood plasma for the manufacture of our products and product candidates. As part of our plans for expansion, we are looking to initiate the buildout of additional plasma centers in the U.S. A typical plasma collection center, such as those operated by ADMA Bio Centers, 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 Bio Centers' 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 transferred ownership of two of our plasma collection facilities to BPC on January 1, 2019.

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 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:

- **Work with the FDA to close-out the Warning Letter.** Following the FDA inspection in April 2018 and the subsequent inspection report close-out with the Boca Facility status classification improvement to VAI, we continue to operate the Boca Facility in compliance with FDA regulations and with ongoing continuous improvements to our quality management systems and enhancements to our manufacturing processes, while releasing commercial drug product. We continue to work with the FDA to officially close-out the Warning Letter status to the Boca Facility. However, the VAI inspection status of the Boca Facility permits substantive reviews to occur.

- **Increase marketing efforts around Nabi-HB.** We plan to increase our marketing efforts and attend relevant medical conferences during 2019, raising awareness of the risks associated with Hepatitis B and the benefits and efficacy of Nabi-HB in its indicated populations.

- **Obtain FDA approval for the BIVIGAM PAS and re-launch.** If we are successful in obtaining FDA approval of the drug substance PAS, which details our optimized BIVIGAM manufacturing process, we plan to re-launch BIVIGAM in the U.S. During the second half of 2018, we filed the PAS seeking FDA authorization which, if obtained, would enable us to resume commercial manufacturing and re-launch and commercialize this product. On December 19, 2018, we received the BIVIGAM CRL from the FDA for our PAS submission for BIVIGAM drug substance. The BIVIGAM CRL requested certain additional information and clarifications related to CMC matters contained in our PAS submission for drug substance, including complete resolution of certain manufacturing related deviations, information pertaining to how certain in-process manufacturing samples are taken, as well as updates on certain stability data previously submitted. As the information we believed necessary to address and respond to the matters raised in the BIVIGAM CRL was readily available in our files, on January 7, 2019 we announced that our responses to the BIVIGAM CRL were submitted to the FDA for further review. Subsequent to the January 7, 2019 resubmission to the FDA, we received an information request for a limited number of questions. We believe that all requests contained in the recently received FDA information request were addressable and we have responded to the FDA. To date, we have not received a formal BIVIGAM CRL resubmission acknowledgment and we have not received formal clarity on the FDA's intended review timing. We can confirm that the FDA is actively reviewing our BIVIGAM CRL resubmission and information request responses, however we cannot provide any assurance or predict with certainty the schedule for when we will, if at all, receive authorization from the FDA with respect to the PAS.

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- **Obtain FDA approval of RI-002 as a treatment for PIDD**. In the third quarter of 2015, the FDA accepted for review the RI-002 BLA for the treatment of PIDD. In July 2016, the FDA issued the RI-002 CRL. The RI-002 CRL did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in the RI-002 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 and receiving an inspection close-out by the FDA, we submitted the RI-002 BLA for review and in October 2018, we received an FDA target action PDUFA date of April 2, 2019.

- **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.

- **Increase the Boca Facility's manufacturing capacity.** During 2019, we plan to execute on our capacity optimization plan to increase the Boca Facility's manufacturing capacity.

- **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 Bio Centers**. In order to maintain partial control of our raw material supply as well as generate revenues through additional sources, we operate ADMA Bio Centers, a subsidiary that was established to operate plasma collection facilities in the U.S. Our facility in Kennesaw, GA holds an FDA license, under which we 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 plasma collection facilities in various regions of the U.S. We believe additional plasma collection facilities will 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.

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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.

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.

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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.

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 600 plasma donation centers in the U.S. As noted in a variety of plasma industry trade reports and related conferences, approximately 42 million liters of source plasma were collected in the U.S. in 2017. 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)*.

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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.

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 $21 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.

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 Bio Centers operates an FDA-licensed source plasma collection facility located in Kennesaw, GA. which provides 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 Bio Centers, 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 Bio Centers' 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 entered into a Termination Agreement with BPC 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.

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Pursuant to the terms of a plasma purchase agreement with BPC, dated as of November 17, 2011 (the "2011 Plasma Purchase Agreement"), 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 plasma collection facilities. During 2015, we amended the 2011 Plasma Purchase Agreement with BPC to allow us the ability to collect our raw material RSV high-titer plasma from other third-party collection organizations, thus allowing us to expand our reach for raw material supply as we approach commercialization for RI-002. Unless terminated earlier, the 2011 Plasma Purchase Agreement expires in June 2027, after which it may be renewed for two additional five-year periods if agreed to by the parties. As part of the closing of the Biotest Transaction, we amended the 2011 Plasma Purchase Agreement to extend the initial term through the ten year anniversary of the closing date of the Biotest Transaction. On December 10, 2018, BPC assigned its rights and obligations under the 2011 Plasma Purchase Agreement to Grifols Worldwide Operations Limited ("Grifols") as its successor-in-interest, effective January 1, 2019. On January 1, 2019, Grifols and ADMA entered into an additional amendment to the 2011 Plasma Purchase Agreement for the purchase of source plasma containing antibodies to RSV from Grifols. Pursuant to this amendment, until January 1, 2022, we may purchase RSV plasma from Grifols from the two previously owned ADMA plasma collection facilities which we transferred to BPC on January 1, 2019 at a price equal to cost plus five percent (5%) (without any additional increase due to inflation).

On March 23, 2016, we entered into an Amended and Restated Plasma Supply Agreement with BPC for the purchase by BPC of normal source plasma to be derived from automated plasmapheresis procedures conducted at the formerly owned ADMA Bio Centers' Norcross, GA and Marietta, GA facilities to be used in BPC's proprietary products' manufacturing (the "Amended and Restated Plasma Supply Agreement"). Under the Amended and Restated Plasma Supply Agreement, BPC obtained GHA certification of the two bio centers which we transferred to BPC on January 1, 2019. The initial term of the Amended and Restated Plasma Supply Agreement expired by its terms on December 31, 2018 and was not renewed.

On June 6, 2017, we entered into a Plasma Supply Agreement with BPC pursuant to which BPC supplies, on an exclusive basis subject to certain exceptions, to ADMA BioManufacturing an annual minimum volume of hyperimmune plasma that contain antibodies to the hepatitis B virus for the manufacture of Nabi-HB. The Plasma Supply Agreement has a 10-year term. On July 19, 2018, we entered into an amendment to the Plasma Supply Agreement with BPC to, among other things, that in the event BPC elects not to supply in excess of ADMA BioManufacturing's specified amount of Hepatitis B plasma and ADMA BioManufacturing is unable to secure Hepatitis B plasma from a third party at a price which is within a low double digit percentage of the price which ADMA BioManufacturing pays to BPC, then BPC shall reimburse ADMA BioManufacturing for the difference in price ADMA BioManufacturing incurs. On December 10, 2018, BPC assigned its rights and obligations under the Plasma Supply Agreement to Grifols, effective January 1, 2019.

On June 6, 2017, we entered into a Plasma Purchase Agreement with BPC (the "2017 Plasma Purchase Agreement"), pursuant to which ADMA BioManufacturing purchases normal source plasma from BPC at agreed upon annual quantities and prices. The 2017 Plasma Purchase Agreement has an initial term of five years after which the 2017 Plasma Purchase Agreement may be renewed for additional two terms of two years each upon the mutual written

consent of the parties. On July 19, 2018, we entered into an amendment to the 2017 Plasma Purchase Agreement with BPC to, among other things, provide agreed upon amounts of normal source plasma to be supplied by BPC to ADMA BioManufacturing in calendar year 2019 at a specified price per liter, provided that ADMA BioManufacturing delivers a valid purchase order to BPC. Additionally, pursuant to the amendment to the 2017 Plasma Purchase Agreement, BPC agrees that, for calendar years 2020 and 2021, it shall supply no less than a high double digit percentage of ADMA BioManufacturing's requested NSP amounts, provided that such requested normal source plasma amounts are within an agreed range, at a price per liter to be mutually determined. Furthermore, pursuant to the amendment to the 2017 Plasma Purchase Agreement, in the event BPC fails to supply ADMA BioManufacturing with at least a high double digit percentage of ADMA BioManufacturing's requested normal source plasma amounts, BPC shall promptly reimburse ADMA BioManufacturing the difference in price ADMA BioManufacturing incurs due to BPC's election not to supply NSP to ADMA BioManufacturing in such amounts as requested. On December 10, 2018, BPC assigned its rights and obligations under the Plasma Purchase Agreement to Grifols, effective January 1, 2019.

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Marketing, Sales and Market Research

We intend to market and sell our product through our specialty sales force, distribution relationships and other customary industry methods. We will focus our efforts specifically on the easily identifiable treatment centers which specialize in the care and management of immune compromised individuals. We estimate that there are approximately 500 leading specialty programs in the U.S. which have significant patient populations for PIDD, suitable for treatment with RI-002. We plan to hire our own specialty sales force which will consist of account managers, medical science liaisons and other normal and customary scientific, medical and detail representatives. Our management and Board has substantial prior direct marketing, sales and distribution experience with plasma derived drugs, specialty immune globulins and other biological products. We also anticipate staffing the company with additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, third-party reimbursement, supply chain and logistics, human resources, financial and other operational management positions. As is customary in the plasma products industry, we may also use a network of national distribution organizations that have specialty divisions that focus on plasma products to fulfill orders for RI-002. We anticipate that due to certain recent events, our current and anticipated plans and intentions will evolve and change. See “Special Note Regarding Forward-Looking Statements.”

On June 6, 2017, we entered into a Termination Agreement with BPC 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 related 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. Pursuant to our Manufacturing, Supply and License Agreement, we granted Biotest an exclusive license to market and sell RI-002 in Europe and in selected countries in North Africa and the Middle East (the “Territory”), to have access to our testing services for testing of BPC’s plasma samples using our proprietary RSV assay, and to reference (but not access) our proprietary information for the purpose of Biotest seeking regulatory approval for the RI-002 in the Territory. As consideration for the license, Biotest provided us with certain services at no charge and also compensated us with cash payments upon the completion of certain milestones. Biotest was also obligated to pay us an adjustable royalty based on a percentage of revenues from the sale of RI-002 in the Territory for 20 years from the date of first commercial sale.

Major Customers

BPC, McKesson Corporation and AmerisourceBergen represented 56%, 16% and 15%, respectively, of our total 2018 revenue and the loss of BPC, McKesson Corporation or AmerisourceBergen as a customer or a material change in the revenue generated by any of these customers could have a material adverse effect on our business, results of operations and financial condition. As discussed above, the initial term of the Amended and Restated Plasma Supply Agreement with BPC, pursuant to which we supplied BPC with normal source plasma, expired by its terms on December 31, 2018 and was not renewed.

Competition

The plasma products industry is highly competitive. We face, and will continue to face, intense competition from both U.S.-based and foreign producers of plasma products, some of which have lower cost structures, greater access to capital, greater resources for research and development, and sophisticated marketing capabilities.

These competitors may include but are not limited to: CSL Behring, Grifols Biologicals, Takeda-Shire, Octapharma and Kedrion. In addition to competition from other large worldwide plasma products providers, we face competition in local areas from smaller entities. In Europe, where the industry is highly regulated and health care systems vary from country to country, local companies may have greater knowledge of local health care systems, more established infrastructures and have existing regulatory approvals or a better understanding of the local regulatory process, allowing them to market their products more quickly. Moreover, plasma therapy generally faces competition from non-plasma products and other courses of treatments. For example, recombinant Factor VIII products compete with plasma-derived products in the treatment of Hemophilia A.

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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 our RI-002 product, 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 compositions comprising pooled plasma, as well as immunoglobulin prepared therefrom, that contains a standardized, elevated titer of RSV neutralizing antibodies as well as elevated levels of antibodies specific for one or more other respiratory pathogens, as well as methods of making and using the compositions. Our proprietary methods allow us to effectively identify and isolate donor plasma with high-titer RSV neutralizing antibodies and to standardize RI-002’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 ADMA’s investigational drug candidate RI-002, that contains elevated, neutralizing antibody titers to RSV as well as elevated antibody titers to other respiratory pathogens, such as influenza virus, coronavirus, parainfluenza virus, and metapneumovirus. The term of the issued patent extends to January 2035.

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.

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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.

Government Regulation and Product Approval

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon, among other things, the testing (preclinical and clinical), manufacturing, labeling, storage, recordkeeping, advertising, promotion, import, export, marketing and distribution of products and product candidates. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products and we may be criminally prosecuted. We and our manufacturers may also be subject to regulations under other federal, state and local laws.

U.S. Government Regulation

In the U.S., the FDA regulates products under the Federal Food, Drug, and Cosmetic Act (the “FDCA”) and related regulations. Our current and anticipated future product candidates are considered “biologics” under the FDA regulatory framework. The FDA's regulatory authority for the approval of biologics resides in the Public Health Service Act. However, biologics are also subject to regulation under the FDCA because most biological products also meet the FDCA’s definition of "drugs." Most pharmaceuticals or “conventional drugs” consist of pure chemical substances and their structures are known. Most biologics, however, are complex mixtures that are not easily identified or characterized. Biological products differ from conventional drugs in that they tend to be heat-sensitive and susceptible to microbial contamination. This requires sterile processes to be applied from initial manufacturing steps. The process

required by the FDA before our product candidates may be marketed in the U.S. generally involves the following (although the FDA is given wide discretion to impose different or more stringent requirements on a case-by-case basis):

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies performed in accordance with the FDA's good laboratory practice regulations and other regulations;

- submission to the FDA of an Investigational New Drug ("IND") application which must become effective before clinical trials may begin;

- performance of adequate and well-controlled clinical trials meeting FDA requirements to establish the safety and efficacy of the product candidate for each proposed indication;

- manufacturing (through an FDA-licensed contract manufacturing organization) of product in accordance with cGMP to be used in the clinical trials and providing manufacturing information need in regulatory filings;

- submission of a BLA to the FDA;

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- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product candidate is produced, and potentially other involved facilities as well, to assess compliance with cGMP regulations and other applicable regulations; and

- the FDA review and approval of a BLA prior to any commercial marketing, sale or shipment of the product.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. See “Item 1A Risk Factors” appearing elsewhere in this Annual Report.

We submit manufacturing and analytical data, among other information, to the FDA as part of an IND application. Subject to certain exceptions, an IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, issues a clinical hold to delay a proposed clinical investigation due to concerns or questions about the product or the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND, or those of our collaboration partners, may not result in the FDA allowance to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. The FDA must also approve certain changes to an existing IND, such as certain manufacturing changes. Further, an independent institutional review board (“IRB”) duly constituted to meet FDA requirements for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the safety of the study and study subjects until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice requirements and regulations for informed consent.

Clinical Trials

For purposes of BLA submission and approval, clinical trials are typically conducted in the following three sequential phases, which may overlap (although additional or different trials may be required by the FDA as well):

- Phase I clinical trials are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients.

- Phase II clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product candidate for specific targeted indications and to determine

tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials.

- Certain Phase III clinical trials are referred to as pivotal trials. When Phase II clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to provide substantial evidence of reproducibility of clinical efficacy results and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

In addition, under the Pediatric Research Equity Act of 2003, a BLA application or supplement for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain data that is adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the applicant has obtained a waiver or deferral. In 2012, the Food and Drug Administration Safety and Innovation Act amended the FDCA to require that a sponsor who is planning to submit such an application submit an initial Pediatric Study Plan ("PSP") within sixty days of an end-of-phase 2 meeting or as may be agreed between the sponsor and the FDA. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers. The FDA and the sponsor must reach agreement on the PSP.

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In some cases, the FDA may condition continued approval of a BLA on the sponsor's agreement to conduct additional clinical trials, or other commitments. Such post-approval studies are typically referred to as Phase IV studies.

Biologics License Application

The results of product candidate development, preclinical testing and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, and the payment of a user fee, are submitted to the FDA as part of a BLA. The FDA reviews all BLAs submitted before it accepts them for filing and may reject the filing as inadequate to merit review or may request additional information to be submitted in a very short time frame before accepting a BLA for filing. Once a BLA is accepted for filing, the FDA begins an in-depth review of the application.

During its review of a BLA, the FDA may refer the application to an advisory committee of experts for their review, evaluation and recommendation as to whether the application should be approved, which information is taken into consideration along with the FDA's own review findings. The FDA may refuse to approve a BLA and issue a CRL if the applicable regulatory criteria are not satisfied or the FDA has additional open questions for which it requires clarification. A CRL may also require additional clinical or other data, including one or more additional pivotal Phase III clinical trials. Even if such requested data are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval and issue a denial of the BLA. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we do. If the FDA's evaluations of the BLA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue an approval letter; if the evaluations are not favorable the FDA will issue a CRL, which may contain the conditions that must be met in order to secure final approval of the BLA. If a CRL is issued, a company has up to twelve months to resubmit or withdraw the BLA, unless the FDA allows for an extension as requested by a sponsor. If a CRL is issued, resubmissions for original applications and supplements of different types are subject to varying agency review procedures and review timing goals. For example, upon the resubmission of an original BLA application or efficacy supplement, the Center for Biologics Evaluation and Research (CBER)'s written Standard Operating Policy and Procedure (SOPP) 8405.1 states that it will classify the resubmission as either Class 1 (triggering a two-month review goal for the FDA) or Class 2 (triggering a six-month review goal for the FDA) depending on the circumstances, and in this SOPP CBER stated goal for review of manufacturing and labeling supplement resubmissions for PDUFA BLAs is (using the timeframes referenced in 21 C.F.R.§ 314.110(b)(1)(iii)) to review them within the same timeframe as the initial review cycle for the supplement (excluding any extension due to a major amendment of the initial supplement) (for example, under the FDA's published PDUFA goals for fiscal years 2018 – 2022, a goal of acting on 90% of manufacturing PASs within four months of receipt). In practice, FDA reviews may take longer than the stated goals. If and when the items identified in a CRL have been resolved to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the product for certain indications. The FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV post-approval clinical trials, and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Products may be marketed only for the FDA-approved indications and in accordance with the FDA-approved label. The FDA generally does not allow drugs

to be promoted for “off-label” uses – that is, uses that are not described in the product’s approved labeling and that differ from those that were approved by the FDA. Furthermore, the FDA generally limits approved uses to those studied in clinical trials. If there are any modifications to the product, including changes in indications, other labeling changes, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require us to develop additional data or conduct additional preclinical studies and clinical trials, and/or require additional manufacturing data.

Satisfaction of the FDA regulations and approval requirements or similar requirements of foreign regulatory agencies typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Typically, if a product candidate is intended to treat a chronic disease, as is the case with RI-002, safety and efficacy data must be gathered over an extended period of time. Government regulation may delay or prevent marketing of product candidates for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for changes in dose form or new indications for a product candidate on a timely basis, or at all. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain, regulatory approvals for any of our product candidates would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

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Other Regulatory Requirements

Biological drug products manufactured or distributed pursuant to FDA approvals are subject to extensive and continuing regulation by the FDA, including, among other things, requirements related to recordkeeping (including certain electronic record and signature requirements), periodic reporting, product sampling and distribution, advertising and promotion and reporting of certain adverse experiences, deviations, and other problems with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

Manufacturers must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Manufacturers and certain other entities involved in the manufacturing and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release. For biologics products in particular, for each product lot the applicant must submit materials related to that lot to the FDA before the lot can be released for distribution.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

The FDA may impose a number of post-approval requirements as a condition of approval of an application. The FDA may withdraw a product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, problems with manufacturing processes or failure to comply with regulatory requirements, may result in restrictions on the product or even complete withdrawal of the product from the market. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to

possible legal or regulatory action, such as warning letters, suspension of manufacturing, sales or use, seizure of product, injunctive action or possible fines and other penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a product from distribution, or withdraw approval of our BLA for that product.

The FDA closely regulates the post-approval marketing and promotion of products, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning and/or other regulatory letters, corrective advertising and potential major fines and other penalties.

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The commercial distribution of prescription drugs (including biological drug products) is subject to the Drug Supply Chain Security Act ("DSCSA"), which regulates the distribution of the products at the federal level, and sets certain standards for federal or state registration and compliance of entities in the supply chain (manufacturers and repackagers, wholesale distributors, third-party logistics providers, and dispensers). The DSCSA preempts previously enacted state pedigree laws and the pedigree requirements of the Prescription Drug Marketing Act ("PDMA"). Trading partners within the drug supply chain must now ensure certain product tracing requirements are met, and are required to exchange transaction information, transaction history, and transaction statements. Further, the DSCSA limits the distribution of prescription pharmaceutical products and imposes requirements to ensure overall accountability and security in the drug supply chain. The distribution of product samples continues to be regulated under the PDMA.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance, and policies are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Regulation of ADMA Bio Centers

All blood and blood product collection and manufacturing centers which engage in interstate commerce must be licensed by the FDA. In order to achieve licensure, the organization must submit a BLA and undergo pre-licensure inspection. ADMA Bio Centers has completed these requirements and holds an FDA license for its Kennesaw, GA plasma collection facility. In order to maintain an FDA license, each such facility operated by ADMA Bio Centers will be inspected at least every two years. ADMA Bio Centers is also required to submit annual reports to the FDA.

Blood plasma collection and manufacturing centers are also subject to the Clinical Laboratory Improvement Amendments, state licensure and compliance with industry standards such as the International Quality Plasma Program. Compliance with state and industry standards is verified by means of routine inspection. We believe that our ADMA Kennesaw, GA facility is currently in compliance with state and industry standards. Delays in obtaining, or failures to maintain, regulatory approvals for any facilities operated by ADMA Bio Centers would harm our business. In addition, we cannot predict what adverse federal and state regulations and industry standards may arise in the future.

Foreign Regulation

In addition to regulations in the U.S., if we choose to pursue clinical development and commercialization in the European Union, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of any future product. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval, refuse it or request additional information.

Product Coverage, Pricing and Reimbursement

Significant uncertainties exist as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the U.S., sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payers. Third-party payers include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payer will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payer will pay for the drug product. Third-party payers may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Moreover, a payer’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

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Third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. If third-party payers do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the Healthcare Reform Law contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on cost containment measures in the U.S. has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Employees

As of December 31, 2018, we had a total of 318 employees, comprised of 314 full-time employees and four part-time employees. Over the course of the next year, we anticipate hiring additional full-time employees devoted to sales and marketing, medical and scientific affairs, general and administrative, as well as hiring additional staff to the plasma collection centers as appropriate. We intend to use Clinical Research Organizations(" CROs"), third parties and consultants to perform our clinical studies and manufacturing, regulatory affairs and quality control services in addition to corporate marketing, branding and commercialization activities.

Corporate Information

ADMA Biologics, Inc. was founded on June 24, 2004 as a New Jersey corporation and re-incorporated in Delaware on July 16, 2007. We operate through our wholly-owned subsidiaries ADMA Plasma Biologics, ADMA BioManufacturing and ADMA Bio Centers. ADMA BioManufacturing was formed in January 2017 to facilitate the acquisition of BTBU. ADMA Bio Centers is the Company's source plasma collection business which operates in the U.S. Each operational ADMA bio center, once approved, will have a license with the FDA and may obtain additional certifications from other regulatory agencies such as the GHA and the Korean Ministry of Food and Drug Safety. ADMA Bio Centers' facility supplies ADMA with a portion of its raw material plasma for the manufacture of its products and product candidates.

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We maintain our headquarters at 465 State Route 17, Ramsey, NJ 07446. Our telephone number is (201) 478-5552. Our Florida campus is located at 5800 Park of Commerce Boulevard, Northwest, Boca Raton, FL 33487. The Florida telephone number is (561) 989-5800. We maintain a website at www.admabiologics.com; however, the information on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. This Annual Report and all of our filings under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including copies of Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports, are available free of charge through our website on the date we file those materials with, or furnish them to, the U.S. Securities and Exchange Commission (the "SEC"). Such filings are also available to the public on the internet at the SEC's website at www.sec.gov.

Item 1A. Risk Factors

Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected. You should carefully consider the following risk factors and the section entitled "Special Note Regarding Forward-Looking Statements" before you decide to invest in our securities.

Risks Relating to our Business

To date, we have generated limited product revenues, have a history of losses and will need to raise additional capital to operate our business, which may not be available on favorable terms, if at all.

To date, we have generated a substantial portion of our revenues from the sale of plasma by our plasma collections facilities. Following completion of the Biotest Transaction, we began generating revenues from the sale of Nabi-HB, and we recorded additional revenue in connection with a contract manufacturing agreement. Unless and until we receive approval from the FDA and other regulatory authorities for BIVIGAM and RI-002 and other products and product candidates in our pipeline, we do not expect to sell and generate revenue from the commercialization of BIVIGAM or RI-002 and other products and product candidates in our pipeline, and we will be required to raise additional funds through the sale of our equity and/or debt securities in order to establish a commercial sales force, develop our commercial infrastructure and recognize any significant revenues.

Our long-term liquidity will depend upon our ability to raise additional capital, fund our research and development and commercial programs, establish and build out a commercial sales force and commercial infrastructure and meet our ongoing obligations. If we are unable to successfully raise additional capital by the fourth quarter of 2019, we will likely not have sufficient cash flow and liquidity to fund our business operations as we currently operate, forcing us to potentially curtail our activities and significantly reduce or cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, resulting in significant dilution of stockholders' interests and, in such event, the value and potential future market price of our Common Stock may decline. In addition, if we raise additional funds through license arrangements or through the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or assets or grant licenses on terms that are not favorable to us.

Based upon our projected revenue and expenditures for fiscal 2019, including continued implementation of our commercialization and expansion activities and certain other assumptions, we currently believe that our cash, cash equivalents, projected revenue and accounts receivable, along with the additional $27.5 million we anticipate being able to draw down through our existing senior credit facility (see “Management’s Discussion and Analysis of Financial Condition and Results of Operations”), which is contingent upon, among other things, the FDA approval of either the BIVIGAM PAS or the RI-002 BLA, will be sufficient to fund our operations, as currently conducted, into the fourth quarter of 2019. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing by the fourth quarter of 2019. However, if we do not receive FDA approval of either the BIVIGAM PAS or the RI-002 BLA, we believe that our cash balance will be sufficient to fund our operations, as currently conducted, into the third quarter of 2019, and we will be required to raise additional capital by the third quarter of 2019. This timeframe may change based upon how quickly we are able to execute on our ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options we are exploring. These estimates may change based upon whether or when the FDA approves BIVIGAM or RI-002 or if any of our other assumptions change. We currently do not have arrangements to obtain additional financing. Any such financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution to stockholders. Failure to secure necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan and financial performance and could delay, discontinue or prevent product development, clinical trials, commercialization activities or the approval of any of our potential products. In addition, we could be forced to reduce or forgo sales and marketing efforts and forgo attractive business opportunities.

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Failure to timely and effectively remediate and close out the outstanding Warning Letter and other inspection issues and deficiencies at the Boca Facility will have a material adverse effect on our business.

Prior to the closing of the Biotest Transaction, BTBU was our third-party manufacturer for RI-002. In response to our RI-002 BLA submission in 2015, in July 2016 the FDA issued the CRL. The CRL did not specify or request the need for any addition clinical trials or data; however, the CRL reaffirmed the issues set forth in the Warning Letter issued to Biotest relating to inspection issues identified at the Boca Facility. The FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies related to CMC and 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 RI-002 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 one of our highest priorities is to close out the Warning Letter. In June 2017, 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 cGMP issues and deficiencies. In April 2018, the FDA inspected the Boca Facility and in July 2018 our FDA status improved from OAI to VAI and this inspection of the Boca Facility has been successfully closed-out as indicated on the FDA's website inspection database. Upon our receiving FDA compliance status, we responded to the RI-002 CRL through resubmitting the RI-002 BLA on September 28, 2018 and the FDA assigned a PDUFA action due date of April 2, 2019. Upon approval of the RI-002 BLA by the FDA, we intend to commercialize RI-002. We cannot provide any assurances or predict with certainty the schedule for when we will, if at all, receive approval from the FDA for the RI-002 BLA. Similarly, there can be no assurances that our efforts to remediate the Warning Letter will be effective or whether the FDA will accept these efforts. Failure to timely remediate the issues identified in the Warning Letter and other inspection issues and deficiencies and/or receive approval from the FDA, as well as passing an FDA inspection within this timeline, if at all, will have a material adverse effect on our business, prospects, financial condition and results of operations. We may be issued additional 483 observations, Warning Letters or have other negative regulatory actions taken against us should we be found to be noncompliant.

We are currently not profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. For the years ended December 31, 2018 and 2017, we incurred net losses of $65.7 and $43.8 million, respectively, and from our inception in 2004 through December 31, 2018, we have incurred an accumulated deficit of $216.4 million. Even if we succeed in developing and commercializing one or more of our products and product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our operating expenses will increase substantially in the foreseeable future as we:

- remediate the outstanding compliance deficiencies identified by the FDA in the CRL and Warning Letter at the Boca Facility;

- seek regulatory approval(s);

- initiate commercialization and marketing efforts;

- implement additional internal systems, controls and infrastructure;

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- hire additional personnel;

- expand and build out our plasma center network; and

- expand production capacity at the Boca Facility.

We also expect to experience negative cash flows for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our securities.

Although our financial statements have been prepared on a going concern basis, we must raise additional capital by the second half of 2019 to fund our operations in order to continue as a going concern.

CohnReznick LLP, our independent registered public accounting firm, has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2018, indicating that our current liquidity position and history of losses raise substantial doubt about our ability to continue as a going concern. If we are unable to improve our liquidity position we may not be able to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements. We may also be forced to make reductions in spending, including delaying or curtailing our clinical development, trials or commercialization efforts, or seek to extend payment terms with our vendors and creditors. Our ability to raise or borrow the capital needed to improve our financial condition may be hindered by a variety of factors, including market conditions and the availability of such financing on acceptable terms, if at all. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge our liabilities other than in the normal course of business, which could cause our security holders to suffer the loss of all or a substantial portion of their investment.

We anticipate that our principal sources of liquidity will only be sufficient to fund our activities, as currently conducted, into the fourth quarter of 2019. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing by the fourth quarter of 2019. However, if we do not receive FDA approval of either the BIVIGAM PAS or the RI-002 BLA, we believe that our cash balance will be sufficient to fund our operations, as currently conducted, into the third quarter of 2019, and we will be required to raise additional capital by the third quarter of 2019. This time frame may change based upon how quickly we are able to execute on our quality management systems' remediation plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options we are

exploring. In order to have sufficient cash to fund our operations thereafter, we will need to raise additional equity or debt capital, and we cannot provide any assurance that we will be successful in doing so. If our assumptions underlying our estimated expenses prove to be wrong, we may have to raise additional capital sooner than the second half of 2019.

We have a limited operating history upon which to base an investment decision.

We have not demonstrated an ability to perform the functions necessary for the successful commercialization of RI-002. The successful development and commercialization of any product candidate will require us or our collaborators to perform a variety of functions, including:

- undertaking product development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities once product approval is received.

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Our operations thus far provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

Business interruptions could adversely affect our business.

Our operations, including our headquarters located in Ramsey, NJ, the Boca Facility and our Kennesaw, GA plasma collection center, are vulnerable to interruption by fire, weather related events such as hurricanes, wind and rain, other acts of God, electric power loss, telecommunications failure, equipment failure and breakdown, human error, employee issues, product liability claims and events beyond our control. While we maintain several insurance policies with reputable carriers, which we believe are in acceptable amounts and contain market terms common within the industry which provide adequate coverage for a variety of these risks, including replacing or rebuilding a substantial part of our facilities, these policies are subject to the insurance carriers' final determination of compensation to us. In addition, our disaster recovery plans for our facilities may not be adequate and we do not have an alternative manufacturing facility or contractual arrangements with other manufacturers in the event of a casualty to or destruction of any of our facilities. If we are required to rebuild or relocate any of our facilities, a substantial investment in improvements and equipment would be necessary. We carry only a limited amount of business interruption insurance, which may not sufficiently compensate us for losses that may occur. As a result, any significant business interruption could adversely affect our business and results of operations.

Our lead pipeline product candidate, RI-002, requires extensive clinical data analysis and regulatory review and may require additional testing. Clinical trials and data analysis can be very expensive, time-consuming and difficult to design and implement. If we are unsuccessful in obtaining regulatory approval for RI-002, or any of our product candidates do not provide positive results, we may be required to delay or abandon development of such product, which would have a material adverse impact on our business.

Continuing product development requires additional and extensive clinical testing. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. While we have met the primary endpoint for our pivotal Phase III trial for RI-002, we cannot provide any assurance or certainty regarding when we might receive regulatory approval of our RI-002 BLA. Furthermore, failure can occur at any stage of the process, and we could encounter problems that cause us to abandon our RI-002 BLA or repeat clinical trials. The commencement and completion of clinical trials for any current or future development product candidate may be delayed by several factors, including:

- unforeseen safety issues;

- determination of dosing issues;

- lack of effectiveness during clinical trials;

- slower than expected rates of patient recruitment;

- inability to monitor patients adequately during or after treatment; and

- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, the FDA or an independent institutional review board may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. In the event we do not ultimately receive regulatory approval for RI-002, we may be required to terminate development of our only product candidate. Unless we acquire or develop other product candidates that are saleable, our business will be limited to plasma collection and sales, as well as sales of Nabi-HB and, potentially, manufacturing intermediates.

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If the results of our clinical trials do not support our product candidate claims, completing the development of such product candidate may be significantly delayed or we may be forced to abandon development of such product candidate altogether.

Even though our clinical trials for RI-002 have been completed as planned, we cannot be certain that their results will support our product candidate claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials involve a relatively small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results. In addition, certain portions of the clinical trial and product testing for RI-002 were performed outside of the U.S., and therefore, may not have been performed in accordance with standards normally required by the FDA and other regulatory agencies.

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.

If we cannot obtain regulatory approval for RI-002, we will not be able to generate revenue from this product candidate. As a result, our sources of revenue may continue to be from a product mix consisting only of plasma collection and sales revenues, revenues generated from sales of our FDA-approved commercial products, revenues generated from ongoing contract manufacturing for third parties and revenues generated from the sales of manufacturing intermediates. 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 product candidate requiring FDA approval, our clinical development must demonstrate that the product candidate is safe for humans and effective for its intended use, and we must successfully complete an FDA BLA review. Obtaining 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. 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 RI-002 BLA. In addition, the FDA could determine that we must test additional subjects and/or require that we conduct further studies with more subjects. We may never obtain regulatory approval for RI-002, or any other future potential product candidate or label expansion activity. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without the ability to generate additional accretive revenues. There is no guarantee that we will ever be able to develop or acquire other product candidates. In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any products or product candidates outside the U.S. Foreign regulatory approval processes generally include all of the risks and uncertainties 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 U.S.

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Even if we receive approval from the FDA to market RI-002 for PIDD, our ability to market RI-002 for alternative indications could be limited, unless additional clinical trials are conducted.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the Internet and off-label promotion. The FDA generally does not allow drugs to be promoted for "off-label" uses — that is, uses that are not described in the product's labeling and that differ from those that were approved by the FDA. Generally, the FDA limits approved uses to those studied by a company in its clinical trials. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. We have sought approval from the FDA to market RI-002 for the treatment of PIDD and, even if approved, we cannot be sure whether we will be able to obtain FDA approval for any desired future indications for RI-002.

While physicians in the U.S. may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling, and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote our products is narrowly limited to those indications that are specifically approved by the FDA. "Off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. Although recent court decisions suggest that certain off-label communications, such as truthful and non-misleading speech, may be protected under the First Amendment, the scope of any such protection is unclear, and there are still significant risks in this area as it is unclear how these court decisions will impact the FDA's enforcement practices, and there is likely to be substantial disagreement and difference of opinion regarding whether any particular statement is truthful and not misleading. Moreover, while we intend to promote our products consistent with what we believe to be the approved indication for our drugs, the FDA may disagree. If the FDA determines that our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines related to promotion and advertising may cause the FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our reputation and our business.

We depend on third-party researchers, developers and vendors to develop, manufacture and test RI-002 and our other products, and such parties are, to some extent, outside of our control.

We depend on independent investigators and collaborators, such as universities and medical institutions, contract laboratories, clinical research organizations, contract manufacturers and consultants to conduct our preclinical, clinical trials, CMC testing and other activities under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign

as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our product-development programs, or if their performance is substandard, the approval of our FDA application(s), if any, and our introduction of new products, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed. Additionally, any change in the regulatory compliance status of any of our vendors may impede our ability to receive approval for our product candidates.

Historically a single customer has accounted for a significant amount of our total revenue and, collectively with two other customers, represented 87% of our total revenue for the year ended December 31, 2018, and therefore the loss of any of these customers could have a material adverse effect on our business, results of operations and financial condition.

Historically, a significant amount of our total revenue is attributable to a single customer, BPC. For the year ended December 31, 2018, BPC, McKesson Corporation and AmerisourceBergen represented 56%, 16% and 15%, respectively, of our total revenue.

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The loss of any key customers or a material change in the revenue generated by any of these customers could potentially have a material adverse effect on our business, results of operations and financial condition. The initial term of our Amended and Restated Plasma Supply Agreement with BPC, pursuant to which we supplied BPC with normal source plasma, expired by its terms on December 31, 2018 and was not renewed. Factors that could influence our relationships with our customers include, among other things:

- our ability to sell our products at competitive prices;
- our ability to maintain features and quality standards for our products sufficient to meet the expectations of our customers; and
- our ability to produce and deliver a sufficient quantity of our products in a timely manner to meet our customers' requirements.

Additionally, an adverse change in the financial condition of BPC, McKesson Corporation or AmerisourceBergen could have a material adverse effect on our business and results of operations.

Issues with product quality and compliance could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.

Our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our products and services and assuring the safety and efficacy of our products. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue by us or by a third-party vendor in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully commercializing our current products and launching new products.

If physicians, payers and patients do not accept and use our current products or our future product candidates, our ability to generate revenue from these products will be materially impaired.

Even if the FDA approves a product made by ADMA Biologics, physicians, payers and patients may not accept and use it. Acceptance and use of our products will depend on a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products;
- cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or other healthcare payers; and
- the effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of our current and future products to find market acceptance would harm our business and could require us to seek additional financing or make such financing difficult to obtain on favorable terms, if at all.

Industry and other market data used in our periodic reports filed with the SEC and our other materials, including those undertaken by us or our engaged consultants, may not prove to be representative of current and future market conditions or future results.

Our periodic reports filed with the SEC and our other materials include statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties and surveys and studies we commissioned regarding the market potential for our current products as well as RI-002. Although we believe that such information has been obtained from sources believed to be reliable, neither the sources of such data, nor we, can guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. With respect to the information from third-party consultants, the results of this data represent the independent consultants' own methodologies, assumptions, research, analysis, projections, estimates, composition of respondent pool, presentation of data and adjustments, each of which may ultimately prove to be incorrect, and cause actual results and market viability to differ materially from those presented in any such report or other materials. Readers should not place undue reliance on this information.

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Our long-term success may depend on our ability to supplement our existing product portfolio through new product development or the in-license or acquisition of other new products and product candidates, and if our business development efforts are not successful, our ability to achieve profitability may be adversely impacted.

Our current product development portfolio consists primarily of RI-002 and label expansion activities for Nabi-HB and BIVIGAM. We have initiated small scale preclinical activities to potentially expand our current portfolio through new product development efforts or to in-license or acquire additional products and product candidates. If we are not successful in developing or acquiring additional products and product candidates, we will have to depend on our ability to raise capital for, and the successful development and commercialization of, RI-002, as well as the revenue we may generate from the sale of Nabi-HB, BIVIGAM, contract manufacturing, and intermediates and plasma attributable to the operations of ADMA Bio Centers, to support our operations.

Our ADMA Bio Centers operations collect information from donors in the U.S. that subjects us to consumer and health privacy laws, which could create enforcement and litigation exposure if we fail to meet their requirements.

Consumer privacy is highly protected by federal and state law. The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and their respective implementing regulations, impose, among other things, obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by covered entities and business associates. A “covered entity” is the primary type of HIPAA-regulated entity. Health plans/insurers, health care providers engaging in standard transactions (insurance/health plan claims and encounters, payment and remittance advice, claims status, eligibility, enrollment/disenrollment, referrals and authorizations, coordination of benefits and premium payments), and health care clearinghouses (switches that convert data between standard and non-standard data sets) are covered entities. A “business associate” provides services to covered entities (directly or as subcontractors to other business associates) involving arranging, creating, receiving, maintaining, or transmitting protected health information (“PHI”) on a covered entity’s behalf. In order to legally provide access to PHI to service providers, covered entities and business associates must enter into a “business associate agreement” (“BAA”) with the service provider PHI recipient. Among other things, HITECH made certain aspects of the HIPAA’s rules (notably the Security Rule) directly applicable to business associates – independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions. The Department of Health and Human Services Office of Civil Rights (“OCR”) has increased its focus on compliance and continues to train state attorneys general for enforcement purposes. OCR has recently increased both its efforts to audit HIPAA compliance and its level of enforcement, with one recent penalty exceeding $5 million.

While we are not a covered entity or business associa