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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2017

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

For the transition period from to

Commission File Number: 001-36728

ADMA BIOLOGICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**56-2590442**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

465 State Route 17, Ramsey, New Jersey 07446
(Address of Principal Executive Offices) (Zip Code)
Registrant's telephone number, including area code: **(201) 478-5552**

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

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

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

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

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ¨

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

ADMA BIOLOGICS, INC.

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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:

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

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

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

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

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

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

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

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

- our plans to increase our supplies of plasma;

- the potential indications for our product candidates;

- potential investigational new product applications;

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

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

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

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

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

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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.

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 BioCenters") and ADMA BioManufacturing, LLC, a Delaware limited liability company ("ADMA BioManufacturing").

Overview

We are a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and prevention of certain infectious diseases. Our targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons. We currently have two marketed products: Nabi-HB, indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen ("HBsAg"); and Bivigam, indicated for the treatment of primary humoral immunodeficiency. We are also developing a pipeline of plasma-derived therapeutics, including our lead pipeline product candidate, RI-002, for the treatment of Primary Immune Deficiency Disease ("PIDD"). Our products and product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients with or at risk for certain infectious diseases. Through ADMA BioCenters, we operate two United States Food and Drug Administration (the "FDA")-licensed, German Health Authority ("GHA") and Korean Ministry of Food and Drug Safety ("KMFDS")-certified source plasma collection facilities located in the U.S., which provide us with a portion of our blood plasma for the manufacture of our products and product candidates. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase and market conditions at the time of sale. Plasma collected from ADMA BioCenters' facilities that is not used to manufacture our products or product candidates is sold to third-party customers in the U.S., in other locations where we are approved globally under supply agreements or in the open "spot" market.

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

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

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

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

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Our Marketed Products

Nabi-HB

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

Bivigam

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

Our Lead Pipeline Product Candidate – RI-002

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

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

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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. In the U.S., sales of immune globulin products for all its uses were reported to be approximately $4.8 billion in 2014.

The RI-002 pivotal Phase III clinical trial was conducted as a single arm study in which patients were treated approximately once per month for a period of 12 months plus 90 days for follow up. Fifty-nine patients were enrolled in nine treatment centers in the U.S. The pivotal Phase III primary endpoint followed published FDA industry guidance, which provides for a reduction in the incidence of serious infections to less than one per year in each subject receiving IVIG. The secondary outcome was safety and included other pharmacokinetic ("PK") data collection points including antibody titers for certain agents, including RSV antibody levels at various time points after infusion.

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

On February 22, 2015, at the 2015 American Academy of Allergy, Asthma & Immunology Annual Meeting, scientific investigators reported on the secondary outcomes that included: a total of 93 days, or 1.66 days per patient per year lost from work or school due to infection; one hospitalization due to an infection of only five days duration in the entire study and IgG trough levels above those required by the FDA for IVIG products. Additionally, there was a marked increase in all of the measured specific anti-pathogen antibodies in PK subjects (n=31). The mean of maximum fold increases in specific antibody levels after infusion of RI-002 ranged from 1.9 fold (S. pneumonia type 19A) to 5.3 fold (RSV), which were statistically significant fold increases from the pathogen's specific measured baselines. The safety profile of RI-002 is comparable to that of other immunoglobulins.

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

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

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

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

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

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

Manufacturing and Supply of Our Products

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

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

Sales and Commercialization of Our Products

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

While we have been working towards remediating the Warning Letter and other CMC and GMP inspection deficiencies and eventually refiling our BLA resubmission for RI-002, we expect to continue our commercialization efforts for our approved products and plan to bolster these initiatives by hiring a small, specialty sales force to market Nabi-HB, Bivigam upon its relaunch and, upon approval by the FDA, RI-002 to hospitals, physician offices/clinics, and other specialty treatment organizations. We also anticipate staffing our company with additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, third-party reimbursement, inventory and logistics, human resources and financial and operational management. If and when we receive FDA approval, we may also use a network of national distributors to assist with order fulfillment for RI-002 for use by healthcare professionals and hospitals.

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Pharmaceutical Pricing and Reimbursement of Our Products

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

Plasma Collection Facilities

ADMA BioCenters operates FDA-licensed, GHA and KMFDS certified source plasma collection facilities located in the U.S. which provide us with a portion of our blood plasma for the manufacture of our products and product candidates. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase, and market conditions at the time of sale. Plasma collected from ADMA BioCenters' facilities that is not used to manufacture our products or product candidates are sold to third-party customers in the U.S. and other locations where we are approved globally under supply agreements or in the open "spot" market.

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

Leadership

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

Our Strategy

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

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

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

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

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

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

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

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

The Plasma Industry

Primary Immunodeficiency Disease

PIDD is a class of hereditary disorders characterized by defects in the immune system, due to either a lack of necessary antibodies or a failure of these antibodies to function properly. According to the World Health Organization, there are over 150 different presentations of PIDD. As patients suffering from PIDD lack a properly functioning immune system, they typically receive monthly, outpatient infusions of IVIG therapy. Without this exogenous antibody immune support, these patients would be susceptible to a wide variety of infectious diseases. PIDD has an estimated prevalence of 1:1,200 in the U.S., or approximately 250,000 people. Of these 250,000 people diagnosed with PIDD in the U.S., approximately 125,000 receive monthly infusions of IVIG and it is estimated that over 300,000 patients worldwide receive monthly IVIG infusions for PIDD.

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

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

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

RI-002, our IVIG product candidate, contains polyclonal antibodies against various infectious agents, such as streptococcus pneumoniae, H. influenza type B, CMV, measles and tetanus, including standardized antibodies against RSV. RSV is a common respiratory virus that often presents during the winter months. Nearly all children will have been infected with RSV by three years of age; however, the immune systems of most healthy children prevent significant morbidity and mortality. Conversely, in patients who are immune-compromised, such as those with PIDD or who have undergone a hematopoietic stem cell or solid organ transplant and may be on immunosuppressive drugs or chemotherapy, RSV infection can be associated with significant morbidity and mortality. Immune-compromised patients historically have a 5% to 15% rate of RSV infection, and, if left untreated, lower respiratory tract RSV infections in immune-compromised patients can result in a mortality rate of up to 40% of infected patients. In hematopoietic stem cell transplant ("HSCT") patients, a subset of the immune-compromised patient population with approximately 25,000 transplants being performed annually in the U.S., it is estimated that about 25% of patients treated with the current standard of care (aerosolized Ribavirin) will progress to Lower Respiratory Tract Infection ("LRTI") while 41% of patients untreated with the current standard of care will progress to LRTI.

Plasma - Background, Composition and Manufacturing

Human blood contains a number of components including:

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

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

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

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

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

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

Immune Globulins

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

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

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

As of 2014, the worldwide market for plasma-derived therapeutic drug products was approximately $15 billion and the U.S. market for all plasma-derived products was approximately $7.8 billion. IVIG products accounted for approximately $4.8 billion of sales in the U.S. in 2014. IVIG products are used to treat primary immune deficiencies, certain autoimmune diseases, and other illnesses for immune-compromised patients and certain neuropathy indications. New research and data, additional labeled indications, an aging population and emerging countries with new markets are all adding to the worldwide growth of IVIG utilization.

Manufacturing and Supply

In order to produce plasma-derived therapeutics that can be administered to patients, raw material plasma is collected from healthy donors at plasma collection facilities licensed by the FDA. ADMA BioCenters operates FDA-licensed, GHA and KMFDS certified source plasma collection facilities located in the U.S. which provide us with a portion of our blood plasma for the manufacture of our current products and product candidates. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase, and market conditions at the time of sale. Plasma collected from ADMA BioCenters' facilities that is not used for the manufacture of our current products and product candidates is sold to third-party customers in the U.S., and other locations where we are approved globally under supply agreements or in the open "spot" market.

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

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

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On June 22, 2012, we entered into a Plasma Supply Agreement with BPC for the purchase of normal source plasma from ADMA BioCenters' Norcross facility to be used in BPC's proprietary products' manufacturing, which was subsequently amended on February 25, 2014 and then amended and restated on March 23, 2016. After the initial term, the agreement may be renewed on an annual basis upon the mutual consent of the parties. In addition to any other remedy it may have, either party has the right to terminate the agreement if the other party fails to remedy any material default in the performance of a material condition or obligation under the agreement following written notice. In addition, upon giving the appropriate written notice, either party may terminate the agreement upon the occurrence of any of the following events: a proceeding under bankruptcy, reorganization, agreement of debts, insolvency or receivership law is filed by or against the other party, and is not dismissed or stayed, or a receiver or trustee is appointed for all or a substantial portion of the assets of the other party, or the other party makes an assignment for the benefit of its creditors or becomes insolvent. Neither party can assign the agreement or any of its rights or obligations thereunder without the express written consent of the other party. However, with notice to the other party, either party without the other party's consent may assign the agreement to (i) its affiliate, or (ii) a successor to all or substantially all of the assets related to the business of that party which is involved in the fulfillment of its obligations under the agreement. Under the agreement, BPC applied to the GHA for, and we have subsequently obtained, GHA certification.

On June 7, 2012, we entered into a Testing Services Agreement with Quest Diagnostics Clinical Laboratories, Inc. ("Quest") in which Quest agreed to provide biomarker testing and related support services for protocol screening and recertification which are exclusive to us. All data, test results, studies and other information generated by Quest in performing services under the agreement is our sole property, and either party can terminate the agreement without cause upon written notice. Neither party can assign the agreement or any of its right or obligations under the agreement without the express written consent of the other party, except under specified circumstances. Quest agreed and acknowledged that we paid for the development and validation of the testing assay and as such, the assay is our sole property and shall only be utilized for our benefit.

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 normal and 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, including our Biotest Transaction, our current and anticipated plans and intentions will evolve and change. See

“Special Note Regarding Forward-Looking Statements.”

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On June 6, 2017, we and BPC entered into a Termination Agreement with respect to the Manufacturing Supply and License Agreement and Master Services Agreement, which included, effective as of January 21, 2017, a mutual release with respect to any claims 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.

Competition

Although blood plasma and its derivative proteins are not subject to patent protection, the FDA recognizes each immune globulin product as unique and generally requires a separate Investigational New Drug (“IND”) clinical trial and BLA for each as a condition to approval. Regardless of whether competitors are able to develop an assay that can achieve our level of consistency and reproducibility in providing RSV antibody titer data, we believe they would still be required to validate and qualify such an assay as well as conduct clinical trials and undergo an FDA review prior to marketing an immune globulin product. 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: CSL Behring, Grifols Biologicals, 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.

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 ADMA, 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.

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

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

We currently hold multiple trademarks, including *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 IND application which must become effective before clinical trials may begin;

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- 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;

- 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.

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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.

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.

Biological 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. 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 or a CRL, which contains 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, of which ADMA has requested. If a CRL is issued, if and when those items 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 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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Upon the resubmission of a BLA application, the FDA will classify the resubmission as Class 1 (triggering a 2-month review goal for the FDA) or Class 2 (triggering a 6-month review goal for the FDA).

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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In addition, the distribution of prescription drug products (including biological drug products) is subject to the Prescription Drug Marketing Act (the "PDMA"), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription product samples and impose requirements to ensure accountability in distribution.

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 agency 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 BioCenters

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 BioCenters has completed these requirements and holds FDA licenses, along with GHA and KMFDS certifications, for its Norcross, GA and Marietta, GA facilities. In order to maintain these licenses, the facilities operated by ADMA BioCenters will be inspected at least every two years. ADMA BioCenters 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 both of our ADMA BioCenters facilities are currently in compliance with state and industry standards. Delays in obtaining, or failures to maintain, regulatory approvals for any facilities operated by ADMA BioCenters 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.

Research and Development

ADMA's expenditures on research and development were approximately $6.2 million and $7.7 million for the fiscal years ended December 31, 2017 and 2016, respectively.

Employees

As of December 31, 2017, we had a total of 295 employees, comprised of 291 full-time employees and 4 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, or 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 BioCenters. ADMA BioManufacturing was formed in January 2017 to facilitate the acquisition of BTBU. ADMA BioCenters is the Company's source plasma collection business which operates in the U.S. Each operational ADMA BioCenter, once approved, will have a license with the FDA and may obtain additional certifications from other regulatory agencies such as the GHA and the KMFDS. ADMA BioCenters 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. The public may also read and copy any document that we file at the SEC's Public Reference Room located at 100 F Street, NE, Washington, D.C. 20549 on official business days during the hours of 10 a.m. to 3 p.m. For further information on the Public Reference Room, the public is instructed to call the SEC at 1-800-SEC-0330.

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 our RI-002 product candidate and other products and product candidates in our pipeline, we do not expect to sell and generate revenue from the commercialization of 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 end of 2018, 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 2018, including regulatory and consulting fees for the remediation of the Warning Letter and ongoing discussions with the FDA, continuing 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 $10.0 million we expect to be able to draw down through our existing senior credit facility (see “Management’s Discussion and Analysis of Financial Condition and Results of Operations”) will be sufficient to fund our operations, as currently conducted, through the end of 2018. 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 end of 2018. This timeframe 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. These estimates may change based upon whether or when the FDA approves 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 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 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 BLA until, among other things, these deficiencies are resolved. Following the completion of the Biotest Transaction, we now have control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility, and our highest priority is to remediate the outstanding compliance issues at the Boca Facility in the Warning Letter. We engaged a leading consulting firm with extensive experience in remediating compliance and inspection issues related to quality management systems that manages a robust team of subject matter experts in plasma derived products and biologic drugs to assist us in addressing all identified CMC and cGMP issues and deficiencies. We believe that we have been inspection-ready since the end of 2017 and expect to have the FDA inspection classification relative to the Warning Letter improved after the next inspection by the FDA. However, there can be no assurances that our efforts to remediate the Warning Letter and other inspection issues and deficiencies at the Boca Facility 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 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, 2017 and 2016, we incurred net losses of $43.8 and $19.5 million, respectively, and from our inception in 2004 through December 31, 2017, we have incurred an accumulated deficit of $150.7 million. Even if we succeed in developing and commercializing one or more of our 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;
- hire additional personnel;
- expand and build out our plasma center network; and
- continue to integrate the Biotest Assets into our business.

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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 end of 2018 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, 2017, 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, through the end of 2018. 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 end of 2018. 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 fourth quarter of 2018.

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.

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.

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Business interruptions could adversely affect our business.

ADMA BioCenters operates FDA-licensed, GHA and KMFDS certified source plasma collection facilities located in the U.S., which provide us with a portion of our blood plasma for the manufacture of our products and product candidates. Plasma collected from ADMA BioCenters' facilities that is not used to manufacture our 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. Furthermore, we have completed the construction of our third plasma collection facility, and we filed our BLA with the FDA and initiated collections for this facility in December 2017. Nabi-HB and Bivigam are manufactured at the Boca Facility, an FDA-licensed facility certified by the GHA. A portion of our revenues are dependent upon the continued operation of these facilities. Our operations 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 and events beyond our control. We do not have detailed disaster recovery plans for our facilities nor do we have a backup manufacturing facility, other than our other facilities, or contractual arrangements with any other manufacturers in the event of a casualty to or destruction of any facility or if any facility ceases to be available to us for any other reason. 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.

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 BLA for RI-002. Furthermore, failure can occur at any stage of the process, and we could encounter problems that cause us to abandon our 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 Investigational New Drug ("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 Bivigam.

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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 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.

Even if we receive approval from the FDA to market RI-002, our ability to market RI-002 for alternative applications could be limited.

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.

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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 RI-002, 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, together with a second customer, represented 78% of our total revenue for the year ended December 31, 2017, and therefore the loss of such single customer 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, 2017, BPC and Sanofi Pasteur S.A. (“Sanofi”), represented 78% of our total revenue, with BPC representing 47% of our total revenue and Sanofi representing 31% of our total revenue. Although we expect this concentration to decrease during 2018 as additional sales of Nabi-HB, revenues from our contract manufacturing services and sale of intermediate by-products are reflected in our consolidated financial statements, BPC is still expected to account for a significant portion of our total revenue.

The loss of BPC as a customer or a material change in the revenue generated by BPC could have a material adverse effect on our business, results of operations and financial condition. Factors that could influence our relationships with our customers include, among other things:

· our ability to sell our products at competitive prices;

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- 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 could have a material adverse effect on our business and results of operations.

Issues with product quality 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 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 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;

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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 this Annual Report 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.

This Annual Report 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 such report. 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 BioCenters, to support our operations.

Our ADMA BioCenters facilities 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 associate subject to HIPAA, even when HIPAA does not apply, according to the U.S. Federal Trade Commission (the "FTC"), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. In addition, states impose a variety of laws protecting consumer information, with certain sensitive information such as HIV/Sexually Transmitted Disease status subject to heightened standards. In addition, federal and state privacy, data security, and breach notification laws, rules and regulations, and other laws apply to the collection, use and security of personal information, including social security number, driver's license numbers, government identifiers, credit card and financial account numbers. We could be subject to enforcement action and litigation exposure if we fail to adhere to these data privacy and security laws.

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We may not realize the strategic and financial benefits currently anticipated from the Biotest Transaction.

We may not realize all of the strategic and financial benefits currently anticipated from the Biotest Transaction. For example, we may not realize the anticipated benefits of acquiring control of all aspects of RI-002 drug manufacturing, regulatory affairs and business operations. In addition, we may not be able to resolve the outstanding issues at the Boca Facility that resulted in the Warning Letter. As part of the remediation of the Warning Letter, in December 2016 BTBU temporarily suspended the production of Bivigam in order to focus on the completion of planned improvements to the manufacturing process. As a result, Bivigam was not available for sale or distribution throughout fiscal 2017. If we are unable to address the underlying concerns at the Boca Facility that resulted in the Warning Letter and the CRL in July 2016 that identified deficiencies and inspection issues related to certain of our third-party contract manufacturers, including BPC, and provide requested documentation of corrections for a number of these issues, we will not be able to apply for the PAS related to the manufacturing of Bivigam or reapply for FDA approval to market and sell RI-002, which could have a material adverse effect on us. Failure to resolve any outstanding issues or any administrative actions taken or changes made by the FDA toward our contract manufacturers, vendors or us could impact our ability to receive approval for RI-002, including the timing thereof, disrupt our business operations and the timing of our commercialization efforts and may have a material adverse effect on our financial condition and operating results.

Through the Biotest Transaction, we assumed a contract manufacturing agreement related to the fractionation of plasma provided by one of our third-party customers that includes certain minimum production requirements. If we are unable to meet our contractual obligations under this agreement, we may be liable for the payment of liquidated damages. If we are unable to resolve these issues, such failure could have a material adverse effect on us.

There is also uncertainty as to whether the combined business will be able to operate at a profitable level in the future given the relatively small size of the Biotest Assets and the competitive environment in which we operate. Furthermore, there is no assurance and no definitive timeline as to when or if the Warning Letter will be resolved by the FDA, or when the FDA will inspect our operations. These factors could have a material adverse effect on us.

We may not be successful in integrating the Biotest Assets into our business.

The Biotest Transaction involves the integration of two businesses that previously have operated independently with principal offices in two distinct locations. We are expending significant management attention and resources to integrate the two companies following completion of the Biotest Transaction. The failure to integrate successfully and to manage successfully the challenges presented by the integration process may result in the combined company’s failure to achieve some or all of the anticipated benefits of the Biotest Transaction.

Potential difficulties that may be encountered in the integration process include, but are not limited to, the following:

- using our cash and other assets efficiently to develop the business on a post-Biotest Transaction basis;
- appropriately managing the liabilities of our Company on a post-Biotest Transaction basis;
- potential unknown or currently unquantifiable liabilities associated with the Biotest Transaction and the operations of our Company on a post-Biotest Transaction basis;
- potential unknown and unforeseen expenses, delays or regulatory conditions associated with the Biotest Transaction; and
- performance shortfalls in one or both of the businesses as a result of the diversion of the applicable management's attention caused by completing the Biotest Transaction and integrating the business.

Delays in the integration process could adversely affect the combined company's business, financial results, financial condition and stock price following the Biotest Transaction. Even if the combined company were able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration or that these benefits will be achieved within a reasonable period of time.

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By completing the Biotest Transaction, we agreed to transfer assets that have historically generated substantially all of our revenue.

As part of the purchase price to acquire the Biotest Assets, we have agreed to transfer to BPC ownership of our two licensed plasma collection facilities in the U.S. and certain related assets and liabilities. These plasma collection facilities to be transferred have historically been the source of substantially all of our revenue. Although we have completed construction of a new plasma collection facility, there can be no assurances that we will generate similar revenues as historically reported from the plasma collection facilities we will transfer to BPC on January 1, 2019.

The Biotest Transaction exposes us to liabilities, a release of claims and competition that could have a material adverse effect on our business, financial condition, results of operations and stock price.

As part of the consideration for the Biotest Transaction, we agreed to assume certain liabilities of BPC related to BTBU. Because we agreed to assume liabilities related to the Biotest Assets, we are exposed to liabilities that are not within our control and we cannot predict the extent to which these liabilities may arise in the future. Any liabilities that may arise could have a material adverse effect on our business, financial condition, results of operations and stock price.

The Master Purchase and Sale Agreement, dated as of January 21, 2017 (as amended, restated, supplemented or otherwise modified from time to time, the “Purchase Agreement”), with BPC, and for certain limited purposes set forth in the Purchase Agreement, Biotest AG, BPC’s parent corporation, and Biotest US Corporation, a Delaware corporation and subsidiary of Biotest AG (together with Biotest AG, the “Biotest Guarantors”), contains indemnification undertakings by the parties thereto for certain losses, including, among other things, indemnification for any losses arising from breaches of its representations, warranties, covenants and agreements in the Purchase Agreement. In addition, we have agreed to indemnify BPC for any assumed liability, and BPC has agreed to indemnify us for any excluded asset or excluded liability. The parties' representations and warranties (other than fundamental representations and warranties) survive for 15 months following the closing of the Biotest Transaction, fundamental representations survive indefinitely, tax representations survive until the date that is 30 days following the applicable statute of limitations, covenants to be performed on or prior to the closing of the Biotest Transaction survive for 15 months following the closing of the Biotest Transaction, and post-closing covenants survive in accordance with their terms or if no term is specified, indefinitely. Each party’s indemnification obligations with respect to (a) its representations and warranties (other than its fundamental representations) are subject to a $25,000 mini-basket and $750,000 true deductible and (b) its representations, warranties and pre-closing covenants are subject to a $25,000,000 cap. Significant indemnification claims by BPC or its affiliates or a breach by BPC or its affiliates of any indemnity obligations owed to us under the Purchase Agreement could have a material adverse effect on our business, financial condition, results of operations and stock price.

As part of the consideration for the Biotest Transaction, the parties also agreed to a mutual release, pursuant to which the parties agreed not to bring any suit, action or claim for any breach or default under the existing manufacturing and supply agreement or master services agreement prior to the closing of the Biotest Transaction. This release remains effective from and after the closing of the Biotest Transaction. Without this release, we would have otherwise been permitted to bring a claim against BPC related to the Warning Letter that could have possibly entitled us to remedies in the event that we are unable to resolve the Warning Letter. The inability to seek these remedies could have a material adverse effect on our business, financial condition, results of operations and stock price.

In addition, while the Purchase Agreement contains certain non-compete clauses, such clauses do not prohibit either the Biotest Guarantors or their other affiliates from directly or indirectly (other than through BPC) competing with BTBU after the closing of the Biotest Transaction. Such competition could result in the loss of existing or new customers, price reductions, reduced operating margins and loss of market share, which could have a material adverse effect on our business, financial condition, results of operations and stock price.

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If our due diligence investigation for the Biotest Transaction was inadequate and/or the representations, warranties and indemnification given to us by BPC was inadequate, then it could result in a material adverse effect on our business.

Even though we believe that we conducted a reasonable and customary due diligence investigation of BTBU and we received market representations, warranties and indemnities from Biotest and BPC, we cannot be sure that our due diligence investigation uncovered all material or non-material issues that may be present. There also can be no assurances that we received access to or had the ability to diligence certain information, as well as appropriate representations and or warranties, that it would be possible to uncover all material issues through customary due diligence, that issues outside of our control will not later arise or that all material issues which are or could be discovered are otherwise covered by the representations and warranties of Biotest and BPC and therefore indemnifiable. If we failed to identify any important issues, or if it were not possible to uncover all material issues or if we did not receive representations and warranties and indemnification concerning any or all material or non-material issues, it could result in a material adverse effect on our business, financial condition, results of operations and stock price.

Our credit agreement (the "Credit Agreement") with Marathon Healthcare Finance Fund, L.P. ("Marathon") is subject to acceleration in specified circumstances, which may result in Marathon taking possession and disposing of any collateral.

On October 10, 2017, we entered into the Credit Agreement with Marathon which provides for a senior secured term loan facility in an aggregate amount of up to $40.0 million (collectively, the "Credit Facility"), comprised of (i) a term loan in the principal amount of $30.0 million (the "Tranche One Loan"), (ii) an additional term loan to be made in the maximum principal amount not to exceed $10.0 million (the "Tranche Two Loan;" and, together with the Tranche One Loan, the "Loans"), which Tranche Two Loan availability is subject to the satisfaction of certain conditions. The Loans each have a maturity date of April 10, 2022 (the "Maturity Date"), subject to acceleration pursuant to the Credit Agreement, including upon an Event of Default (as defined in the Credit Agreement). The Loans are secured by substantially all of our assets, including our intellectual property. Events of Default include, among others, non-payment of principal, interest, or fees, violation of covenants, inaccuracy of representations and warranties, bankruptcy and insolvency events, material judgments, cross-defaults to material contracts and events constituting a change of control. In addition to an increase in the rate of interest on the Loans of 5% per annum, the occurrence of an Event of Default could result in, among other things, the termination of commitments under the Credit Facility, the declaration that all outstanding Loans are immediately due and payable in whole or in part, and Marathon taking immediate possession of, and selling, any collateral securing the Loans.

Developments by competitors may render our products or technologies obsolete or non-competitive.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our current products, RI-002 (if we obtain regulatory approval) and any future product we may develop will have to compete with other marketed therapies. In addition, other companies may pursue the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the U.S. and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, longer product development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations.

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If we are unable to protect our patents, trade secrets or other proprietary rights, if our patents are challenged or if our provisional patent applications do not get approved, our competitiveness and business prospects may be materially damaged.

As we move forward in clinical development we are also uncovering novel aspects of our product and are drafting patents to cover our inventions. We rely on a combination of patent rights, trade secrets and nondisclosure and non-competition agreements to protect our proprietary intellectual property, and we will continue to do so. There can be no assurance that our patent, trade secret policies and practices or other agreements will adequately protect our intellectual property. Our issued patents may be challenged, found to be over-broad or otherwise invalidated in subsequent proceedings before courts or the USPTO. Even if enforceable, we cannot provide any assurances that they will provide significant protection from competition. The processes, systems, and/or security measures we use to preserve the integrity and confidentiality of our data and trade secrets may be breached, and we may not have adequate remedies as a result of any such breaches. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. There can be no assurance that the 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, or any other security measures relating 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 could lose market exclusivity of a product earlier than expected.

In the pharmaceutical and biotechnology industries, the majority of an innovative product’s commercial value is realized during its market exclusivity period. In the U.S. and in some other countries, when market exclusivity expires and generic versions are approved and marketed or when biosimilars are introduced (even if only for a competing product), there are usually very substantial and rapid declines in a product’s revenues.

Market exclusivity for our products is based upon patent rights and certain regulatory forms of exclusivity. The scope of our patent rights may vary from country to country and may also be dependent on the availability of meaningful legal remedies in a country. The failure to obtain patent and other intellectual property rights, or limitations on the use or loss of such rights, could be material to us. In some countries, basic patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents and/or we (or our licensors) did not file in those markets. In addition, the patent environment can be unpredictable and the validity and enforceability of patents cannot be predicted with certainty. Absent relevant patent protection for a product, once the data exclusivity period expires, generic versions can be approved and marketed.

Patent rights covering RI-002 may become subject to patent litigation. In some cases, manufacturers may seek regulatory approval by submitting their own clinical trial data to obtain marketing approval or choose to launch a generic product “at risk” before the expiration of our patent rights/or before the final resolution of related patent litigation. Enforcement of claims in patent litigation can be very costly and no assurance can be given that we will prevail. There is no assurance that RI-002, or any other of our products for which we are issued a patent, will enjoy market exclusivity for the full time period of the respective patent.

Third parties 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.

We may not be able to operate our business without infringing third-party patents. Numerous U.S. and foreign patents and pending patent applications owned by third parties exist in fields that relate to the development and commercialization of immune globulins. In addition, many companies have employed intellectual property litigation as a way to gain a competitive advantage. It is possible that infringement claims may occur as the number of products and competitors in our market increases. In addition, to the extent that we gain greater visibility and market exposure as a public company, we face a greater risk of being the subject of intellectual property infringement claims. We cannot be certain that the conduct of our business does not and will not infringe intellectual property or other proprietary rights of others in the U.S. and in foreign jurisdictions. If our products, methods, processes and other technologies are found to infringe third-party patent rights, we could be prohibited from manufacturing and commercializing the infringing technology, process or product unless we obtain a license under the applicable third-party patent and pay royalties or are able to design around such patent. We may be unable to obtain a license on terms acceptable to us, or at all, and we may not be able to redesign our products or processes to avoid infringement. Even if we are able to redesign our products or processes to avoid an infringement claim, our efforts to design around the patent could require significant time, effort and expense and ultimately may lead to an inferior or more costly product and/or process. Any claim of infringement by a third party, even those without merit, could cause us to incur substantial costs defending against the claim and could distract our management from our business. Furthermore, if any such claim is successful, a court could order us to pay substantial damages, including compensatory damages for any infringement, plus prejudgment interest and could, in certain circumstances, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently prohibit us, our licensees, if any, and our customers from making, using, selling, offering to sell or importing one or more of our products or practicing our proprietary technologies or processes, or could enter an order mandating that we undertake certain remedial activities. Any of these events could seriously harm our business, operating results and financial condition.

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If we are unable to successfully manage our growth, our business may be harmed.

Our success will depend on the expansion of our commercial and manufacturing activities, supply of plasma and overall operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business could be harmed.

The loss of one or more key members of our management team could adversely affect our business.

Our performance is substantially dependent on the continued service and performance of our management team, who have extensive experience and specialized expertise in our business. In particular, the loss of Adam S. Grossman, our President and Chief Executive Officer, could adversely affect our business and operating results. We do not have "key person" life insurance policies for any members of our management team. We have employment agreements with each of our executive officers; however, the existence of an employment agreement does not guarantee retention of members of our management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our product candidates and diversion of management resources. Notwithstanding the foregoing, in the event Mr. Grossman is terminated for cause or resigns other than for good reason, then the standstill provisions contained in the Stockholders Agreement, dated as of June 6, 2017, by and between the Company and BPC, which prohibits BPC and its affiliates collectively from, among other things, acquiring more than (i) 50%, less one share, of the Company’s issued and outstanding shares of capital stock on an as-converted basis, or (ii) 30% of the issued and outstanding shares of Common Stock, will terminate and be of no further force and effect. Such event could result in Biotest acquiring additional shares of our Common Stock or taking other actions with the goal of acquiring additional shares of our Common Stock.

Cyberattacks and other security breaches could compromise our proprietary and confidential information, which could harm our business and reputation.

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is important to our operations and reputation. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate our proprietary and confidential information including e-mails and other electronic communications. In addition, an employee, contractor, or other third party with whom we do business may attempt to obtain such information, and may purposefully or inadvertently cause a breach involving such information. While we have certain safeguards in place to reduce the risk of and detect cyber-attacks, including a company-wide cybersecurity policy, our information technology networks and infrastructure may be vulnerable to unpermitted access

by hackers or other breaches, or employee error or malfeasance. Any such compromise of our data security and access to, or public disclosure or loss of, confidential business or proprietary information could disrupt our operations, damage our reputation, provide our competitors with valuable information and subject us to additional costs, which could adversely affect our business.

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If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

We will need to hire additional qualified personnel with expertise in commercialization, sales, marketing, medical affairs, reimbursement, government regulation, formulation and manufacturing and finance and accounting. In particular, over the next 12-24 months, we expect to hire several new employees devoted to commercialization, sales, marketing, medical and scientific affairs, regulatory affairs, quality control, financial, general and operational management. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot assure you that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success and any failure to do so successfully may have a material adverse effect on us.

We currently collect human blood plasma at our ADMA BioCenters facilities, and if we cannot maintain FDA approval for these facilities we may be adversely affected and may not be able to sell or use this human blood plasma for future commercial purposes.

We intend to maintain FDA and other governmental and regulatory approvals of our ADMA BioCenters collection facilities for the collection of human blood plasma. These facilities are subject to FDA and other governmental and regulatory inspections and extensive regulation, including compliance with current cGMP, FDA and other government approvals. Failure to comply with applicable governmental regulations or to receive applicable approvals for our future facilities, including our third facility, may result in enforcement actions, such as 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 regulatory authority approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses, any of which may significantly delay or suspend our operations for these locations, potentially having a materially adverse effect on our ability to manufacture our products or offer for sale plasma collected at the affected site(s).

We currently manufacture our current marketed products, pipeline products, and products for third parties in our manufacturing and testing facilities, and if we cannot maintain appropriate FDA status for these facilities, we may be adversely affected, and may not be able to sell, manufacture or commercialize these products.

We currently operate under the Warning Letter due to issues identified by the FDA in their prior inspections while the Boca Facility was under Biotest's operational control. We engaged a leading consulting firm with extensive experience in remediating compliance and inspection issues related to quality management systems and which 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. We believe that we have been inspection-ready since the end of 2017 and expect to have the FDA inspection classification relative to the Warning Letter improved after the next inspection by the FDA.

If we do not receive FDA approval for additional plasma collection centers, including our third center for which construction was completed in late 2017, before January 1, 2019, then we may be required to seek a waiver and extension from Biotest for the contractually required transfer of two of our facilities.

We recently completed construction our third plasma center and plan to leverage our existing plasma center license in order to seek approval for this new facility with the FDA. The BLA for this facility was filed with the FDA in December 2017. If we do not receive FDA approval for this third plasma center on or before January 1, 2019, then we will be required to seek a waiver and extension from Biotest for our contractual obligation to transfer the two facilities under the Purchase Agreement. However, there can be no assurances that Biotest will waive or extend its rights with respect to such transfer. In the event Biotest refuses to waive and extend such right, we will be obligated to transfer the two facilities under the Purchase Agreement and risk not having an FDA-approved plasma center in the event of a delay or refusal to issue our future license for the new plasma center by the FDA. Any such delay or refusal to issue the license by the FDA could have a material adverse effect on our operations.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, either alone or with collaborators.

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Many of our business practices are subject to scrutiny by federal and state regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.

The laws governing our conduct in the U.S. are enforceable on the federal and state levels by criminal, civil and administrative penalties. Violations of laws such as the Federal Food, Drug, and Cosmetic Act, the Social Security Act (including the Anti-Kickback Law), the Public Health Service Act and the Federal False Claims Act, and any regulations promulgated under the authority of the preceding, may result in jail sentences, fines or exclusion from federal and state programs, as may be determined by Medicare, Medicaid and the Department of Health and Human Services and other regulatory authorities as well as by the courts. Similarly, the violation of applicable laws, rules and regulations of the State of Florida with respect to the manufacture of our products and product candidates may result in jail sentences, fines or exclusion from applicable state programs. There can be no assurance that our activities will not come under the scrutiny of federal and/or state regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

For example, under the Anti-Kickback Law and similar state laws and regulations, the offer or payment of anything of value for patient referrals, or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease, or ordering of any time or service reimbursable in whole or in part by a federal health care program is prohibited. This places constraints on the marketing and promotion of products and on common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose products for patients, such as physicians and hospitals, and these practices can result in substantial legal penalties, including, among others, exclusion from the Medicare and Medicaid programs. Arrangements with referral sources such as purchasers, group purchasing organizations, physicians and pharmacists must be structured with care to comply with applicable requirements. Also, certain business practices, such as payments of consulting fees to healthcare providers, sponsorship of educational or research grants, charitable donations, interactions with healthcare providers that prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid any possibility of wrongfully influencing healthcare providers to prescribe or purchase particular products or as a reward for past prescribing. Under the Patient Protection and Affordable Care Act and the companion Health Care and Education Reconciliation Act, which together are referred to as the “Healthcare Reform Law”, such payments by pharmaceutical manufacturers to U.S. healthcare practitioners and academic medical centers must be publicly disclosed. A number of states have similar laws in place. Additional and stricter prohibitions could be implemented by federal and state authorities. Where such practices have been found to be improper incentives to use such products, government investigations and assessments of penalties against manufacturers have resulted in substantial damages and fines. Many manufacturers have been required to enter into consent decrees or orders that prescribe allowable corporate conduct.

Failure to satisfy requirements under the Federal Food, Drug, and Cosmetic Act can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct. In addition, while regulatory authorities generally do not regulate physicians' discretion in their choice of treatments for their patients,

they do restrict communications by manufacturers on unapproved uses of approved products or on the potential safety and efficacy of unapproved products in development. Companies in the U.S., Canada and the European Union cannot promote approved products for other indications that are not specifically approved by the competent regulatory authorities such as the FDA in the U.S., nor can companies promote unapproved products. In limited circumstances, companies may disseminate to physicians information regarding unapproved uses of approved products or results of studies involving investigational products. If such activities fail to comply with applicable regulations and guidelines of the various regulatory authorities, we may be subject to warnings from, or enforcement action by, these authorities. Furthermore, if such activities are prohibited, it may harm demand for our products. Promotion of unapproved drugs or devices or unapproved indications for a drug or device is a violation of the Federal Food, Drug, and Cosmetic Act and subjects us to civil and criminal sanctions. Furthermore, sanctions under the Federal False Claims Act have recently been brought against companies accused of promoting off-label uses of drugs, because such promotion induces the use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for off-label promotion have been initiated by several states for Medicaid fraud. The Healthcare Reform Law significantly strengthened provisions of the Federal False Claims Act, the Anti-Kickback Law that applies to Medicare and Medicaid, and other health care fraud provisions, leading to the possibility of greatly increased qui tam suits by relators for perceived violations. Violations or allegations of violations of the foregoing restrictions could materially and adversely affect our business.

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We are required to report detailed pricing information, net of included discounts, rebates and other concessions, to the Centers for Medicare & Medicaid Services (“CMS”) for the purpose of calculating national reimbursement levels, certain federal prices and certain federal and state rebate obligations. Inaccurate or incomplete reporting of pricing information could result in liability under the False Claims Act, the federal Anti-Kickback Law and various other laws, rules and regulations.

We will need to establish systems for collecting and reporting this data accurately to CMS and institute a compliance program to assure that the information collected is complete in all respects. If we report pricing information that is not accurate to the federal government, we could be subject to fines and other sanctions that could adversely affect our business. If we choose to pursue clinical development and commercialization in the European Union or otherwise market and sell our products outside of the U.S., we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all, which would preclude us from commercializing products in those markets.

In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Such trials may be time-consuming and expensive, and may not show an advantage in efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the U.S. or the European Union, we could be adversely affected.

Also, under the U.S. Foreign Corrupt Practices Act, the U.S. has increasingly focused on regulating the conduct by U.S. businesses occurring outside of the U.S., generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business. To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities such as the U.S. Health and Human Services Department Office of Inspector General (the “OIG”) have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the U.S. Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. In the future, we may need to adopt healthcare compliance and ethics programs that would incorporate the OIG's recommendations, and train our applicable employees in such compliance. Such a program may be expensive and may not assure that we will avoid compliance issues.

We are also required to comply with the applicable laws, rules, regulations and permit requirements of the various states in which our business operates, including the State of Florida where our manufacturing facility is located. These regulations and permit requirements are not always in concert with applicable federal laws, rules and regulations regulating our business. Although compliant with applicable federal requirements, we may be required to

comply with additional state laws, rules, regulations and permits. Failure to appropriately comply with such state requirements could result in temporary or long-term cessation of our manufacturing operations, as well as fines and other sanctions. Any such penalties may have a material adverse effect on our business and results of operations.

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The manufacturing processes for plasma-based biologics are complex and involve biological intermediates that are susceptible to contamination.

Plasma is a raw material that is susceptible to damage and contamination and may contain human pathogens, any of which would render the plasma unsuitable as raw material for further manufacturing. For instance, improper storage of plasma, by us or third-party suppliers, may require us to destroy some of our raw material. If unsuitable plasma is not identified and discarded prior to the release of the plasma to the manufacturing process, it may be necessary to discard intermediate or finished product made from that plasma or to recall any finished product released to the market, resulting in a charge to cost of product revenue. The manufacture of our plasma products is an extremely complex process of fractionation, purification, filling and finishing. Our products can become non-releasable or otherwise fail to meet our stringent specifications or regulatory agencies' specifications through a failure in one or more of these process steps. We may detect instances in which an unreleased product was produced without adherence to our manufacturing procedures or plasma used in our production process was not collected or stored in a compliant manner consistent with our cGMP or other regulations. Such an event of noncompliance would likely result in our determination that the implicated products should not be released or maybe replaced or withdrawn from the market and therefore should be destroyed. Once manufactured, our plasma-derived products must be handled carefully and kept at appropriate temperatures. Our failure, or the failure of third parties that supply, ship or distribute our products, to properly care for our products may require that those products be destroyed. Even if handled properly, biologics may form or contain particulates or have other issues or problems after storage which may require products to be destroyed or recalled. While we expect to write off small amounts of work-in-progress in the ordinary course of business due to the complex nature of plasma, our processes and our products, unanticipated events may lead to write-offs and other costs materially in excess of our expectations and the reserves we have established for these purposes. Such write-offs and other costs could cause material fluctuations in our results of operations.

Furthermore, contamination of our products could cause investors, consumers, or other third parties with whom we conduct business to lose confidence in the reliability of our manufacturing procedures, which could adversely affect our revenues. In addition, faulty or contaminated products that are unknowingly distributed could result in patient harm, threaten the reputation of our products and expose us to product liability damages and claims from companies for whom we do contract manufacturing.

Our ability to continue to produce safe and effective products depends on the safety of our plasma supply and manufacturing processes against transmittable diseases.

Despite overlapping safeguards, including the screening of donors and other steps to remove or inactivate viruses and other infectious disease causing agents, the risk of transmissible disease through blood plasma products cannot be entirely eliminated. For example, since plasma-derived therapeutics involves the use and purification of human plasma, there has been concern raised about the risk of transmitting human immunodeficiency virus (“HIV”), prions, West Nile virus, H1N1 virus or "swine flu" and other blood-borne pathogens through plasma-derived products. There are also concerns about the future transmission of H5N1 virus, or "bird flu." In the 1980s, thousands of hemophiliacs

worldwide were infected with HIV through the use of contaminated Factor VIII. Other producers of Factor VIII, though not us, were defendants in numerous lawsuits resulting from these infections. New infectious diseases emerge in the human population from time to time. If a new infectious disease has a period during which time the causative agent is present in the bloodstream but symptoms are not present, it is possible that plasma donations could be contaminated by that infectious agent. Typically, early in an outbreak of a new disease, tests for the causative agent do not exist. During this early phase, we must rely on screening of donors for behavioral risk factors or physical symptoms to reduce the risk of plasma contamination. Screening methods are generally less sensitive and specific than a direct test as a means of identifying potentially contaminated plasma units. During the early phase of an outbreak of a new infectious disease, our ability to manufacture safe products would depend on the manufacturing process' capacity to inactivate or remove the infectious agent. To the extent that a product's manufacturing process is inadequate to inactivate or remove an infectious agent, our ability to manufacture and distribute that product would be impaired. If a new infectious disease were to emerge in the human population, the regulatory and public health authorities could impose precautions to limit the transmission of the disease that would impair our ability to procure plasma, manufacture our products or both. Such precautionary measures could be taken before there is conclusive medical or scientific evidence that a disease poses a risk for plasma-derived products. In recent years, new testing and viral inactivation methods have been developed that more effectively detect and inactivate infectious viruses in collected plasma. There can be no assurance, however, that such new testing and inactivation methods will adequately screen for, and inactivate, infectious agents in the plasma used in the production of our products.

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We could become supply-constrained and our financial performance would suffer if we cannot obtain adequate quantities of FDA-approved source plasma with proper specifications.

In order for plasma to be used in the manufacturing of our products, the individual centers at which the plasma is collected must be licensed by the FDA and approved by the regulatory authorities of any country in which we may wish to commercialize our products. When we open a new plasma center, and on an ongoing basis after licensure, it must be inspected by the FDA for compliance with cGMP and other regulatory requirements. An unsatisfactory inspection could prevent a new center from being licensed or risk the suspension or revocation of an existing license. We do not and will not have adequate plasma to manufacture our products. Therefore, we are reliant on the purchase of plasma from third parties to manufacture our products. We can give no assurances that appropriate plasma will be available to us on commercially reasonable terms, or at all, to manufacture our products. In order to maintain a plasma center's license, its operations must continue to conform to cGMP and other regulatory requirements. In the event that we determine that plasma was not collected in compliance with cGMP, we may be unable to use and may ultimately destroy plasma collected from that center, which would be recorded as a charge to cost of product revenue. Additionally, if non-compliance in the plasma collection process is identified after the impacted plasma has been pooled with compliant plasma from other sources, entire plasma pools, in-process intermediate materials and final products could be impacted. Consequently, we could experience significant inventory impairment provisions and write-offs which could adversely affect our business and financial results. We plan to increase our supplies of plasma for use in the manufacturing processes through increased purchases of plasma from third-party suppliers as well as collections from our existing ADMA BioCenters plasma collection centers. This strategy is dependent upon our ability to maintain a cGMP compliant environment in both plasma centers and to expand production and attract donors to both centers. There is no assurance that the FDA will inspect and license our unlicensed plasma collection centers in a timely manner consistent with our production plans. If we misjudge the readiness of a center for an FDA inspection, we may lose credibility with the FDA and cause the FDA to more closely examine all of our operations. Such additional scrutiny could materially hamper our operations and our ability to increase plasma collections. Our ability to expand production and increase our plasma collection centers to more efficient production levels may be affected by changes in the economic environment and population in selected regions where ADMA BioCenters operates its current or future plasma centers, by the entry of competitive plasma centers into regions where ADMA BioCenters operates such centers, by misjudging the demographic potential of individual regions where ADMA BioCenters expects to expand production and attract new donors, by unexpected facility related challenges, or by unexpected management challenges at selected plasma centers.

Our ability to commercialize our products, alone or with collaborators, will depend in part upon the extent to which reimbursement will be available from governmental agencies, health administration authorities, private health maintenance organizations and health insurers and other healthcare payers, and also depends upon the approval, timing and representations by the FDA or other governmental authorities for our product candidates. As the FDA BLA review process is ongoing, we are subject to information requests and communications from the FDA on a routine basis and may not have clarity on any or all specific aspects of the approval timing, language, name, claims and any other future requirements that may be imposed by the FDA or other governmental agencies for marketing, authorization and ultimately financial reimbursement for patient utilization.

Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of coverage. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, as well as to the timing, language, specifications and other details pertaining to the approval of such products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for products. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such product. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our products, once approved, market acceptance of such product could be reduced. Prices in many countries, including many in Europe, are subject to local regulation and certain pharmaceutical products, such as plasma-derived products, are subject to price controls in several of the world's principal markets, including many countries within the European Union. In the U.S., where pricing levels for our products are substantially established by third-party payers, including Medicare, if payers reduce the amount of reimbursement for a product, it may cause groups or individuals dispensing the product to discontinue administration of the product, to administer lower doses, to substitute lower cost products or to seek additional price-related concessions. These actions could have a negative effect on our financial results, particularly in cases where our products command a premium price in the marketplace, or where changes in reimbursement induce a shift in the site of treatment. The existence of direct and indirect price controls and pressures over our products could materially adversely affect our financial prospects and performance.

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The new biosimilar pathway established as part of the healthcare reform may make it easier for competitors to market biosimilar products.

The Healthcare Reform Law introduced an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to an FDA-licensed biological product. A biological product may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to an already-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. The law provides that a biosimilar application may be submitted as soon as four years after the reference product is first licensed, and that the FDA may not make approval of an application effective until 12 years after the reference product was first licensed. Since the enactment of the law, the FDA has issued several guidance documents to assist sponsors of biosimilar products in preparing their approval applications. The FDA approved the first biosimilar product in 2015, and approved three biosimilar products in 2016. As a result of the biosimilar pathway in the U.S., we expect in the future to face greater competition from biosimilar products, including a possible increase in patent challenges.

The implementation of the Healthcare Reform Law in the U.S. may adversely affect our business.

Through the March 2010 adoption of the Healthcare Reform Law in the U.S., substantial changes are being made to the current system for paying for healthcare in the U.S., including programs to extend medical benefits to millions of individuals who currently lack insurance coverage. The changes contemplated by the Healthcare Reform Law are subject to rule-making and implementation timelines that extend for several years, and this uncertainty limits our ability to forecast changes that may occur in the future. However, implementation has already begun with respect to certain significant cost-saving measures under the Healthcare Reform Law, for example with respect to several government healthcare programs, including Medicaid and Medicare Parts B and D, that may cover the cost of our future products, and these efforts could have a material adverse impact on our future financial prospects and performance. For example, in order for a manufacturer's products to be reimbursed by federal funding under Medicaid, the manufacturer must enter into a Medicaid rebate agreement with the Secretary of the U.S. Department of Health and Human Services and pay certain rebates to the states based on utilization data provided by each state to the manufacturer and to CMS and pricing data provided by the manufacturer to the federal government. The states share these savings with the federal government, and sometimes implement their own additional supplemental rebate programs. Under the Medicaid drug rebate program, the rebate amount for most branded drug products was previously equal to a minimum of 15.1% of the Average Manufacturer Price ("AMP") or the AMP less Best Price, whichever is greater. Effective January 1, 2010, the Healthcare Reform Law generally increased the size of the Medicaid rebates paid by manufacturers for single source and innovator multiple source (brand name) drug products from a minimum of 15.1% to a minimum of 23.1% of AMP, subject to certain exceptions. For non-innovator multiple source (generic) products, the rebate percentage is increased from a minimum of 11.0% to a minimum of 13.0% of AMP. In 2010, the Healthcare Reform Law also newly extended this rebate obligation to prescription drugs covered by Medicaid managed care organizations. These increases in required rebates may adversely affect our future financial prospects and performance. In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is

calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As the 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

Effective in 2011, the Healthcare Reform Law imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs. These fees may adversely affect our future financial prospects and performance. The Healthcare Reform Law established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation through 2019.

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The Healthcare Reform Law also creates new rebate obligations for our products under Medicare Part D, a partial, voluntary prescription drug benefit created by the U.S. federal government primarily for persons 65 years old and over. The Part D drug program is administered through private insurers that contract with CMS. Beginning in 2011, the Healthcare Reform Law generally requires that in order for a drug manufacturer's products to be reimbursed under Medicare Part D, the manufacturer must enter into a Medicare Coverage Gap Discount Program agreement with the Secretary of the U.S. Department of Health and Human Services, and reimburse each Medicare Part D plan sponsor an amount equal to 50% savings for the manufacturer's brand name drugs and biologics which the Part D plan sponsor has provided to its Medicare Part D beneficiaries who are in the "donut hole" (or a gap in Medicare Part D coverage for beneficiaries who have expended certain amounts for drugs). The Part D plan sponsor is responsible for calculating and providing the discount directly to its beneficiaries and for reporting these amounts paid to CMS's contractor, which notifies drug manufacturers of the rebate amounts it must pay to each Part D plan sponsor. The rebate requirement could adversely affect our future financial performance, particularly if contracts with Part D plans cannot be favorably renegotiated or the Part D plan sponsors fail to accurately calculate payments due in a manner that overstates our rebate obligation. Regarding access to our products, the Healthcare Reform Law established and provided significant funding for a Patient-Centered Outcomes Research Institute to coordinate and fund Comparative Effectiveness Research (“CER”). While the stated intent of CER is to develop information to guide providers to the most efficacious therapies, outcomes of CER could influence the reimbursement or coverage for therapies that are determined to be less cost-effective than others. Should any of our products be determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our future financial prospects and results.

There have been repeated attempts by Congress to repeal or change the Healthcare Reform Law. At this time, it remains unclear whether there will be any changes made to or any repeal or replacement of the Healthcare Reform Law, with respect to certain of its provisions or in its entirety.

Developments in the worldwide economy may adversely impact our business.

The difficult economic environment may adversely affect demand for our products. RI-002, our current product candidate, is expected to be sold to hospitals, specialty pharmacies and clinicians in the U.S. As a result of loss of jobs, patients may lose medical insurance and be unable to purchase our products or may be unable to pay their share of deductibles or co-payments. Hospitals adversely affected by the economy may steer patients to less costly therapies, resulting in a reduction in demand, or demand may shift to public health hospitals, which may purchase at a lower government price.

Risks Relating to our Finances, Capital Requirements and Other Financial Matters

We require additional funding and may be unable to raise capital when needed, which would force us to delay, curtail or eliminate one or more of our research and development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. For the years ended December 31, 2017 and 2016, we had negative cash flows from operations of approximately $37.3 million and $18.3 million, respectively. We expect to continue to spend substantial amounts on product development, including commercialization activities, procuring raw material plasma, manufacturing, conducting potential future clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. We currently anticipate , based upon our projected revenue and expenditures, as well as the additional $10.0 million we expect to be able to draw down under the Credit Agreement, that our current cash, cash equivalents and accounts receivable will be sufficient to fund our operations, as currently conducted, through the end of 2018. 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 end of 2018. This time frame may change based upon how quickly we are able to execute on our operational initiatives and the various financing options we are exploring**.** However, if the assumptions underlying our estimated expenses prove to be incorrect, we may have to raise additional capital sooner than we currently expect. Until such time, if ever, as we can generate a sufficient amount of product revenue to achieve profitability, we expect to continue to finance our operations through additional equity or debt financings or corporate collaboration and licensing arrangements. If we are unable to raise additional capital as needed, we will have to delay, curtail or eliminate our product development activities, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers, as well as future commercialization efforts.

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that, among other restrictions, limit our ability to incur liens or additional debt, pay dividends, redeem or repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. In addition, if we raise additional funds through licensing arrangements or the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

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Our cash, cash equivalents and short-term investments could be adversely affected if the financial institutions in which we hold our cash, cash equivalents and short-term investments fail.

We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation insurance limit. While we monitor the cash balances in our operating accounts on a daily basis and adjust the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on our business, if one or more of the financial institutions with which we deposit cash fails or is subject to other adverse conditions in the financial or credit markets. To date, we have experienced no loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurance that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets.

If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our Common Stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and related rules, our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), we have been required to upgrade, and may need to implement further upgrades, to our financial, information and operating systems, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

Our ability to use our net operating loss carryforwards (“NOLs”) may be limited.

We have incurred substantial losses during our history. As of December 31, 2017, we had federal and state NOLs of $125.3 million and $201.5 million, respectively. These NOLs will begin to expire at various dates beginning in 2027, if not limited by triggering events prior to such time. Under the provisions of the Internal Revenue Code, changes in our ownership, in certain circumstances, will limit the amount of federal NOLs that can be utilized annually in the future to offset taxable income. In particular, Section 382 of the Internal Revenue Code imposes limitations on a company’s ability to use NOLs upon certain changes in such ownership. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership that we cannot predict or control that could result in further limitations being placed on our ability to utilize our federal NOLs.

The recently passed Tax Cuts and Jobs Act (the "TCJA") could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the TCJA, which significantly reforms the Internal Revenue Code. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses generated after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, immediate deductions for certain new investments instead of deductions for depreciation expense over time and modifying or repealing many business deductions and credits. Federal net operating losses arising in taxable years ending after December 31, 2017 will be carried forward indefinitely pursuant to the TCJA. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our Common Stock.

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Risks Associated with our Common Stock

The market price of our Common Stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Our stock price may experience substantial volatility as a result of a number of factors, including:

- sales or potential sales of substantial amounts of our Common Stock;
- our ability to successfully leverage the anticipated benefits and synergies from 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;
- delay or failure in initiating or completing preclinical or clinical trials or unsatisfactory results of these trials;
- delay in FDA approval for RI-002;
- the timing of acceptance, third-party reimbursement and sales of RI-002;
- our ability to resume the manufacturing of Bivigam once the deficiencies identified in the CRL have been resolved by us to the satisfaction of the FDA;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors or third-party vendors;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnology companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These

broad market and industry factors could reduce the market price of our Common Stock, regardless of our actual operating performance.

An investment in our Common Stock is extremely speculative and there can be no assurance of any return on any such investment.

An investment in our Common Stock is extremely speculative and there is no assurance that investors will obtain any return on their investment. Investors will be subject to substantial risks involved in an investment in us, including the risk of losing their entire investment.

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Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the market price of our Common Stock.

As of December 31, 2017, most of our 45,316,659 outstanding shares of common stock, as well as a substantial number of shares of our Common Stock underlying outstanding warrants, were available for sale in the public market, subject to certain restrictions with respect to sales of our Common Stock by our affiliates, either pursuant to Rule 144 under the Securities Act ("Rule 144") or under effective registration statements. The 12,886,740 shares of common stock, including 8,591,160 shares of Non-Voting Common Stock, acquired by BPC in the Biotest Transaction were subject to a lock-up for six months after closing of the Biotest Transaction, which lock-up expired on December 6, 2017. For three years after the end of such six-month period, subject to certain limited exceptions, under the stockholders agreement entered into between the Company and BPC upon closing the Biotest Transaction, sales by BPC of our equity interests may not exceed 15% of the issued and outstanding common stock of ADMA in any twelve-month period; provided, however, that if our market capitalization increases to double our market capitalization immediately following the closing of the Biotest Transaction, then BPC may sell up to 20% of our issued and outstanding common stock in any twelve-month period; provided, further, that (x) if our market capitalization increases to triple our market capitalization immediately following the closing of the Biotest Transaction, or (y) upon the one-year anniversary of BPC holding less than a 25% economic interest in us, then BPC may sell its equity interests in us at any time (subject to applicable securities laws). At the closing of the Biotest Transaction, we entered into a registration rights agreement with BPC, pursuant to which BPC will have, among other things, certain registration rights under the Securities Act with respect to its shares of our common stock, subject to certain transfer restrictions. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the market price of our Common Stock.

Our affiliates control a substantial amount of our shares of common stock. Provisions in our Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), our Amended and Restated Bylaws (the "Bylaws") and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our Common Stock.

Provisions of our Certificate of Incorporation, our Bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our Company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. As of December 31, 2017, BPC, our directors and executive officers and their affiliates beneficially owned in excess of 55% of the outstanding shares of our common stock. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings;

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the ability of our Board to institute a stockholder rights plan, also known as a poison pill, that would work to dilute our stock,

- classification of our Board and limitation on filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company; and

- authorization of the issuance of "blank check" preferred stock, with such designation rights and preferences as may be determined from time to time by the Board, without any need for action by stockholders.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition. In addition, as a result of the concentration of ownership of our shares of common stock, our stockholders may, from time to time, observe instances where there may be less liquidity in the public markets for our securities.

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We have never paid and do not intend to pay cash dividends in the foreseeable future. As a result, capital appreciation, if any, will be your sole source of gain.

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

If we fail to adhere to the strict listing requirements of the Nasdaq Capital Market ("Nasdaq"), we may be subject to delisting. As a result, our stock price may decline and our Common Stock may be delisted. If our stock were no longer listed on Nasdaq, the liquidity of our securities likely would be impaired.

Our Common Stock currently trades on Nasdaq under the symbol "ADMA." If we fail to adhere to Nasdaq's strict listing criteria, including with respect to stock price, our market capitalization and stockholders' equity, our stock may be delisted. This could potentially impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which may be depressed by the relative illiquidity, but also through delays in the timing of transactions and the potential reduction in media coverage. As a result, an investor might find it more difficult to dispose of our Common Stock. We believe that current and prospective investors would view an investment in our Common Stock more favorably if it continues to be listed on Nasdaq. Any failure at any time to meet the Nasdaq continued listing requirements could have an adverse impact on the value of and trading activity of our Common Stock. Although we currently satisfy the listing criteria for Nasdaq, if our stock price declines dramatically, we could be at risk of failing to meet the Nasdaq continued listing criteria.

Penny stock regulations may affect your ability to sell our Common Stock.

Because the price of our Common Stock currently trades below $5.00 per share, our Common Stock is subject to Rule 15g-9 under the Exchange Act, which imposes additional sales practice requirements on broker dealers which sell these securities to persons other than established customers and accredited investors. Under these rules, broker-dealers who recommend penny stocks to persons other than established customers and "accredited investors" must make a special written suitability determination for the purchaser and receive the purchaser's written agreement to a transaction prior to sale, which includes an acknowledgement that the purchaser's financial situation, investment experience and investment objectives forming the basis for the broker-dealer's suitability determination are accurately stated in such written agreement. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the associated risks. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our Common Stock and may make it more difficult for holders of our Common Stock to sell shares to third parties or to otherwise dispose of them.

We are an "emerging growth company," and elect to comply with reduced public company reporting requirements applicable to emerging growth companies, which could make our Common Stock less attractive to investors.

We are an "emerging growth company," as defined by the Jumpstart Our Business Startups Act (the "JOBS Act"). The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for qualifying public companies. As an "emerging growth company," we may, under Section 7(a)(2)(B) of the Securities Act, delay adoption of new or revised accounting standards applicable to public companies until such standards would otherwise apply to private companies. We may continue to take advantage of this extended transition period until the first to occur of the date that we (i) are no longer an "emerging growth company" or (ii) affirmatively and irrevocably opt out of this extended transition period.

We could be an emerging growth company until December 31, 2018, which is the last day of the fiscal year following the fifth anniversary of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1 billion or we issue more than $1 billion of non-convertible debt in any three-year period, we would cease to be an emerging growth company prior to the end of such five-year period.

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We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Securities Act Section 7(a)(2)(B), upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard. As an emerging growth company, we are also exempt from the requirement to have our independent registered public accounting firm provide an attestation report on our internal control over financial reporting.

We cannot predict if investors will find our Common Stock less attractive as a result of our reliance on these exemptions. If some investors find our Common Stock less attractive as a result of any choice we make to reduce disclosure, there may be a less active trading market for our Common Stock, our stock price may be more volatile and our stock price may decline dramatically.

Our Board may, without stockholder approval, issue and fix the terms of shares of preferred stock and issue additional shares of Common Stock adversely affecting the rights of holders of our common stock.

Our Certificate of Incorporation authorizes the issuance of up to 10,000,000 shares of "blank check" preferred stock, with such designation rights and preferences as may be determined from time to time by the Board. Currently, our Certificate of Incorporation authorizes the issuance of up to 75,000,000 shares of Common Stock, of which 34,469,713 shares remain available for issuance and may be issued by us without stockholder approval, and up to 8,591,160 shares of Non-Voting Common Stock, all of which are issued and outstanding.

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Item 1B. Unresolved Staff Comments

Not Applicable.

Item 2. Properties

Our headquarters are located in approximately 4,200 square feet of space at 465 State Route 17, Ramsey, NJ. Our telephone number is (201) 478-5552. Currently we operate under a shared services agreement with Areth, LLC ("Areth") for the office, warehouse space and certain related services and have the ability to cancel this agreement upon 30 days' notice. Areth is a company controlled by Dr. Jerrold B. Grossman, our Vice Chairman, and Adam S. Grossman, our President and Chief Executive Officer, and we pay Areth monthly fees for the use of such office space and for other information technology, general warehousing and administrative services. Effective October 1, 2017, rent under the shared services agreement is $10,000 per month.

ADMA BioCenters' facilities are located in Norcross, GA, Marietta, GA and Kennesaw, GA. The combined facilities have a total of approximately 40,000 square feet of space, and total rent for the three facilities is approximately $53,000 per month. The Norcross, GA lease, the term of which was extended by five years on January 1, 2014 pursuant to the first of two available five-year renewal options, expires on September 30, 2023, and the Marietta, GA lease expires on January 31, 2024. The Kennesaw, GA lease expires April 1, 2026.

As part of the Biotest Transaction, we acquired the Boca Facility, which consists of two buildings aggregating 83,543 square feet residing on approximately 14.6 acres of land in Boca Raton, FL. All of our plasma fractionation and drug product manufacturing are conducted at the Boca Facility, which also contains administrative office space for our ADMA BioManufacturing subsidiary and for certain of our centralized corporate functions. In connection with the acquisition of the Biotest Assets, we assumed two warehouse leases in Boca Raton, FL for additional storage space for raw materials, spare parts and other supplies related to its business. One of these leases expired on December 31, 2017 and the other lease expires on July 31, 2018. The aggregate minimum lease payments for these two leases are approximately $9,000 per month.

Additionally, on January 1, 2019, pursuant to the terms of a separate purchase agreement entered into between ADMA BioManufacturing and BPC at the closing, we agreed to sell, transfer and convey to BPC for no additional consideration, all of our right, title and interest in and to certain of our plasma collection facilities located in the U.S., which are subject to a repurchase right in favor of us if within five years after January 1, 2019, the Biotest stockholders and its related entities own less than 20% of our issued and outstanding capital stock.

We believe that our leased and owned properties are adequate to meet our current and future needs.

Item 3. Legal Proceedings

We are and may become subject to certain legal proceedings and claims arising in connection with the normal course of our business. In the opinion of management, there are currently no claims that would have a material adverse effect on our consolidated financial position, results of operations or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our Common Stock has been listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "ADMA" since November 10, 2014.

The following table sets forth, for each of the calendar periods indicated, the high and low sales prices for our Common Stock, as reported by Nasdaq:

	Year Ended December 31, 2017		Year Ended December 31, 2016	
	High	Low	High	Low
First Quarter	$5.79	$4.44	$8.28	$4.15
Second Quarter	$5.44	$2.93	$8.85	$5.71
Third Quarter	$3.95	$2.67	$8.00	$5.00
Fourth Quarter	$3.48	$2.01	$7.34	$4.34

Holders

As of February 28, 2018, there were eight record holders of our Common Stock, based upon information received from our transfer agent. However, this number does not include beneficial owners whose shares were held of record by nominees or broker dealers. We estimate that there are more than 1,400 beneficial owners of our Common Stock. As of March 1, 2018, BPC was the sole record holder of our Non-Voting Common Stock.

Dividend Policy

We have never paid any cash dividends on our capital stock. We anticipate that we will retain earnings, if any, to support operations and to finance the growth and development of our business. In addition, the terms of our Credit Agreement with Marathon precludes us from paying cash dividends without the consent of Marathon. Therefore, we do not expect to pay cash dividends for the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth certain information regarding our equity compensation plans as of December 31, 2017:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	**Number of securities remaining available for future issuance under equity compensation plans**
Equity compensation plans approved by security holders	3,276,043	$ 5.52	654,645
Equity compensation plans not approved by security holders	—	$ —	—
Total	3,276,043	$ 5.52	654,645

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Stock Performance Graph

Not applicable.

Sale of Unregistered Securities

During the three months ended December 31, 2017, we had no sales of unregistered securities that have not been previously disclosed in a Current Report on Form 8-K or Quarterly Reports on Form 10-Q.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our securities during the three months ended December 31, 2017.

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. The various sections of this discussion contain a number of forward-looking statements, all of which are based on our current expectations and could be materially affected by the uncertainties and risk factors described throughout this Annual Report. See "Special Note Regarding Forward-Looking Statements." Our actual results may differ materially.

OVERVIEW

Our Business

We are a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and prevention of certain infectious diseases. Our targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons. We currently have two marketed products: Nabi-HB, indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen (“HBsAg”); and Bivigam, indicated for the treatment of primary humoral immunodeficiency. We are also developing a pipeline of plasma-derived therapeutics, including our lead pipeline product candidate, RI-002, for the treatment of Primary Immune Deficiency Disease (“PIDD”). Our products and product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients with or at risk for certain infectious diseases. Through our wholly-owned subsidiary, ADMA Bio Centers Georgia, Inc., (“ADMA BioCenters”), we operate two United States Food and Drug Administration (the “FDA”)-licensed, German Health Authority (“GHA”) and Korean Ministry of Food and Drug Safety (“KMFD”)certified source plasma collection facilities located in the U.S., which provide us with a portion of our blood plasma for the manufacture of our products and product candidates. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase and market conditions at the time of sale. Plasma collected from ADMA BioCenters' facilities that is not used to manufacture our products or product candidates is sold to third-party customers in the U.S., in other locations where we are approved globally under supply agreements or in the open "spot" market.

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

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Concurrent with the closing of the Biotest Transaction, Biotest committed to an aggregate of $40.0 million of funding for the Company. Upon the closing of the Biotest Transaction, we received $27.5 million in cash from Biotest, consisting of $12.5 million in cash and $15.0 million from a subordinated note at 6% interest payable to BPC with a maturity of five years. At the closing of the Biotest Transaction, we delivered to BPC an aggregate equity interest equal to 50%, less one share, of our then-issued and outstanding capital stock comprised of 25%, or 4,295,580 shares, of our voting common stock, $0.0001 par value per share ("Common Stock"), and 8,591,160 shares in the form of our non-voting common stock, $0.0001 par value per share ("Non-Voting Common Stock") (calculated as of immediately following the closing and on a post-closing issuance basis). The Non-Voting Common Stock is convertible into our Common Stock upon the occurrence of certain specified events.

As part of their commitment under the Biotest Transaction, Biotest participated in our November 2017 follow-on public offering of our Common Stock and invested $12.5 million of the $42.0 million of total gross proceeds from the offering (see "Liquidity and Capital Resources"). As a result, Biotest currently owns 41.3% of our total issued and outstanding capital stock, comprised of 10,109,534 shares, or 27.5%, of our Common Stock and 8,591,160 shares, or 100%, of our Non-Voting Common Stock.

On February 15, 2018, Dr. Bernhard Ehmer notified us that he has resigned as a member of our Board of Directors (the "Board"). This resignation was precipitated by certain commitments made by Biotest with the Committee on Foreign Investment in the United States ("CFIUS") in connection with a transaction unrelated to the Company. There was no disagreement between Dr. Ehmer and us on any matter related to our operations, policies or practices. Dr. Ehmer had served as a member of our Board since June 2017 and did not hold any positions on any committee of the Board. Also on February 15, 2018, we received notification from Michael Ramroth that he has resigned as an observer of the Board, effective immediately. This resignation was also precipitated by certain commitments made by Biotest with CFIUS in connection with a transaction unrelated to the Company. Mr. Ramroth had served as a Board observer since June 2017. Pursuant to the terms of that certain Stockholders Agreement, dated as of June 6, 2017, by and between the Company and BPC, BPC holds the right to designate (i) one person as a nominee to the Board, subject to Board approval, and (ii) one person as a Board observer.

Our Marketed Products

Nabi-HB

Nabi-HB is a hyperimmune globulin that is rich in antibodies to the Hepatitis B virus. Nabi-HB is a purified human polyclonal antibody product collected from plasma donors who have been previously vaccinated with a Hepatitis B vaccine. Nabi-HB is indicated for the treatment of acute exposure to blood containing HBsAg, prenatal exposure to infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection. Hepatitis B is a potentially life-threatening liver infection caused by the

Hepatitis B virus. It is a major global health problem. It can cause chronic infection and puts people at high risk of death from cirrhosis and liver cancer. Nabi-HB has a well-documented record of long-term safety and effectiveness since its initial market introduction. FDA approval for Nabi-HB was received on March 24, 1999. Biotest acquired Nabi-HB from Nabi Biopharmaceuticals in 2007. Production of Nabi-HB at the Boca Facility has continued since the third quarter of 2017. Subsequent to the end of 2017, we received authorization from the FDA for the release of our first commercial batch of Nabi-HB for commercial distribution in the U.S.

Bivigam

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

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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 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 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, measles and tetanus. We use our proprietary RSV microneutralization assay to test for standardized levels of neutralizing antibodies to RSV in the final drug product.

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

Plasma Collection Facilities

ADMA BioCenters operates two FDA-licensed, GHA and KMFD certified source plasma collection facilities located in the U.S., which provide us with a portion of our blood plasma for the manufacture of our products and product candidates. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect

approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase and market conditions at the time of sale. Plasma collected from ADMA BioCenters' facilities that is not used to manufacture our products or product candidates is sold to third-party customers in the U.S., and other locations where we are approved globally under supply agreements or in the open "spot" market.

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

RESULTS OF OPERATIONS

Critical Accounting Policies and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our consolidated financial statements, which have been prepared in accordance with Accounting Principles Generally Accepted in the United States of America ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate these estimates and assumptions, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

Some of the estimates and assumptions we have to make under U.S. GAAP require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summary of accounting policies and their application are considered to be critical to understanding our business operations, financial condition and results of operations. For a detailed discussion on the application of these and our other accounting policies, see Note 2 to the Consolidated Financial Statements included elsewhere in this Annual Report.

Revenue Recognition

Revenues for the year ended December 31, 2017 are comprised of (i) revenues from Nabi-HB, (ii) product revenues from the sale of human plasma collected from our plasma collection centers segment, (iii) a compensation fee related to the amendment of our contract manufacturing agreement with Sanofi Pasteur S.A. ("Sanofi"); and (iv) license and other revenues primarily attributable to the out-licensing of RI-002 to Biotest to market and sell in Europe and selected countries in North Africa and the Middle East. Biotest has provided us with certain services and financial payments in accordance with the related Biotest license agreement and is obligated to pay us certain amounts in the future if certain milestones are achieved. Deferred revenue is recognized over the term of the Biotest license. Deferred

revenue is amortized into income for a period of approximately 22 years, the term of the Biotest license agreement.

Revenue from the sale of Nabi-HB is recognized when the product reaches the customer's destination. Nabi-HB revenue is recorded net of estimated customer prompt pay discounts and contractual allowances in accordance with managed care agreements, including wholesaler chargebacks, rebates, customer returns and other wholesaler fees.

Product revenues from the sale of human plasma collected at our plasma collection centers are recognized at the time of transfer of title and risk of loss to the customer, which generally occurs at the time of shipment. Product revenues are recognized at the time of delivery if the Company retains the risk of loss during shipment.

For the year ended December 31, 2017, BPC represented 47% of our consolidated revenues, and the revenue attributable to the amendment of a contract manufacturing agreement represented 31% of our consolidated revenues. For the year ended December 31, 2016, BPC and another customer represented approximately 82% and 14%, respectively, of our consolidated revenues.

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Accounts Receivable

Accounts receivable are reported at realizable value, net of allowances for contractual credits and doubtful accounts, which are recognized in the period the related revenue is recorded. At December 31, 2017, Sanofi accounted for 48% of our total accounts receivable and Sanofi, BPC, AmerisourceBergen and McKesson Corporation accounted for 96% of consolidated accounts receivable. At December 31, 2016, BPC accounted for 95% of our total accounts receivable.

Cost of Product Revenue

Cost of product revenue includes expenses related to process development as well as scientific and technical operations when these operations are attributable to marketed products. When the activities of these operations are attributable to new products in development, the expenses are classified as research and development expenses. Expenses associated with remediating the issues identified in the Warning Letter for the year ended December 31, 2017 of approximately $3.8 million are expensed as incurred and are reflected in cost of product revenue. In addition, for the year ended December 31, 2017, all operating expenses associated with the Boca Facility, other than the limited Nabi-HB production that was capitalized into inventory, have been expensed as incurred since the date of the Biotest Transaction.

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the grantee's requisite vesting period on a straight-line basis. For the purpose of valuing stock options granted to our employees, directors and officers, we use the Black-Scholes option pricing model. We granted options to purchase an aggregate of 3,276,043 and 1,535,187 shares of Common Stock during the years ended December 31, 2017 and 2016, respectively. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of the grant with a term consistent with the expected term of our awards. The expected term of the options granted is in accordance with Staff Accounting Bulletins 107 and 110, and is based on the average between vesting terms and contractual terms. The expected dividend yield reflects our current and expected future policy for dividends on our Common Stock. The expected stock price volatility for our stock options was calculated by examining the pro rata historical volatilities for similar publicly traded industry peers and the trading history for our Common Stock. We will continue to analyze the expected stock price volatility and expected term assumptions and will adjust our Black-Scholes option pricing assumptions as appropriate. In accordance with Accounting Standards Update ("ASU") No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, we have elected not to establish a forfeiture rate, as stock-based compensation expense related to forfeitures of unvested stock options is fully reversed at the time of forfeiture.

Research and Development Expenses

Our research and development ("R&D") costs are expensed as incurred, including costs associated with (i) planning and conducting clinical trials; (ii) drug product manufacturing for RI-002, including the cost of plasma, plasma storage and transportation costs; (iii) quality testing, validation, regulatory consulting and filing fees; and (iv) employees' compensation expenses directly related to R&D activities.

Impairment of Long-Lived Assets

We assess the recoverability of its long-lived assets, which include property and equipment and definite-lived intangible assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the year ended December 31, 2017, we recorded an impairment charge in the amount of $0.8 million related to assets acquired in the Biotest Transaction. For the year ended December 31, 2016, we determined that there was no impairment of its long-lived assets.

Goodwill is not amortized, but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. We have the option to perform a qualitative assessment of goodwill to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill and other intangible assets. If we were to conclude that this is the case, then we must perform a goodwill impairment test by comparing the fair value of the reporting unit to its carrying value. An impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value, with the impairment loss recognized not to exceed the total amount of goodwill allocated to that reporting unit. We did not recognize any impairment charges related to goodwill for the year ending December 31, 2017.

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Recent Accounting Pronouncements

On April 5, 2012, the Jumpstart Our Business Startups Act (the "JOBS Act"), was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for qualifying public companies. We could be an emerging growth company until December 31, 2018, which is the last day of the fiscal year following the fifth anniversary of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Securities Act"). However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1 billion or we issue more than $1 billion of non-convertible debt in any three-year period, we would cease to be an emerging growth company prior to the end of such five-year period. As an "emerging growth company," we may, under Section 7(a)(2)(B) of the Securities Act, delay adoption of new or revised accounting standards applicable to public companies until such standards would otherwise apply to private companies. We may take advantage of this extended transition period until the first to occur of the date that we (i) are no longer an "emerging growth company" or (ii) affirmatively and irrevocably opt out of this extended transition period. We have elected to take advantage of the benefits of this extended transition period. Our consolidated financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Securities Act Section 7(a)(2)(B), upon issuance of a new or revised accounting standard that applies to our consolidated financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard. As an emerging growth company, we are also exempt from the requirement to have our independent auditors provide an attestation report on our internal control over financial reporting.

In May 2017, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2017-09, *Modification Accounting for Share-Based Payment Arrangements*, which amends the scope of modification accounting for share-based payment arrangements. The ASU provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. The ASU is effective for annual reporting periods, including interim periods within those annual reporting periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. We do not expect this new guidance to have a material impact on our consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations – Clarifying the Definition of a Business*, which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The standard introduces a screen for determining when assets acquired are not a business and clarifies that a business must include, at a minimum, an input and a substantive process that contribute to an output to be considered a business. This standard is effective for fiscal years beginning after December 15, 2017, including interim periods within that reporting period. We adopted this standard in the second quarter of 2017, and the adoption of this standard did not have a material impact on our consolidated financial statements as of and for the year ended December 31, 2017.

In January 2017, the FASB issued ASU 2017-04, *Intangibles – Goodwill and Other (Topic 350)*, which removes the requirement to compare the implied fair value of goodwill with its carrying amount as part of step 2 of the goodwill impairment test. As a result, under the ASU, "an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount and should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The ASU is effective prospectively for fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We adopted ASU 2017-04 in the fourth quarter of 2017, and adoption of this update did not have a material impact on our consolidated financial statements as of and for the year ended December 31, 2017.

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In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash*, which clarifies guidance and presentation related to restricted cash in the statement of cash flows, including stating that restricted cash should be included within cash and cash equivalents in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, with early adoption permitted, and is to be applied retrospectively. We adopted this standard in the fourth quarter of 2017, and adoption of this update did not have a material impact on our consolidated financial statements as of and for the years ended December 31, 2017 and 2016.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. We adopted this standard in the first quarter of 2017, and the adoption of this standard did not have a material impact on our consolidated financial statements as of and for the year ended December 31, 2017.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. We are currently evaluating the impact that the standard may have on our consolidated financial statements and related disclosures.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740), Balance Sheet Classification of Deferred Taxes*, which includes amendments that require deferred tax liabilities and assets be classified as non-current in a classified statement of financial position. The amendments in this ASU are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Earlier application is permitted as of the beginning of an interim or annual reporting period. The amendments may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. We adopted this standard in the second quarter of 2017. Because we carry a full valuation allowance against our deferred tax assets as of December 31, 2017 and 2016, adoption of this standard did not have a material impact on our consolidated financial statements.

In September 2015, the FASB issued ASU No. 2015-16, *Business Combinations (Topic 805), Simplifying the Accounting for Measurement-Period Adjustments*, which includes amendments that require an acquirer to recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments in this ASU require that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the changes to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. The amendments in this ASU require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current period earnings by line item that would

have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The amendments should be applied prospectively to adjustments to provisional amounts that occur after the effective date of the ASU with earlier application permitted for financial statements that have not yet been made available for issuance. We adopted this standard in the first quarter of 2017, and the adoption of this standard did not have a material impact on our consolidated financial statements as of and for the year ended December 31, 2017.

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. The standard requires entities to measure most inventory "at the lower of cost and net realizable value," thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market (market in this context is defined as one of three different measures, one of which is net realizable value). We adopted this standard in the first quarter of 2017, and the adoption of this standard did not have a material impact on our consolidated financial statements as of and for the year ended December 31, 2017.

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In May 2014, the FASB issued new guidance related to revenue recognition, ASU 2014-09, *Revenue from Contracts with Customers ("ASC 606")*, which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new guidance requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. ASC 606 defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The new guidance becomes effective in calendar year 2018 and early adoption in calendar year 2017 is permitted. Two methods of adoption are permitted: (a) full retrospective adoption, meaning the standard is applied to all periods presented; or (b) modified retrospective adoption, meaning the cumulative effect of applying the new guidance is recognized at the date of initial application as an adjustment to the opening retained earnings balance.

In March 2016, April 2016 and December 2016, the FASB issued ASU No. 2016-08, *Revenue From Contracts with Customers (ASC 606): Principal Versus Agent Considerations*, ASU No. 2016-10, *Revenue From Contracts with Customers (ASC 606): Identifying Performance Obligations and Licensing*, and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue From Contracts with Customers*, respectively, which further clarify the implementation guidance on principal versus agent considerations contained in ASU No. 2014-09. In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers*, narrow-scope improvements and practical expedients that provide clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for non-cash consideration and completed contracts at transition. These standards became effective for the Company in the first quarter of 2018.

We will adopt the new standard and related updates effective January 1, 2018, using the modified retrospective method of adoption. Based on our review of the terms and conditions of our existing customer contracts and applying the five discrete criteria required for recognizing revenue as set forth in ASU 2014-09, we do not expect the new revenue recognition guidance to have a material impact on our consolidated financial statements.

Year Ended December 31, 2017 Compared to December 31, 2016

Our results of operations for the year ended December 31, 2017 reflect the results of operations attributable to the Biotest Assets effective as of June 6, 2017. As a result, our operating results for the year ended December 31, 2017 are generally not comparable to our operating results for the year ended December 31, 2016. The following table presents a summary of the changes in our results of operations for the year ended December 31, 2017 as compared to December 31, 2016:

	Year Ended December 31,		Percentage **Increase/ (Decrease)**
	2017	2016	

Revenues	$22,760,560	$10,661,037	113	%
Cost of product revenue (exclusive of amortization expense shown below)	29,164,321	6,360,761	359	%
Gross (loss) profit	(6,403,761)	4,300,276	-249	%
Research and development expenses	6,229,587	7,688,238	-19	%
Plasma center operating expenses	6,503,750	5,447,691	19	%
Asset impairment charge	845,389	—	NM	
Amortization of intangibles	1,234,674	—	NM	
Selling, general and administrative expenses	18,092,835	8,494,742	113	%
Loss from operations	(39,309,996)	(17,330,395)	127	%
Interest expense	(3,285,847)	(2,239,569)	47	%
Other (expense) income, net	(1,163,132)	54,813	NM	
Net loss	$(43,758,975)	$(19,515,151)	124	%

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Revenues

We recorded total revenues of $22.8 million for the year ended December 31, 2017, as compared to $10.7 million for the year ended December 31, 2016. The increase in total revenue of $12.1 million is primarily due to: (i) sales of Nabi-HB in the amount of $4.0 million for 2017, with no comparable amount in 2016, (ii) $7.0 million of revenue related to an amendment to the Sanofi Manufacturing Agreement (as defined below) that we assumed as part of the Biotest Transaction; and (iii) an increase in sales of plasma attributable to our ADMA BioCenters plasma collection centers segment of $1.1 million in 2017 due to higher collection volume.

In September 2011, BPC entered into a manufacturing agreement, as subsequently amended, with Sanofi (the "Manufacturing Agreement") in which Sanofi purchased from BPC specific Batches (as defined therein) of purified Rabies Fraction II Paste manufactured from human plasma containing rabies antibodies (the "Product"). The number of Batches of Product purchased by Sanofi under the Manufacturing Agreement vary from year to year and are subject to certain minimum purchase requirements by Sanofi. In the event that Sanofi fails to purchase any quantity of Product as part of its Firm Purchase Commitment (as defined under the Manufacturing Agreement), Sanofi is required to pay us, as the successor-in-interest to BPC, for the number of Batches not purchased in any given year. In addition, under the Manufacturing Agreement, damages are owed to Sanofi in the event the minimum Batch amounts are not manufactured or fail to comply with the supply plan and an escalating low single digit to low double digit percentage discount is applied to Batches which are delayed. The Manufacturing Agreement contains customary representations and warranties, mutual confidentiality provisions and mutual indemnification provisions subject to limitations of liability, and continues in effect for up to two years from the date of termination of the human Rabies Hyperimmune Plasma agreement between Sanofi and BPC.

In December 2017, we further amended the Manufacturing Agreement to modify the number of Batches of Product which Sanofi is to purchase from us in 2018 and 2019 and to update the supply plan which describes the agreed-upon timing for production of such Batches of Product. Pursuant to this third amendment to the Manufacturing Agreement, we are liable to Sanofi for liquidated damages in the event that we fail to supply a minimum number of Batches of Product or in the event we fail to adhere to the updated supply plan. Furthermore, pursuant to this third amendment to the Manufacturing Agreement, in consideration for certain quantities of Product that we would have otherwise been contractually obligated to supply, and that Sanofi would have been contractually obligated to purchase, prior to entry into such amendment, Sanofi agreed to pay us a one-time compensation fee in the aggregate amount of $7.0 million.

Cost of Product Revenue

Cost of product revenue was $29.2 million for the year ended December 31, 2017, as compared to $6.4 million for the year ended December 31, 2016, an increase of $22.8 million. The increase is mainly attributable to unabsorbed manufacturing costs related to the Boca Facility of $12.8 million, third party consultant fees pertaining to the

remediation efforts in response to the Warning Letter in the amount of $3.8 million, cost of product revenue related to Nabi-HB in the amount of $3.3 million, $1.6 million of production costs incurred in the fourth quarter of 2017 related to of two lots of Bivigam and a sales volume-related increase at ADMA BioCenters of $0.9 million.

Cost of product revenue related to Nabi-HB reflects the sale of inventory acquired in the Biotest Transaction, which has been carried on our consolidated balance sheet at its estimated fair value. As this inventory is liquidated in the normal course of business and replaced with inventory produced subsequent to the date of the Biotest Transaction, we expect that the margins for Nabi-HB will be higher in future periods as compared to those realized during the year ended December 31, 2017.

Although we expect that our Bivigam inventory will ultimately be available for commercial sale, we have established an allowance for all of this inventory in the amount of $1.6 million at December 31, 2017, due to uncertainties surrounding the Warning Letter and the PAS related to improvements in the manufacturing process that must be filed with and approved by the FDA prior to this inventory being available for commercial sale.

Research and Development Expenses

R&D expenses were $6.2 million for the year ended December 31, 2017, a decrease of $1.4 million as compared to the same period of a year ago. The decrease is primarily the result of lower validation, testing, BLA and production costs related to RI-002 in 2017. Once we have further clarity from the FDA regarding the timing of our expected BLA resubmission and anticipated RI-002 approval, we would then expect our R&D costs to increase.

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Plasma Center Expenses

Plasma center expenses were $6.5 million for the year ended December 31, 2017, an increase of $1.1 million from the $5.4 million of plasma center expenses for the year ended December 31, 2016. The increase in plasma center expenses is attributable to hiring additional staff and increasing the hours of operations at our Marietta, GA location during the first quarter of 2017.

Selling, General and Administrative Expenses

Selling, general and administrative expenses ("SG&A") were $18.1 million for the year ended December 31, 2017, an increase of $9.6 million as compared to the year ended December 31, 2016. The year ended December 31, 2017 reflects $5.9 million of SG&A expenses associated with BTBU with no comparable amounts in 2016, and Biotest Transaction costs of $3.9 million, including fees paid for legal, accounting and financial advisory services related to due diligence and other costs associated with the acquisition of the Biotest Assets and the issuance of a fairness opinion, as compared to $1.9 million for the year ended December 31, 2016. SG&A expenses in 2017 also include $0.3 million of one-time compensation expense associated with the Biotest Transaction, an increase in insurance expense of $0.5 million associated with the acquisition of the Biotest Assets and an increase in stock-based compensation of approximately $0.3 million.

Amortization of Intangibles

During the year ended December 31, 2017, we incurred amortization expense of $1.2 million related to intangible assets acquired in the Biotest Transaction (see Notes 3 and 6 to the consolidated financial statements), with no comparable amount for the year ended December 31, 2016.

Asset Impairment Charge

During the year ended December 31, 2017, we recorded an impairment charge in the amount of $0.8 million related to certain assets acquired in the Biotest Transaction (see Note 3 to the consolidated financial statements), with no comparable amount for the year ended December 31, 2016.

Loss from Operations

Our operating loss was $39.3 million for the year ended December 31, 2017, as compared to $17.3 million for the year ended December 31, 2016. The increase was mainly due to the increase in cost of product revenue of $22.8 million, the $9.6 million increase in SG&A expenses, the $1.1 million increase in plasma center expenses and amortization of intangible assets of $1.2 million, partially offset by the $12.1 million increase in total revenues and the $1.4 million decrease in R&D expenses.

Interest Expense

Interest expense was $3.3 million for the year ended December 31, 2017, compared to $2.2 million for the year ended December 31, 2016. The increase is due to higher interest expense, including amortization of debt discount, resulting from higher average debt balances in 2017 due to (i) the $15 million note payable to BPC, (ii) the increase of $4.0 million to our then-current debt to Oxford Finance, LLC (“Oxford”) in May 2016 and (iii) the refinancing of the Oxford debt in October 2017, which resulted in an additional $10 million of interest-bearing debt (see “Liquidity and Capital Resources”).

Other (Expense) Income

Other expense, net was $1.2 million for the year ended December 31, 2017, as compared to other income of approximately $55,000 for the year ended December 31, 2016. The increase is mainly due to the loss on extinguishment of debt in the amount of $1.2 million, primarily the result of writing off unamortized debt discount, recognized in 2017 in connection with the refinancing of the Oxford debt.

Net Loss

Net loss was $43.8 million for the year ended December 31, 2017, an increase of $23.9 million from the prior year. The increase was mainly due to the increases in operating loss and, to a lesser extent, interest expense, as well as the loss on extinguishment of debt in 2017, with no comparable amount in 2016.

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LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2017, we had working capital of $53.7 million, including cash and cash equivalents of $43.1 million, and stockholders' equity of $40.3 million, as compared to working capital of $10.4 million, including cash and cash equivalents of $9.9 million, and a stockholders' deficit of $4.5 million as of December 31, 2016. We have had limited revenue from operations, incurred an accumulated deficit of $150.7 million since inception, and for the years ended December 31, 2017 and 2016 we had negative cash flows from operations of $37.3 million and $18.3 million, respectively. We have funded our operations to date primarily from the sale of our equity and debt securities, acquisition proceeds from the Biotest Transaction and loans from our primary stockholders.

We expect to continue to spend substantial amounts on product development, quality assurance, regulatory affairs, procurement of raw material plasma, manufacturing, marketing, sales and conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers, some of which may be required by the FDA. We currently anticipate, based upon our projected revenue and expenditures, that our cash, cash equivalents, projected revenue and accounts receivable, along with the $10.0 million we expect to be able to draw down under the Credit Agreement (as defined below), will be sufficient to fund our operations, as currently conducted, through the end of 2018. 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 prior to the end of 2018. This time frame may change based upon how quickly we are able to execute on our quality management systems' enhancement plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options we are exploring. We currently have no firm commitments for additional financing, and we cannot provide any assurance that we will be able to secure additional financing on terms that are acceptable to us, or at all. Failure to secure any necessary financing in a timely manner and on commercially reasonable terms could have a material adverse effect on our business plan and financial performance and we could be forced to delay or discontinue our product development, clinical trial or commercialization activities, delay or discontinue the approval efforts for any of our potential products, or potentially cease operations. In addition, we could also be forced to reduce or forgo sales and marketing efforts and forgo attractive business opportunities.

Furthermore, if the assumptions underlying our estimated expenses are incorrect, we may have to raise additional capital sooner than anticipated. Because of numerous risks and uncertainties associated with the research and development and potential future commercialization of our product candidates, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our anticipated clinical trials and development activities. Our current estimates may be subject to change as circumstances regarding our business requirements evolve. We may decide to raise capital through public or private equity offerings and 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. We may also decide to obtain additional debt financing or a bank credit facility, subject to the restrictions contained in the Credit Agreement, or to enter into corporate collaboration and licensing arrangements. The sale of additional equity or debt securities, if convertible, could result in dilution to our current stockholders. The incurrence of additional indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations or other future financing alternatives.

Our long-term liquidity depends upon our ability to raise additional capital, fund our research and development and commercial programs and achieve commercial status for our products and product candidates in order to generate sufficient revenues to cover our operating expenses and meet our obligations on a timely basis. We believe that we will continue to incur losses and negative cash flows from operating activities through the foreseeable future. As such, these conditions raise substantial doubt about our ability to continue as a going concern.

On November 13, 2017, we completed an underwritten public offering of 19,523,255 shares of Common Stock for gross proceeds of $42.0 million. Net proceeds from this offering, after payment of underwriting discounts and offering expenses of $2.8 million, were $39.2 million. The proceeds from this offering have been or are being used for (i) the purchase of raw material inventory and the ramp-up of our manufacturing capabilities, (ii) continued remediation of the issues identified in the CRL and the Warning Letter and completion of our internal quality management systems overhaul, (iii) capital expenditures for the Boca Facility, (iv) product launch and medical education campaigns, (v) the build-out of our third plasma collection facility, (vi) research and development activities for our plasma collection programs and specialty plasma products, and (vii) working capital needs and general corporate purposes, including expenses associated with improving the FDA inspection classification relative to the Warning Letter, filing the PAS and obtaining marketing clearance for the relaunch of Bivigam and refiling the BLA for RI-002.

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On October 10, 2017 (the "Marathon Closing Date"), we entered into a Credit Agreement (the "Credit Agreement") with Marathon Healthcare Finance Fund, L.P. ("Marathon" or the "Lender") and Wilmington Trust, National Association, as the administrative agent for the Lender (the "Administrative Agent"). The Credit Agreement provides for a senior secured term loan facility in an aggregate amount of up to $40.0 million (collectively, the "Credit Facility"), comprised of (i) a term loan made on the Marathon Closing Date in the principal amount of $30.0 million (the "Tranche One Loan"), and (ii) an additional term loan to be made in the maximum principal amount not to exceed $10.0 million (the "Tranche Two Loan" and, together with the Tranche One Loan, the "Loans"), which Tranche Two Loan availability is subject to the satisfaction of certain conditions, including, but not limited to, those described below. The Loans each have a maturity date of April 10, 2022 (the "Maturity Date"), subject to acceleration pursuant to the Credit Agreement, including upon an Event of Default (as defined in the Credit Agreement).

On the Marathon Closing Date, we used approximately $17.0 million of the Tranche One Loan to retire and pay in full our previously existing credit facility, as amended, with Oxford Finance, LLC ("Oxford") and all of the obligations thereunder, including the end-of-term liability of $1.8 million and prepayment penalties of $0.2 million. We also (i) used $5.5 million of the Tranche One Loan to pre-fund a debt service reserve account in accordance with the terms of the Credit Agreement, and (ii) paid diligence fees, legal and other expenses associated with the Credit Facility in the amount of approximately $1.5 million, which fees exclude a deferred facility fee to Marathon equal to 9.20% of the Tranche One Loan payable at maturity. The remaining $6.0 million of proceeds was used for the continued remediation of the issues identified in the CRL and the Warning Letter and for general corporate purposes.

The obligation of Marathon to make the Tranche Two Loan is subject to the satisfaction of certain conditions related to FDA approval for specified products and the Company's financial condition, including, without limitation, the following: (a) (i) the FDA must validate the improved manufacturing process of Bivigam and (ii) not less than $0.5 million in net revenue must be generated in calendar year 2018 from the sale in the U.S. of Bivigam; or (b) (i) the FDA must approve the commercialization of RI-002 and (ii) not less than $0.5 million in net revenue must be generated in calendar year 2019 from the sale in the U.S. of RI-002.

On the Marathon Closing Date, we issued a promissory note in favor of the Administrative Agent in the principal amount of $30.0 million (the "Tranche One Note"), evidencing our indebtedness resulting from the Tranche One Loan. Borrowings under the Credit Agreement bear interest at a rate per annum equal to LIBOR plus 9.50% with a 1% LIBOR floor; provided, however, that in the event that we achieve sales of not less than $61.7 million for the 2018 calendar year and the Tranche Two Loan has been funded, then the interest rate on the borrowings under the Credit Agreement will decrease to LIBOR plus 7.75% with a 1% LIBOR floor. During an Event of Default under the Credit Agreement, the outstanding amount of indebtedness under the Credit Agreement will bear interest at a rate per annum equal to the interest rate then applicable to the borrowings under the Credit Agreement plus 5% per annum. Quarterly cash interest payments are due the first business day of each March, June, September and December, beginning on December 1, 2017.

The Company will pay Marathon a facility fee in an amount equal to 9.20% of the amount funded, payment of which is deferred until the Maturity Date pursuant to the terms of the Credit Agreement. Commencing on October 10, 2020, and on the first business day of each month, we are required to make principal payments on the Tranche One Loan (and Tranche Two Loan in the event it shall have been funded) in equal monthly installments over 18 months, subject to certain conditions in the Credit Agreement. The outstanding principal amount of the Loans, together with all accrued interest thereon, is due on the Maturity Date.

As consideration for the Credit Agreement, we issued warrants to purchase an aggregate of 339,301 shares of our Common Stock to the Lender and certain of the Lender's affiliates (the "Tranche One Warrants"). The Tranche One Warrants, which we valued at $0.6 million, have (i) an exercise price equal to $3.0946, which was the trailing 10-day volume weighted-average price of our Common Stock prior to the Marathon Closing Date, and (ii) an expiration date of October 10, 2024. We issued the Tranche One Warrants in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The Tranche One Warrants and the shares of Common Stock issuable thereunder may not be offered, sold, pledged or otherwise transferred in the U.S. absent registration or an applicable exemption from the registration requirements under the Securities Act.

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Based on the fair value of the Tranche One Warrants, the facility fee and the fees and expenses associated with obtaining the Credit Facility, the effective interest rate on the Tranche One Note is approximately 16.5%. Our obligations under the Credit Agreement are secured by a first-priority lien and security interest in substantially all of our assets, including a mortgage on the Boca Facility, and those of ADMA's subsidiaries as well as all of the equity interests in each subsidiary.

The Credit Agreement contains market representations and warranties, affirmative covenants, negative covenants, financial covenants, and conditions that are customarily required for similar financings. The affirmative covenants, among other things, require us to undertake various reporting requirements. The negative covenants restrict or limit our and our subsidiaries' ability to, among other things, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes or changes to our business activities; sell or otherwise dispose of assets; repurchase stock, pay dividends; repay certain other indebtedness; engage in certain affiliate transactions; or enter into any other agreements that restrict our ability to make loan repayments. In addition, we may not permit our liquidity, defined in the Credit Agreement as cash held in the debt service reserve account and any other deposit account subject to a control agreement with the Administrative Agent, to be less than $5.5 million at any time. The Credit Agreement also required the establishment of the debt service reserve account. We are currently required to maintain a minimum balance in this account of $5.5 million. Upon the satisfaction of certain conditions related to some of our leased properties, the minimum required balance in the debt service reserve account will be reduced to $4.0 million.

The Credit Agreement also contains customary Events of Default which include, among others, non-payment of principal, interest or fees, violation of covenants, inaccuracy of representations and warranties, bankruptcy and insolvency events, material judgments, cross-defaults to material contracts and events constituting a change of control. The occurrence of an Event of Default could result in, among other things, the termination of commitments under the Credit Facility and the declaration that all outstanding Loans are immediately due and payable in whole or in part.

In June 2017, we received $27.5 million in connection with the Biotest Transaction, comprised of $12.5 million in cash from BPC and an unsecured subordinated 6% note payable to BPC in the amount of $15.0 million. Also in June 2017, BPC provided us with a firm equity commitment to invest up to an additional $12.5 million in future equity financings of the Company, and this commitment was invested in the foregoing November 2017 public offering of Common Stock.

The following table sets forth a summary of our cash flows for the periods indicated:

	Year Ended December 31,	
	2017	2016
Net cash used in operating activities	$(37,271,774)	$(18,268,973)

Net cash provided by investing activities	15,213,856	904,583
Net cash provided by financing activities	60,750,625	16,838,298
Net change in cash and cash equivalents	38,692,707	(526,092)
Cash and cash equivalents - beginning of year	9,914,867	10,440,959
Cash and cash equivalents, including restricted cash - end of year	$48,607,574	$9,914,867

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The following table illustrates the primary components of our cash flows from operations:

	Year Ended December 31,	
	2017	2016
Net loss	$(43,758,975)	$(19,515,151)
Non-cash expenses, gains and losses	6,769,443	2,253,759
Changes in accounts receivable	(2,862,127)	(93,559)
Changes in inventories	589,318	(1,574,373)
Changes in prepaid expenses and other current assets	(941,272)	(202,887)
Changes in accounts payable and accrued expenses	3,426,549	893,798
Other	(494,710)	(30,560)
Cash used in operations	$(37,271,774)	$(18,268,973)

Cash used in operations increased by $19.0 million for the year ended December 31, 2017 as compared to the year ended December 31, 2016, mainly due to the higher net loss, partially offset by an increase in non-cash charges. The increase in net loss in 2017 is primarily the result of the Biotest Transaction and the operations associated with the Boca Facility. The increase in non-cash expenses in 2017 is mainly due to increased depreciation expense on property and equipment and amortization expense for intangible assets acquired in the Biotest Transaction (see Note 3 to the consolidated financial statements), and to the loss on extinguishment of debt recognized in connection with repayment of the indebtedness under the Oxford credit facility.

Net cash provided by investing activities was $15.2 million for the year ended December 31, 2017, which reflects the $12.5 million cash received by us in connection with the acquisition of the Biotest Assets, and the redemptions of short-term investments in the amount of $5.4 million, partially offset by capital expenditures in the amount of $2.7 million. Our capital expenditures were mainly the result of the continued build out of our third ADMA BioCenters plasma collection facility. We expect our total capital expenditures will be between $3.5 million and $4.0 million for fiscal 2018.

Net cash provided by investing activities was $0.9 million for the year ended December 31, 2016, which was related to the redemption of short-term investments, net of purchases of such investments.

Net cash provided by financing activities totaled $60.8 million for the year ended December 31, 2017, consisting primarily of $39.2 million of net proceeds from a public offering of Common Stock, $15.0 million received from the issuance of the note payable to BPC and the refinancing of the Oxford indebtedness with the Marathon Credit Facility, which resulted in net proceeds of approximately $11.5 million (including $5.5 million in cash held in the debt service reserve account), partially offset by repayments on the principal balances of our notes payable to Oxford in the

amount of $5.0 million.

Net cash provided by financing activities totaled $16.8 million for the year ended December 31, 2016, which consisted primarily of $12.9 million of net proceeds received from the issuance of Common Stock during the second quarter of 2016 and $4.0 million received from the issuance of notes to Oxford during the second quarter of 2016.

Effect of Inflation

Inflation did not have a significant impact on ADMA's net sales, revenues or income from continuing operations in 2015, 2016 or 2017.

Off-Balance Sheet Arrangements

None.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

Our financial statements required to be filed pursuant to this Item 8 appear in a separate section of this Annual Report on Form 10-K, beginning on page F-1.

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Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We designed our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Exchange Act, to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures as of December 31, 2017. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures as of December 31, 2017 are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding disclosures.

A control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management's Annual Report on Internal Control Over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Internal control over financial reporting is defined in Rules 13a-15(f) and

15d-15(f) promulgated under the Exchange Act.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2017. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organization of the Treadway Commission in its 2013 "Internal Control-Integrated Framework." Based on this assessment, management concluded that, as of December 31, 2017, the Company's internal control over financial reporting is effective.

We are currently integrating the business processes and information systems in effect prior to the closing of the Biotest Transaction with those of ADMA BioManufacturing, including internal controls. In accordance with guidance issued by the SEC, registrants are permitted to exclude acquisitions from their assessment of internal controls over financial reporting during the first year subsequent to the acquisition while integrating the acquired operations. Management's assessment of internal control over financial reporting excluded the operations of BTBU, which was acquired on June 6, 2017 and immediately contributed into ADMA BioManufacturing. At December 31, 2017, ADMA BioManufacturing had total assets of $54.0 million.

As a smaller reporting company, the Company is not required to include in this Annual Report a report on the effectiveness of internal control over financial reporting by the Company's independent registered public accounting firm.

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Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met, and therefore, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. We do not expect that our disclosure controls and procedures or our internal control over financial reporting are able to prevent with certainty all errors and all fraud.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required to be disclosed by this Item with respect to our executive officers is incorporated into this Annual Report on Form 10-K by reference from the section entitled “Executive Officers and Director and Officer Compensation: Executive Officers” contained in our definitive proxy statement for our 2018 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2017.

Information required to be disclosed by this Item about our Board is incorporated into this Annual Report on Form 10-K by reference from the section entitled “Proposal No. 1: Election of Directors” contained in our definitive proxy statement for our 2018 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2017.

Information required to be disclosed by this Item about the Section 16(a) compliance of our directors and executive officers is incorporated into this Annual Report on Form 10-K by reference from the section entitled “Section 16(a) Beneficial Ownership Reporting Compliance” contained in our definitive proxy statement for our 2018 annual meeting

of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2017.

Information required to be disclosed by this Item about our Board, the Audit Committee of our Board, our audit committee financial expert, our Code of Ethics and Business Conduct Standards, and other corporate governance matters is incorporated into this Annual Report on Form 10-K by reference from the section entitled “Corporate Governance” contained in our definitive proxy statement for our 2018 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2017.

The text of our Code of Ethics and Business Conduct Standards, which applies to our directors and employees (including our principal executive officer, principal financial officer, and principal accounting officer or controller, and persons performing similar functions), is posted in the “Corporate Governance” section of the Investors section of our website, http://www.admabiologics.com/. A copy of the Code of Ethics and Business Conduct Standards can be obtained free of charge on our website. We intend to disclose on our website any amendments to, or waivers from, our Code of Ethics and Business Conduct Standards that are required to be disclosed pursuant to the rules of the SEC and The Nasdaq Stock Market.

The information presented on our website is not a part of this Annual Report on Form 10-K and the reference to our website is intended to be an inactive textual reference only.

Item 11. Executive Compensation

Information required to be disclosed by this Item is incorporated into this Annual Report on Form 10-K by reference from the section entitled “Executive Officers and Director and Officer Compensation” contained in our definitive proxy statement for our 2018 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2017.

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Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information required to be disclosed by this Item is incorporated into this Annual Report on Form 10-K by reference from the sections entitled “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” contained in our definitive proxy statement for our 2018 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2017.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the section entitled “Certain Relationships and Related Transactions, and Director Independence” contained in our definitive proxy statement for our 2018 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2017.

Item 14. Principal Accountant Fees and Services

The information required to be disclosed by this Item is incorporated into this Annual Report on Form 10-K by reference from the section entitled “Audit and Other Fees” contained in our definitive proxy statement for our 2018 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2017.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Consolidated Financial Statements.

(2) Financial Statement Schedules.

Required information is included in the footnotes to the financial statements.

(3) Exhibits.

See Exhibit Index immediately following the financial statements to this Annual Report on Form 10-K.

Item 16. Form 10-K Summary

None.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ADMA Biologics, Inc.

Date: March 29, 2018 By: /s/ Adam S. Grossman
Name: Adam S. Grossman

Title: President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Adam S. Grossman Adam S. Grossman	President and Chief Executive Officer (Principal Executive Officer)	March 29, 2018
/s/ Brian Lenz Brian Lenz	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 29, 2018
/s/ Steven A. Elms Steven A. Elms	Chairman of the Board of Directors and Director	March 29, 2018
/s/ Dr. Jerrold B. Grossman Dr. Jerrold B. Grossman	Vice Chairman of the Board of Directors and Director	March 29, 2018
/s/ Bryant E. Fong Bryant E. Fong	Director	March 29, 2018
/s/ Dov A. Goldstein, M.D. Dov A. Goldstein, M.D.	Director	March 29, 2018
/s/ Lawrence P. Guiheen		

Lawrence P. Guiheen	Director	March 29, 2018
/s/ Eric I. Richman Eric I. Richman	Director	March 29, 2018

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of ADMA Biologics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ADMA Biologics, Inc. and Subsidiaries (the Company) as of December 31, 2017 and 2016, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As further discussed in Note 1 to the accompanying consolidated financial statements, management believes that the Company will continue to incur net losses and negative net cash flows from operating activities through the drug development, approval and commercialization preparation process. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as the Company's auditor since 2008.

Roseland, New Jersey

March 29, 2018

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2017 and 2016

	December 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$43,107,574	$9,914,867
Short-term investments	—	5,390,184
Accounts receivable, net	3,880,154	1,018,027
Inventories	12,628,181	5,020,146
Prepaid expenses and other current assets	2,050,740	313,914
Restricted cash	1,500,000	—
Total current assets	63,166,649	21,657,138
Property and equipment, net	30,466,858	2,000,784
Intangible assets, net	4,849,350	—
Goodwill	3,529,509	—
Assets to be transferred under purchase agreement	1,496,410	—
Restricted cash	4,000,000	—
Deposits and other assets	510,057	27,163
TOTAL ASSETS	$108,018,833	$23,685,085
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$5,920,873	$2,564,681
Accrued expenses	3,318,478	2,385,356
Current portion of notes payable	—	6,111,111
Current portion of deferred revenue	142,834	145,154
Other current liabilities	57,998	16,559
Total current liabilities	9,440,183	11,222,861
Notes payable, net of discount	25,368,458	12,321,640
End of term liability, notes payable	2,760,000	1,790,000
Deferred revenue, net of current portion	2,547,199	2,690,033
Note payable - related party, net of discount	14,842,396	—
Obligation to transfer assets under purchase agreement	12,621,844	—
Other non-current liabilities	105,996	117,813
TOTAL LIABILITIES	67,686,076	28,142,347
COMMITMENTS AND CONTINGENCIES	—	—
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred Stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common Stock - voting, $0.0001 par value, 75,000,000 shares		

authorized, 36,725,499 and 12,886,741 shares issued and outstanding	3,673	1,289
Common Stock - non-voting, $0.0001 par value, 8,591,160 shares authorized, 8,591,160 and 0 shares issued and outstanding	859	—
Additional Paid-In Capital	191,022,018	102,476,267
Accumulated Deficit	(150,693,793)	(106,934,818)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	40,332,757	(4,457,262)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$108,018,833	$23,685,085

The accompanying notes are an integral part of these consolidated financial statements.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Years Ended December 31, 2017 and 2016

	2017	2016
REVENUES:		
Product revenue	$15,617,726	$10,518,203
License revenue	142,834	142,834
Other revenue	7,000,000	—
Total Revenues	22,760,560	10,661,037
OPERATING EXPENSES:		
Cost of product revenue (exclusive of amortization expense shown below)	29,164,321	6,360,761
Research and development	6,229,587	7,688,238
Plasma centers	6,503,750	5,447,691
Asset impairment charge	845,389	—
Amortization of intangibles	1,234,674	—
Selling, general and administrative	18,092,835	8,494,742
TOTAL OPERATING EXPENSES	62,070,556	27,991,432
LOSS FROM OPERATIONS	(39,309,996)	(17,330,395)
OTHER INCOME (EXPENSE):		
Interest and other income	57,228	50,317
Interest expense	(3,285,847)	(2,239,569)
Loss on extinguishment of debt	(1,210,216)	—
Other (expense) income	(10,144)	4,496
OTHER EXPENSE, NET	(4,448,979)	(2,184,756)
NET LOSS	$(43,758,975)	$(19,515,151)
BASIC AND DILUTED LOSS PER COMMON SHARE	$(1.91)	$(1.61)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic and Diluted	22,896,042	12,153,407

The accompanying notes are an integral part of these consolidated financial statements.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
Years Ended December 31, 2017 and 2016

	Common Stock Voting Shares	Amount	Non-Voting Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at December 31, 2015	10,713,087	$1,072	—	$ —	$88,239,569	$(87,419,667)	$820,974
Issuance of common stock, net of offering expenses	2,176,154	217	—	—	12,900,324	—	12,900,541
Stock-based compensation	—	—	—	—	1,250,074	—	1,250,074
Restricted stock	(2,500)	—	—	—	—	—	—
Warrants issued in connection with note payable	—	—	—	—	86,300	—	86,300
Net loss	—	—	—	—	—	(19,515,151)	(19,515,151)
Balance at December 31, 2016	12,886,741	1,289	—	—	102,476,267	(106,934,818)	(4,457,262)
Stock-based compensation	—	—	—	—	1,561,659	—	1,561,659
Shares issued in connection with acquisition	4,295,580	430	8,591,160	859	47,164,179	—	47,165,468
Warrants issued in connection with note payable	—	—	—	—	614,513	—	614,513
Issuance of common stock, net of offering expenses	19,523,255	1,952	—	—	39,197,898	—	39,199,850
Stock options exercised	19,923	2	—	—	7,502	—	7,504
Net loss	—	—	—	—	—	(43,758,975)	(43,758,975)
Balance at December 31, 2017	36,725,499	$3,673	8,591,160	$ 859	$191,022,018	$(150,693,793)	$40,332,757

The accompanying notes are an integral part of these consolidated financial statements.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2017 and 2016

	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(43,758,975)	$(19,515,151)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,692,301	469,576
Loss on disposal of fixed assets	10,144	—
Stock-based compensation	1,561,659	1,250,074
Asset impairment charge	845,389	—
Amortization of debt discount	781,567	676,943
Loss on extinguishment of debt	1,021,217	
Amortization of license revenue	(142,834)	(142,834)
Changes in operating assets and liabilities, net of acquisition:		
Accounts receivable	(2,862,127)	(93,559)
Inventories	589,318	(1,574,373)
Prepaid expenses and other current assets	(941,272)	(202,887)
Other assets	(482,894)	—
Accounts payable	2,812,066	476,826
Accrued expenses	614,483	416,972
Other current liabilities	(11,816)	(30,560)
Net cash used in operating activities	(37,271,774)	(18,268,973)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Sales of short-term investments	5,390,184	16,657,993
Purchase of short-term investments	—	(15,680,000)
Purchase of property and equipment	(2,676,328)	(73,410)
Cash acquired in acquisition transaction	12,500,000	—
Net cash provided by investing activities	15,213,856	904,583
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	(20,000,000)	—
Proceeds from issuance of common stock, net of offering expenses	39,199,850	12,900,541
Proceeds from the exercise of stock options	7,504	—
Payment of end of term fee	(1,790,000)	
Proceeds from issuance of related party note payable	15,000,000	—
Proceeds from issuance of note payable	30,000,000	4,000,000
Payment of debt issuance costs	(1,650,170)	(47,104)
Payments of leasehold improvement loan	(16,559)	(15,139)
Net cash provided by financing activities	60,750,625	16,838,298

Net increase (decrease) in cash and cash equivalents	38,692,707	(526,092)
Cash and cash equivalents - beginning of year	9,914,867	10,440,959
Cash and cash equivalents - end of year, including restricted cash	$48,607,574	$9,914,867

The accompanying notes are an integral part of these consolidated financial statements.

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1. ORGANIZATION AND BUSINESS

ADMA Biologics, Inc. (“ADMA” or the “Company”) is a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and prevention of certain infectious diseases. The Company’s targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons. ADMA operates through its wholly-owned subsidiaries ADMA BioManufacturing, LLC (“ADMA BioManufacturing”) and ADMA Bio Centers Georgia Inc. (“ADMA BioCenters”). ADMA BioManufacturing was formed in January 2017 to facilitate the acquisition of the Biotest Therapy Business Unit (“BTBU”) of Biotest Pharmaceuticals Corporation (“BPC” and, together with Biotest AG, “Biotest”) as more fully described below. ADMA BioCenters is the Company’s source plasma collection business, with facilities located in Norcross, GA, Marietta, GA and Kennesaw, GA. Both the Norcross and Marietta, GA facilities have approved licenses with the U.S. Food and Drug Administration (the “FDA”) and certifications from the German Health Authority (the “GHA”) and the Korean Ministry of Food and Drug Safety, and the Company filed a Biologics License Application with the FDA for its Kennesaw, GA facility in December of 2017. ADMA BioCenters supplies ADMA with a portion of its raw material plasma for the manufacture of RI-002, ADMA’s lead pipeline product candidate, which the Company is currently developing for the treatment of Primary Immune Deficiency Disease (“PIDD”).

As discussed in Note 3, on June 6, 2017, ADMA completed the acquisition of certain assets (the “Biotest Assets”) of BTBU, 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”). In addition to Nabi-HB and Bivigam, BTBU also provides contract manufacturing services for certain clients, including the sale of intermediate by-products. The Boca Facility is FDA-licensed and certified by the GHA. Immediately following the closing of the Biotest Transaction, the Biotest Assets were contributed into ADMA BioManufacturing.

Nabi-HB is a hyperimmune globulin that is rich in antibodies to the hepatitis B virus. Nabi-HB is indicated for the treatment of acute exposure to blood containing hepatitis B surface antigen (“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. FDA approval for Nabi-HB was received on March 24, 1999. ADMA resumed production of Nabi-HB in the third quarter of 2017, as substantially all of the Nabi-HB inventory received as part of the Biotest Transaction has been sold in the normal course of business.

Bivigam is indicated for the treatment of primary humoral immunodeficiency. FDA approval for Bivigam was received on December 19, 2012, and sales commenced in the first quarter of 2013. In December 2016, Biotest temporarily suspended the commercial production of Bivigam in order to focus on the completion of planned improvements to the manufacturing process. ADMA resumed production of Bivigam late in the fourth quarter of 2017. The Bivigam inventory currently being produced will be used in conjunction with a Prior Approval Supplement (the “PAS”), which is expected to be filed with the FDA during the first half of 2018. Upon approval of the PAS, the

Company intends to relaunch Bivigam, and, pending FDA approval, this relaunch is expected to take place in the second half of 2018.

Concurrent with the closing of the Biotest Transaction, the Company received $27.5 million in cash from Biotest, comprised of $12.5 million in cash from BPC and a $15.0 million loan from Biotest evidenced by a 6% subordinated note payable to BPC with a maturity of 5 years (see Note 7). In addition, BPC committed to participate in any future equity offering or private placement undertaken by the Company in an amount equal to up to $12.5 million on a pro-rata basis. The entire $12.5 million commitment was invested in the follow-on public offering of the Company's common stock, which closed on November 13, 2017 (see Note 8).

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Prior to the closing of the Biotest Transaction, BTBU was the Company's third-party manufacturer for RI-002. In the third quarter of 2015, the FDA accepted for review the Company's Biologics License Application for RI-002 (the "BLA") for the treatment of PIDD. In July 2016, the FDA issued a Complete Response Letter (the "CRL") to the Company for the BLA. Although the CRL did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in the BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002, the CRL reaffirmed the issues set forth in the November 2014 warning letter (the "Warning Letter") that had been issued by the FDA to Biotest related to certain compliance issues identified at the Boca Facility, and also identified certain outstanding inspection issues and deficiencies at the Boca Facility and certain of the Company's 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 the BLA until, among other things, these deficiencies are resolved. Following the completion of the Biotest Transaction, ADMA now has control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility, and the Company's highest priority has been the remediation of the outstanding compliance issues that were identified at the Boca Facility in the Warning Letter. The Company has been working with a consulting firm consisting of quality management systems and biologics production subject matter experts in preparation for a re-inspection by the FDA in order to improve the FDA inspection classification relative to the Warning Letter compliance issues as indicated in the CRL, and the Company believes it has been inspection-ready since the end of 2017. The Company expects a re-inspection of the Boca Facility by the FDA to take place during the first half of 2018. Once the Warning Letter status is improved following the FDA inspection, the Company anticipates that it will be in a position to refile the BLA for RI-002 in the second half of 2018.

As of December 31, 2017, the Company had working capital of $53.7 million, including $43.1 million of cash and cash equivalents. Based upon the Company's current projected revenue and expenditures for 2018, including regulatory and consulting fees for the remediation of the Warning Letter and ongoing discussions with the FDA, continued implementation of the Company's commercialization and expansion activities and certain other assumptions, the Company's management currently believes that its cash, cash equivalents, projected revenue and accounts receivable, along with the $10.0 million it expects to be able to draw down under its senior credit facility (see Note 7), will be sufficient to fund ADMA's operations, as currently conducted, through the end of 2018. In order to have sufficient cash to fund its operations thereafter and to continue as a going concern, the Company will need to raise additional capital prior to the end of 2018. These estimates may change based upon how quickly the Company is able to execute on its quality management systems' remediation plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options being explored. The Company currently has no firm commitments for additional financing, and there can be no assurances that the Company will be able to secure additional financing on terms that are acceptable to the Company, or at all. Furthermore, if the Company's assumptions underlying its estimated expenses and revenues are incorrect, it may have to raise additional capital sooner than currently anticipated.

Due to numerous risks and uncertainties associated with ongoing remediation efforts, the research and development and potential future commercialization of its products and product candidates, the Company is unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with its development activities. The Company's current estimates may be subject to change as circumstances regarding its business requirements evolve. The Company may decide to raise capital through public or private equity offerings or debt financings, or obtain a bank credit facility or corporate collaboration and licensing arrangements. The sale of

additional equity or debt securities, if convertible, could result in dilution to the Company's stockholders and, in such event, the value and potential future market price of its common stock may decline. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict the Company's operations or other financing alternatives. Failure to secure any necessary financing in a timely manner and on commercially reasonable terms could have a material adverse effect on the Company's business plan and financial performance and it could be forced to delay or discontinue its product development, clinical trial or commercialization activities, delay or discontinue the approval efforts for any of the Company's potential products or potentially cease operations. The Company has reported losses since inception in June 2004 through December 31, 2017 of $150.7 million. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities to fund its research and development, commercial programs and meet its obligations on a timely basis through the foreseeable future. As such, these factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments related to the recoverability and classification of asset carrying amounts and the classification of liabilities that might be necessary from the outcome of this uncertainty.

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2. SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation and Basis of presentation

The accompanying consolidated financial statements include the accounts of ADMA and its wholly-owned subsidiaries, and have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and in accordance with Article 8 of Regulation S-X of the Securities and Exchange Commission (the "SEC"). All intercompany balances have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board (the "FASB").

During the years ended December 31, 2017 and 2016, comprehensive loss was equal to the net loss amounts presented for the respective periods in the accompanying consolidated statements of operations. In addition, certain prior year balances have been reclassified to conform to the current presentation. Specifically, the current and non-current portions of the Company's tenant allowance liability and leasehold improvement loan have been reclassified to other current liabilities and other non-current liabilities, respectively, in the accompanying consolidated balance sheet as of December 31, 2016.

Use of estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the fair value of assets acquired and liabilities assumed in a business combination, valuation of inventory, assumptions used in the fair value determination of stock-based compensation, warrants, and the allowance for the valuation of future tax benefits.

Cash and cash equivalents

The Company considers all highly-liquid instruments purchased with a maturity of three months or less to be cash equivalents. From time to time, the Company purchases certificates of deposit with maturity schedules of three, six, nine and twelve months. Instruments with original maturities greater than three months but less than twelve months are included in short-term investments.

The Company regularly maintains cash and short-term investments at third-party financial institutions in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance limit. While the Company monitors the daily cash balances in the operating accounts and adjusts the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on the Company's business, if one or more of the financial institutions with which the Company has deposits fails or is subject to other adverse conditions in the financial or credit markets. To date, the Company has not experienced a loss or lack of access to its invested cash or cash equivalents; however, the Company cannot provide assurance that access to its invested cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets in the future.

Restricted cash

Restricted cash consists of cash held in a reserve account as required by the terms of the Company's senior lending agreement (see Note 7).

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Accounts receivable

Accounts receivable are reported at realizable value, net of allowances for contractual credits and doubtful accounts, which are recognized in the period the related revenue is recorded.

Inventories

Inventories, including plasma intended for resale and plasma intended for internal use in the Company's research and development and future anticipated commercialization activities, are carried at the lower of cost or market value determined by the first-in, first-out method. Research and development plasma used in clinical trials is processed to a finished product and subsequently expensed to research and development. Although the Company expects that Bivigam inventory will ultimately be available for commercial sale, due to uncertainties surrounding the Warning Letter and the PAS related to improvements in the manufacturing process that must be filed with and approved by the FDA prior to this inventory being available for commercial sale, all costs related to the production of Bivigam during the year ended December 31, 2017 have been charged to cost of product revenue in the accompanying consolidated statement of operations.

Property and equipment

Assets comprising property and equipment (see Note 5) are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the asset’s estimated useful life. Land is not depreciated. The buildings have been assigned a useful life of 30 years. Property and equipment other than land and buildings have useful lives ranging from 3 to 10 years. Leasehold improvements are amortized over the lesser of the lease term or their estimated useful lives.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill at December 31, 2017 and December 31, 2016 was $3.5 million and $0, respectively. All of the Company’s goodwill is attributable to its ADMA BioManufacturing business segment. The following table presents the changes in the carrying amount of goodwill during the year ended December 31, 2017:

Balance as of January 1, 2017	$—
Goodwill recorded in connection with the acquistion of the Biotest Assets	3,529,509
Balance as of December 31, 2017	$3,529,509

Goodwill is not amortized, but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. The Company has the option to perform a qualitative assessment of goodwill to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill and other intangible assets. If the Company concludes that this is the case, then it must perform a goodwill impairment test by comparing the fair value of the reporting unit to its carrying value. An impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value. The impairment loss recognized would not exceed the total amount of goodwill allocated to that reporting unit. The Company's impairment analysis as of October 1, 2017 did not result in any impairment charges related to goodwill for the year ending December 31, 2017.

Impairment of long-lived assets

The Company assesses the recoverability of its long-lived assets, which include property and equipment and definite-lived intangible assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the year ended December 31, 2017, the Company recorded an impairment charge in the amount of $0.8 million related to assets acquired in the Biotest Transaction. For the year ended December 31, 2016, the Company determined that there was no impairment of its long-lived assets.

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Revenue recognition

Revenues for the year ended December 31, 2017 are comprised of (i) revenues from Nabi-HB, (ii) product revenues from the sale of human plasma collected from the Company's plasma collection centers segment, (iii) revenues related to a contract manufacturing agreement (see Note 6); and (iv) license and other revenues primarily attributable to the out-licensing of RI-002 to Biotest to market and sell in Europe and selected countries in North Africa and the Middle East. Biotest has provided the Company with certain services and financial payments in accordance with the related Biotest license agreement and is obligated to pay the Company certain amounts in the future if certain milestones are achieved. Deferred revenue is recognized over the term of the Biotest license. Deferred revenue is amortized into income for a period of approximately 22 years, the term of the Biotest license agreement.

Revenue from the sale of Nabi-HB is recognized when the product reaches the customer's destination. Nabi-HB revenue is recorded net of estimated customer prompt pay discounts and contractual allowances in accordance with managed care agreements, including wholesaler chargebacks, rebates, customer returns and other wholesaler fees. These estimates are based on historical experience, and the Company believes that such estimates are reasonable. For sales of intermediates, title typically transfers when the product is delivered to a third party warehouse. With all other contract manufacturing, the title transfers to the customer when they take possession of the product from the Boca Facility. As the Company maintains a significant risk of loss throughout the contract manufacturing process, contract manufacturing revenue is not recognized until the product is released and title transfers to the customer.

Product revenues from the sale of human plasma collected at the Company's plasma collection centers are recognized at the time of transfer of title and risk of loss to the customer, which generally occurs at the time of shipment. Product revenues are recognized at the time of delivery if the Company retains the risk of loss during shipment.

Cost of product revenue

Cost of product revenue includes expenses related to process development as well as scientific and technical operations when these operations are attributable to marketed products. When the activities of these operations are attributable to new products in development, the expenses are classified as research and development expenses. Expenses associated with remediating the issues identified in the Warning Letter for the year ended December 31, 2017 of approximately $3.8 million are expensed as incurred and are reflected in cost of product revenue in the accompanying consolidated statements of operations. In addition, for the year ended December 31, 2017, all operating expenses associated with the Boca Facility, other than the limited Nabi-HB production that was capitalized into inventory, have been expensed as incurred since the date of the Biotest Transaction.

Research and development expenses

Research and development expenses consist of clinical research organization costs, costs related to clinical trials, consulting expenses related to regulatory and medical affairs, quality assurance and control, assay development, ongoing testing costs, drug product manufacturing for RI-002, including the cost of plasma, plasma storage and transportation costs, as well as wages, benefits and stock-based compensation for employees directly related to the research and development activities All research and development costs are expensed as incurred.

Advertising and marketing expenses

Advertising and marketing expense includes cost for promotional materials and trade show expenses for the marketing of the Company's products and services. Advertising and marketing expenses were $0.6 million and $0.2 million for the years ended December 31, 2017 and 2016, respectively.

Stock-based compensation

The Company follows recognized accounting guidance which requires all stock-based payments, including grants of stock options, to be recognized in the statement of operations as compensation expense, based on their fair values on the grant date. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated vesting period of the award, which is generally four years.

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The grant date fair values of stock options awarded during the years ended December 31, 2017 and 2016 were determined using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31, 2017	Year Ended December 31, 2016
Expected term	5.8-6.3 years	5.8-6.3 years
Volatility	56-64 %	51-52 %
Dividend yield	0.0	0.0
Risk-free interest rate	1.77-2.29%	1.54-1.79%

Income taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or its tax returns. Under this method, deferred tax assets and liabilities are recognized for the temporary differences between the tax basis of assets and liabilities and their respective financial reporting amounts at enacted tax rates in effect for the years in which the temporary differences are expected to reverse. The Company records a valuation allowance on its deferred income tax assets if it is more likely than not that these deferred income tax assets will not be realized.

In accordance with U.S. GAAP, the Company is required to determine whether a tax position of the Company is more likely than not to be sustained upon examination by the applicable taxing authority, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit to be recognized is measured as the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. Derecognition of a tax benefit previously recognized could result in the Company recording a tax liability that would reduce net assets. Based on its analysis, the Company has determined that it has not incurred any liability for unrecognized tax benefits as of December 31, 2017 and 2016. The Company is subject to income tax examinations by major taxing authorities for all tax years since 2013 and for previous periods as it relates to the Company’s net operating loss carryforward.

Earnings (Loss) Per Share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. For purposes of computing basic and diluted loss per share, the non-voting class of common stock (see Notes 3 and 8) is included in the common stock outstanding as the characteristics of the non-voting class are substantially the same as the voting class of common stock.

Diluted net loss per share is calculated by dividing net loss attributable to common stockholders as adjusted for the effect of dilutive securities, if any, by the weighted average number of shares of common stock, including the non-voting class of common stock, and dilutive common stock outstanding during the period. Potentially dilutive common stock includes the shares of common stock issuable upon the exercise of outstanding stock options and warrants (using the treasury stock method). Potentially dilutive common stock in the diluted net loss per share computation is excluded to the extent that it would be anti-dilutive. No potentially dilutive securities are included in the computation of any diluted per share amounts as the Company reported a net loss for all periods presented. For the years ended December 31, 2017 and 2016, the following securities were excluded from the calculation of diluted loss per common share because of their anti-dilutive effects:

	For the year ended December 31,	
	2017	2016
Stock options	3,276,043	1,535,187
Warrants	528,160	300,446
	3,804,203	1,835,633

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Business Combinations

The Company accounts for business combinations using the acquisition method of accounting in accordance with FASB ASC 805, *Business Combinations*. Identifiable assets acquired, liabilities assumed, and contingent consideration are recorded at their acquisition date fair values. Any change in the fair value of the acquisition-related contingent consideration subsequent to the acquisition date, including changes from events after the acquisition date, will be recognized in the period of the estimated fair value change. Goodwill represents the excess of the purchase price over the fair value of identifiable assets acquired and liabilities assumed as a result of the business combination. Identifiable assets with finite lives are amortized over their useful lives. Acquisition related costs are expensed as incurred.

Fair value of financial instruments

The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, short-term investments, accounts payable, and notes payable are shown at cost, which approximates fair value due to the short-term nature of these instruments. The debt outstanding under the Company's senior notes payable (see Note 7) approximates fair value due to the variable interest rate on this debt. With respect to the related party note payable in the amount of $15.0 million as of December 31, 2017 (see Notes 3 and 7), which is held by a principal stockholder of the Company and was issued concurrent with an acquisition transaction with such stockholder, the Company has concluded that an estimation of fair value for this note is not practicable.

Recent Accounting Pronouncements

In May 2017, the FASB issued ASU No. 2017-09, *Modification Accounting for Share-Based Payment Arrangements*, which amends the scope of modification accounting for share-based payment arrangements. The ASU provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. The ASU is effective for annual reporting periods, including interim periods within those annual reporting periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. The Company does not expect this new guidance to have a material impact on its consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations – Clarifying the Definition of a Business*, which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted

for as acquisitions or disposals of assets or businesses. The standard introduces a screen for determining when assets acquired are not a business and clarifies that a business must include, at a minimum, an input and a substantive process that contribute to an output to be considered a business. This standard is effective for fiscal years beginning after December 15, 2017, including interim periods within that reporting period. The Company adopted this standard in the second quarter of 2017, and the adoption of this standard did not have a material impact on its consolidated financial statements as of and for the year ended December 31, 2017.

In January 2017, the FASB issued ASU 2017-04, *Intangibles – Goodwill and Other (Topic 350)*, which removes the requirement to compare the implied fair value of goodwill with its carrying amount as part of step 2 of the goodwill impairment test. As a result, under the ASU, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount and should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The ASU is effective prospectively for fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company adopted ASU 2017-04 in the fourth quarter of 2017, and adoption of this update did not have a material impact on its consolidated financial statements as of and for the year ended December 31, 2017.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash*, which clarifies guidance and presentation related to restricted cash in the statement of cash flows, including stating that restricted cash should be included within cash and cash equivalents in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, with early adoption permitted, and is to be applied retrospectively. The Company adopted this standard in the fourth quarter of 2017, and adoption of this update did not have a material impact on the Company's consolidated financial statements as of and for the years ended December 31, 2017 and 2016.

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In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures (see Note 8) and classification on the statement of cash flows. The Company adopted this standard in the first quarter of 2017, and the adoption of this standard did not have a material impact on its consolidated financial statements as of and for the year ended December 31, 2017.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company is currently evaluating the impact the standard may have on its consolidated financial statements and related disclosures.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740), Balance Sheet Classification of Deferred Taxes*, which includes amendments that require deferred tax liabilities and assets be classified as non-current in a classified statement of financial position. The amendments in this ASU are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Earlier application is permitted as of the beginning of an interim or annual reporting period. The amendments may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company adopted this standard in the second quarter of 2017. As the Company carried a full valuation allowance against its deferred tax assets as of December 31, 2017 and 2016, adoption of this standard did not have a material impact on its consolidated financial statements.

In September 2015, the FASB issued ASU No. 2015-16, *Business Combinations (Topic 805), Simplifying the Accounting for Measurement-Period Adjustments*, which includes amendments that require an acquirer to recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments in this ASU require that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the changes to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. The amendments in this ASU require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The amendments should be applied prospectively to adjustments to provisional amounts that occur after the effective date of the ASU with earlier application permitted for financial statements that have not yet been made available for issuance. The Company adopted this standard in the first quarter of 2017, and the adoption of this standard did not have a material impact on its consolidated financial statements as of and for the year ended December 31, 2017.

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. The standard requires entities to measure most inventory "at the lower of cost and net realizable value," thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market (market in this context is defined as one of three different measures, one of which is net realizable value). The Company adopted this standard in the first quarter of 2017, and the adoption of this standard did not have a material impact on the Company's consolidated financial statements as and for the year ended December 31, 2017.

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In May 2014, the FASB issued new guidance related to revenue recognition, *ASU 2014-09, Revenue from Contracts with Customers ("ASC 606")*, which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new guidance requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. ASC 606 defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The new guidance becomes effective in calendar year 2018 and early adoption in calendar year 2017 is permitted. Two methods of adoption are permitted: (a) full retrospective adoption, meaning the standard is applied to all periods presented; or (b) modified retrospective adoption, meaning the cumulative effect of applying the new guidance is recognized at the date of initial application as an adjustment to the opening retained earnings balance.

In March 2016, April 2016 and December 2016, the FASB issued ASU No. 2016-08, *Revenue From Contracts with Customers (ASC 606): Principal Versus Agent Considerations*, ASU No. 2016-10, *Revenue From Contracts with Customers (ASC 606): Identifying Performance Obligations and Licensing*, and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue From Contracts with Customers*, respectively, which further clarify the implementation guidance on principal versus agent considerations contained in ASU No. 2014-09. In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers*, narrow-scope improvements and practical expedients which provides clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for non-cash consideration and completed contracts at transition. These standards became effective for the Company beginning in the first quarter of 2018. Early adoption is permitted.

ADMA will adopt ASC 606 and the foregoing related updates effective January 1, 2018, using the modified retrospective method of adoption. Based on the Company's review of the terms and conditions of its existing customer contracts and applying the five discrete criteria required for recognizing revenue as set forth in ASU 2014-09, the Company does not expect the new revenue recognition guidance to have a material impact on its consolidated financial statements.

3. ACQUISITION

On June 6, 2017, ADMA completed the acquisition of the Biotest Assets from BPC. As a result of this transaction, the Company acquired Nabi-HB, Bivigam, the Boca Facility and certain other assets of BTBU. The acquisition of the Biotest Assets expands the Company's product offering with two FDA-approved products and provides direct control over the manufacturing and regulatory processes impacting the Company's RI-002 product candidate, including remediation of the Warning Letter as well as certain other remediation items affecting the Boca Facility. Pursuant to the acquisition, the Company issued to Biotest 4,295,580 voting shares of its common stock and 8,591,160 shares of non-voting common stock. The Company will also transfer ownership of two of its plasma centers to Biotest on January 1, 2019 as additional consideration.

The purchase price was calculated as follows:

Issuance of 12,886,740 shares of common stock (voting and non-voting) valued at $3.66 per share	$47,165,468
Transfer of two plasma collection centers	12,621,844
Total purchase price	$59,787,312

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The following table summarizes the allocation of the purchase consideration to the assets acquired and liabilities assumed based on their estimated fair values:

Cash	$12,500,000
Inventory	8,197,353
Land and buildings	20,000,000
Property and equipment	8,209,800
Assets held for sale	845,389
Other current assets	795,553
Trademark and other intangible rights to Nabi-HB	4,100,046
Right to intermediates	907,421
Customer contract	1,076,557
Goodwill	3,529,510
Liabilities assumed	(374,317)
Total purchase price	$59,787,312

The Company engaged various third party valuation specialists to determine the fair value of the land and buildings, property and equipment, right to intermediates, customer contract and Nabi-HB intangible assets, as well as the assets held for sale. Goodwill is expected to be deductible for tax purposes.

Assets held for sale reflects certain manufacturing equipment acquired in the transaction that will not be utilized in the manufacture or development of any of the Company’s current products or product candidates, and the Company’s plans as of the date of acquisition was to complete the sale of these assets within one year from the date of the Biotest Transaction. These sales efforts have been unsuccessful and at December 31, 2017, the Company recorded an impairment charge for the full carrying value of these assets in the amount of $0.8 million.

As a result of the foregoing transaction, BPC became a principal stockholder and Biotest became a related party of the Company. Therefore, all of the Company’s transactions with Biotest between June 6, 2017 and December 31, 2017, including product and license revenues attributable to Biotest, were related party transactions. The results from BTBU’s operations are included in the Company’s consolidated financial statements from the date of acquisition. The Company incurred a total of approximately $5.8 million in transaction closing costs, which were expensed as incurred as selling, general and administrative expenses in the consolidated statement of operations. For the years ended December 31, 2017 and 2016, transaction closing costs amounted to approximately $3.9 million and $1.9 million, respectively.

The following unaudited pro forma summary presents consolidated information of the Company as if the business combination had occurred on January 1, 2016. The pro forma information is presented for informational purposes only

and is not necessarily indicative of the results of operations that would have been achieved had the acquisition been consummated as of that time or that may result in the future.

	Year Ended December 31,	
	2017	2016
Revenues:		
As reported	$22,760,560	$10,661,037
Proforma	$41,024,330	$86,706,074
Net loss		
As reported	$(43,758,975)	$(19,515,151)
Proforma	$(52,928,428)	$(82,982,280)
Basic and diluted net loss per share:		
As reported	$(1.91)	$(1.61)
Proforma	$(1.17)	$(3.31)

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4. INVENTORIES

The following table provides the components of inventories:

	December 31, 2017	December 31, 2016
Raw materials	$10,395,433	$5,020,146
Work-in-progress	1,265,339	—
Finished goods	967,409	—
Total inventories	$12,628,181	$5,020,146

Inventories are stated at the lower of cost or net realizable value with cost being determined on the first-in, first-out method. Finished goods inventory as of December 31, 2017 is comprised of Nabi-HB, and was recorded at fair value as part of the purchase price allocation of the Biotest Assets acquired. Raw materials includes plasma and other materials expected to be used in the production of RI-002, as there are alternative uses for these materials. All other activities and materials associated with the production of inventories used in research and development activities are expensed as incurred.

5. PROPERTY AND EQUIPMENT

Property, plant and equipment at December 31, 2017 and 2016 is summarized as follows:

	December 31, 2017	December 31, 2016
Manufacturing and laboratory equipment	$7,148,405	$306,411
Office equipment and computer software	1,086,756	188,277
Furniture and fixtures	1,136,623	1,030,257
Construction in process	738,093	—
Leasehold improvements	1,642,903	2,699,104
Land	4,339,441	—
Buildings	15,660,559	—
	31,752,780	4,224,049
Less: Accumulated depreciation and amortization	(1,285,922)	(2,223,265)

	$30,466,858	$2,000,784

The Company recorded depreciation expense on property and equipment of $1.5 million, which includes $0.4 million of depreciation expense on the plasma assets to be transferred (see Note 3) and $0.5 million for the years ended December 31, 2017 and 2016, respectively.

6. INTANGIBLE ASSETS

Intangible assets at December 31, 2017 and 2016 consist of the following:

	December 31, 2017			December 31, 2016		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Trademark and other intangible rights related to Nabi-HB®	$4,100,046	$341,670	$3,758,376	$—	$—	$—
Right to intermediates	907,421	75,618	831,803	—	—	—
Customer contract	1,076,557	817,386	259,171	—	—	—
Total	$6,084,024	$1,234,674	$4,849,350	$—	$—	$—

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Under the previous contract manufacturing agreement between ADMA and BPC, intermediate by-products derived from the manufacture of RI-002 were property of Biotest. As a result of the Biotest Transaction, ADMA obtained the right to these intermediate products, which are being amortized over a period of 7 years. The intangible rights to Nabi-HB is also being amortized over a period of 7 years.

The customer contract pertains to a contract manufacturing agreement with a third party that the Company assumed upon the consummation of the Biotest Transaction. On December 22, 2017, Company and the customer entered into an amendment to this contract which reduced the number of batches the Company was committed to supply to the customer. In connection with this amendment, the customer agreed to pay the Company an aggregate compensation fee of $7.0 million, which was recognized as other revenue in the accompanying consolidated statement of operations for the year ended December 31, 2017. The remaining required production volume is 13 batches over 2018 and 2019, and the Company recorded additional amortization expense of approximately $0.6 million in connection with the reduced volume. The net unamortized balance of this asset as of December 31, 2017 is being amortized through the end of the contract period.

Amortization expense related to the Company's intangible assets for the year ended December 31, 2017 was $1.2 million. Estimated aggregate future aggregate amortization expense for the next five years is expected to be as follows:

2018	$844,938
2019	844,938
2020	715,352
2021	715,352
2022	715,352

7. NOTES PAYABLE

Senior Notes Payable

A summary of outstanding senior notes payable as of December 31, 2017 and 2016 is as follows:

	2017	2016

Notes payable:	$30,000,000	$20,000,000
Less:		
Debt discount	(4,631,542)	(1,567,249)
Current portion	—	(6,111,111)
Senior notes payable	$25,368,458	$12,321,640

On October 10, 2017 (the “Marathon Closing Date”), the Company entered into a Credit Agreement (the “Credit Agreement”) with Marathon Healthcare Finance Fund, L.P. (“Marathon” or the “Lender”) and Wilmington Trust, National Association, as the administrative agent for the Lender (the “Administrative Agent”). The Credit Agreement provides for a senior secured term loan facility in an aggregate amount of up to $40.0 million (collectively, the “Credit Facility”), comprised of (i) a term loan made on the Marathon Closing Date in the principal amount of $30.0 million evidenced by a secured promissory note (the “Tranche One Note”), and (ii) an additional term loan evidenced by a secured promissory note to be made in the maximum principal amount not to exceed $10.0 million (the “Tranche Two Note” and, together with the Tranche One Note, the “Notes”), which Tranche Two Note availability is subject to the satisfaction of certain conditions, including, but not limited to, those described below. The Notes each have a maturity date of April 10, 2022 (the “Maturity Date”), subject to acceleration pursuant to the Credit Agreement, including upon an Event of Default (as defined in the Credit Agreement).

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On the Marathon Closing Date, the Company used approximately $17.0 million of the proceeds from the Tranche One Note to retire and pay in full the Company's previously existing indebtedness under a Loan and Security Agreement (the "LSA") with Oxford Finance, LLC ("Oxford") and all of the obligations thereunder in accordance with the terms of the LSA, as amended, including the end-of-term liability of $1.8 million and prepayment penalties of $0.2 million. The Company also (i) used $5.5 million of the proceeds from the Tranche One Note to pre-fund a debt service reserve account in accordance with the terms of the Credit Agreement, and (ii) paid diligence fees, legal and other expenses associated with the Credit Facility in the amount of approximately $1.5 million. The Company used the remaining $6.0 million of proceeds for the continued remediation of the issues identified in the CRL and the Warning Letter and for general corporate purposes. In connection with the retirement of the Oxford indebtedness, the Company recognized a loss on the extinguishment of debt in the amount of $1.2 million, comprised primarily of the write-off of debt discount related to the LSA.

Borrowings under the Credit Agreement bear interest at a rate per annum equal to LIBOR plus 9.50% with a 1% LIBOR floor; provided, however, that in the event that the Company achieves sales of not less than $61.7 million for the 2018 calendar year and the Tranche Two Loan has been funded, then the interest rate on the borrowings under the Credit Agreement will decrease to LIBOR plus 7.75% with a 1% LIBOR floor. During an Event of Default under the Credit Agreement, the outstanding amount of indebtedness under the Credit Agreement will bear interest at a rate per annum equal to the interest rate then applicable to the borrowings under the Credit Agreement plus 5% per annum. Quarterly cash interest payments are due the first business day of each March, June, September and December, beginning on December 1, 2017.

The Company will pay Marathon a facility fee in an amount equal to 9.20% of the amount of the Tranche One Note, payment of which is deferred until the Maturity Date pursuant to the terms of the Credit Agreement. Commencing on October 10, 2020, and on the first business day of each month, the Company is required to make principal payments on the Tranche One Note (and Tranche Two Note in the event it shall have been funded) in equal monthly installments over 18 months, subject to certain conditions in the Credit Agreement. The outstanding principal amount of the Notes, together with all accrued interest thereon, is due on the Maturity Date.

As consideration for the Credit Agreement, the Company issued a warrant to purchase an aggregate of 339,301 shares of the Company's common stock to the Lender and certain of its affiliates (the "Tranche One Warrants"). The Tranche One Warrants, which the Company valued at $0.6 million, have (i) an exercise price equal to $3.0946, which was the trailing 10-day volume weighted-average price of the Company's common stock prior to the Marathon Closing Date, and (ii) an expiration date of October 10, 2024. The Company issued the Tranche One Warrants in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act of 1933, as amended (the "Securities Act"). The Tranche One Warrants and the shares of common stock issuable thereunder may not be offered, sold, pledged or otherwise transferred in the U.S. absent registration or an applicable exemption from the registration requirements under the Securities Act.

As a result of the diligence fees, legal and other expenses associated with the Credit Facility, the Tranche One Warrants and the facility fee, the Company recognized a discount on the Tranche One Note on the Marathon Closing Date in the amount of $4.8 million as follows:

Facility fee	$2,760,000
Deferred financing fees	1,475,330
Tranche One Warrants	614,513
Total debt discount at Marathon Closing Date	$4,849,843

The obligation of Marathon to purchase the Tranche Two Note is subject to the satisfaction of certain conditions related to FDA approval for specified products and the Company's financial condition, including, without limitation, the following: (a) (i) the FDA must validate the improved manufacturing process of Bivigam and (ii) not less than $0.5 million in net revenue must be generated in calendar year 2018 from the sale in the U.S. of Bivigam; or (b) (i) the FDA must approve the commercialization of RI-002 and (ii) not less than $0.5 million in net revenue must be generated in calendar year 2019 from the sale in the U.S. of RI-002.

Based on the fair value of the Tranche One Warrants, the facility fee and the fees and expenses associated with obtaining the Credit Facility, the effective interest rate on the Tranche One Note is approximately 16.5%. The Company's obligations under the Credit Agreement are secured by a first-priority lien and security interest in substantially all of the Company's assets, including a mortgage on the Boca Facility, and those of the Company's subsidiaries as well as all of the equity interests in each subsidiary.

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The Credit Agreement contains market representations and warranties, affirmative covenants, negative covenants, financial covenants, and conditions that are customarily required for similar financings. The affirmative covenants, among other things, require the Company to undertake various reporting requirements. The negative covenants restrict or limit the ability of the Company and its subsidiaries to, among other things, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes or changes to the Company's business activities; sell or otherwise dispose of assets; repurchase stock, pay dividends; repay certain other indebtedness; engage in certain affiliate transactions; or enter into any other agreements that restrict the Company's ability to make loan repayments. In addition, the Company is required to maintain a minimum liquidity, defined in the Credit Agreement as cash held in the debt service reserve account and any other deposit account subject to a control agreement with the Administrative Agent, of not less than $5.5 million at all times. The Credit Agreement also required the establishment of the debt service reserve account. The Company is currently required to maintain a minimum balance in this account of $5.5 million, and this amount is reflected as restricted cash in the accompanying consolidated balance sheet as of December 31, 2017. Upon the satisfaction of certain conditions related to some of the Company's leased properties, the minimum required balance in the debt service reserve account, as well as the minimum liquidity requirement, will be reduced to $4.0 million. At December 31, 2017 and 2016, the Company was in compliance with all of the covenants contained in its senior lending agreements.

The Credit Agreement also contains customary Events of Default which include, among others, non-payment of principal, interest or fees, violation of covenants, inaccuracy of representations and warranties, bankruptcy and insolvency events, material judgments, cross-defaults to material contracts and events constituting a change of control. The occurrence of an Event of Default could result in, among other things, the termination of commitments under the Credit Facility and the declaration that all outstanding Loans are immediately due and payable in whole or in part.

In the event the Company prepays a term loan for any reason, including the acceleration of indebtedness upon an Event of Default, the Company is obligated to pay a prepayment charge corresponding to a percentage of the principal amount of the applicable term loan prepaid, as well as a make-whole premium based on the excess of the amount of the loan being prepaid over the discounted amount of such prepayment, in accordance with the terms of the Credit Agreement.

Related Party Note Payable

A summary of the outstanding related party note payable is as follows:

	2017	2016
Related party note payable to Biotest	$15,000,000	$ —
Less:		
Debt discount	(157,604)	—

Note payable - related party	$14,842,396	$ —

In connection with the acquisition of the Biotest Assets (see Note 3), ADMA BioManufacturing issued a subordinated note payable to BPC and in connection therewith received cash proceeds of $15.0 million. The note bears interest at a rate of 6.0% per annum and matures on June 6, 2022. The Company is obligated to make semi-annual interest payments, with all principal and unpaid interest due at maturity. The note is subordinate to the Tranche One Note with Marathon. In the event of default, all principal and unpaid interest is due on demand. The subordinated note also contains several non-financial covenants with which the Company was in compliance as of December 31, 2017. The Company incurred $0.2 million of debt issuance costs in connection with the issuance of this note, which were recorded as a debt discount. The debt discount is being amortized as interest expense over the term of the note.

8. STOCKHOLDERS' EQUITY

Preferred Stock

The Company is currently authorized to issue up to 10 million shares of preferred stock, $.0001, par value. There were no shares of preferred stock outstanding at December 31, 2017 and 2016.

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Common Stock

As of December 31, 2017, the Company was authorized to issue 75 million shares of its common stock, and 36,725,499 shares of common stock were outstanding. After giving effect to shares reserved for the issuance of warrants and stock options, 34,470,298 shares of common stock were available for issuance as of December 31, 2017. As of December 31, 2017, 8,591,160 shares of the Company's non-voting common stock were authorized, issued and outstanding.

On November 13, 2017, the Company completed an underwritten public offering of 19,523,255 shares of its common stock for gross proceeds of $42.0 million. Net proceeds from this offering, after payment of underwriting discounts and offering expenses of $2.8 million, were $39.2 million.

On June 6, 2017, the Company issued 4,295,580 shares of common stock and 8,591,160 shares of its non-voting common stock to Biotest in connection with the Biotest Transaction (see Note 3). Except as otherwise required by applicable law, holders of shares of non-voting common stock are not entitled to vote on any matter that is submitted to a vote of the stockholders of the Company; provided, however, that for so long as any shares of non-voting common stock are outstanding, the Company may not, without the prior vote of the holders of at least a majority of the shares of non-voting common stock then outstanding (voting separately as a single class), amend, alter or repeal, whether by merger, consolidation or otherwise, the powers, preferences, or other rights of the shares of non-voting common stock in an adverse manner relative to the powers, preferences or other rights of the shares of the voting common stock, except as permitted by the stockholders' agreement between the Company and BPC or the Company's Amended and Restated Certificate of Incorporation. Under certain conditions, the non-voting common stock is convertible into voting common stock.

On May 3, 2016, the Company completed an underwritten public offering of 2,176,154 shares of its common stock for gross proceeds of approximately $14.1 million. Net proceeds from this offering were $12.9 million, after payment of underwriting discounts and offering expenses of approximately $1.2 million.

Warrants

On October 10, 2017, the Company issued to Marathon the Tranche One Warrants (see Note 7) whereby Marathon may purchase an aggregate of 339,301 shares of common stock with an exercise price $3.0946 per share. The Tranche One Warrants became exercisable on the Marathon Closing Date, were valued at $0.6 million and were recorded as discount to the Tranche One Note.

In May 2016, the Company issued to Oxford warrants to purchase an aggregate of up to 24,800 shares of the Company's common stock at an exercise price equal to $6.37 per share. The warrants became exercisable on May 13, 2016 for cash or by net exercise and will expire seven years after their issuance on May 13, 2023. The fair value of these warrants was $0.1 million, which was recognized as a debt discount to the carrying value of the loan.

The fair values of the warrants issued during the years ended December 31, 2017 and 2016 were determined using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31, 2017	**Year Ended December 31, 2016**
Expected term	7 years	7 years
Volatility	57 %	54 %
Dividend yield	0.0	0.0
Risk-free interest rate	2.18 %	1.51 %

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At December 31, 2017, the Company had outstanding warrants to purchase an aggregate of 528,160 shares of common stock, with a weighted average exercise price of $4.76 per share and with expiration dates ranging between June 2022 and October 2024.

Stock Options

From time to time the Company grants stock options or other equity-based awards under the Company's 2007 Employee Stock Option Plan (the "2007 Plan") and the Amended and Restated 2014 Omnibus Incentive Compensation Plan (the "2014 Plan").

The 2014 Plan, as amended, was approved by the Board of Directors of ADMA (the "Board") on March 15, 2017 and ratified by the Company's stockholders on May 25, 2017. Currently, the maximum number of shares reserved for grant under the 2014 Plan is: (a) 2,334,940 shares, less any shares available as of such date for issuance under the 2007 Plan; plus (b) an annual increase as of the first day of the Company's fiscal year, beginning in 2018 and occurring each year thereafter through 2022, equal to 4% of the outstanding shares of common stock as of the end of the Company's immediately preceding fiscal year, or any lesser number of shares determined by the Board; provided, however, that no more than an aggregate of 10 million shares of common stock may be issued pursuant to incentive stock options intended to qualify under Section 422 of the Internal Revenue Code. As of December 31, 2017, an aggregate of 654,645 shares were available for issuance under the 2007 Plan and the 2014 Plan. In accordance with the foregoing, on January 1, 2018, the aggregate number of shares available for issuance increased to 2,467,311.

During the years ended December 31, 2017 and 2016, the Company recorded stock-based compensation expense to employees of $1.6 million and $1.3 million, respectively. The fair value of employee options granted was determined on the date of grant using the Black-Scholes model. The Black-Scholes option valuation model was developed for use in estimating the fair value of publicly traded options, which have no vesting restrictions and are fully transferable. The Company's employee stock options have characteristics significantly different from those of traded options, and changes in the underlying Black-Scholes assumptions can materially affect the fair value estimate. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of the grant with a term consistent with the expected term of the Company's awards. The expected term of the options granted is in accordance with Staff Accounting Bulletins 107 and 110, which is based on the average between vesting terms and contractual terms. The expected dividend yield reflects the Company's current and expected future policy for dividends on the Company's common stock. The expected stock price volatility for the Company's stock options was calculated by examining the pro rata historical volatilities for similar publicly traded industry peers and the trading history for the Company's common stock. The Company will continue to analyze the expected stock price volatility and expected term assumptions.

The 2007 Plan and 2014 Plan provide for the Board or a Committee of the Board (the "Committee") to grant awards to optionees and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the awards, including acceleration of the vesting of an award at any time. All options granted under the 2007 and 2014 Plans are intended to be incentive stock options ("ISOs"), unless specified by the Committee to be non-qualified options ("NQOs") as defined by the Internal Revenue Code. ISOs and NQOs may be granted to employees, consultants or Board members at an option price not less than the fair market value of the common stock subject to the stock option agreement. The following table summarizes information about stock options outstanding as of December 31, 2017 and 2016:

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	Shares	Weighted Average Exercise Price
Balance at December 31, 2015	1,464,203	$ 8.02
Forfeited	(21,334)	$ 8.02
Expired	(8,666)	$ 7.88
Granted	100,984	$ 6.20
Balance at December 31, 2016	1,535,187	$ 7.90
Forfeited	(94,024)	$ 7.72
Expired	(47,476)	$ 9.02
Granted	1,976,295	$ 3.73
Exercised	(93,939)	$ 2.68
Balance at December 31, 2017	3,276,043	$ 5.52
Options exercisable	1,338,568	$ 7.68

The weighted average remaining contractual term of stock options outstanding and expected to vest at December 31, 2017 is 7.9 years. The weighted average remaining contractual term of stock options exercisable at December 31, 2017 is 5.8 years. The following table summarizes additional information regarding outstanding and exercisable options under the stock option plans at December 31, 2017:

	Stock Options Outstanding				Stock Options Exercisable			
Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$1.34 - $2.06	35,418	8.9	$ 1.97	$ 44,092	4,668	2.4	$ 1.34	$ 8,729
$2.53 - $5.00	1,927,331	9.4	$ 3.75	21,385	133,869	9.0	$ 3.87	3,067
$5.96 - $8.98	1,026,794	5.2	$ 7.64	—	993,581	5.1	$ 7.65	—
$9.37 - $10.80	286,500	7.3	$ 10.33	—	206,450	7.3	$ 10.44	—
	3,276,043	7.9	$ 5.52	$ 65,477	1,338,568	5.8	$ 7.68	$ 11,796

Stock-based compensation expense for the years ended December 31, 2017 and 2016 was as follows:

	2017	2016
Research and development	$ 380,925	$ 439,982

Plasma centers	47,330	52,973
Selling, general and administrative	1,081,236	757,119
Cost of goods sold	52,168	—
Total stock-based compensation expense	$1,561,659	$1,250,074

As of December 31, 2017, the total unrecognized compensation expense related to unvested options was $4.0 million, which is expected to be recognized over a weighted-average period of 2.8 years. The Company's outstanding and exercisable options had an intrinsic value of approximately $12,000 as of December 31, 2017.

9. RELATED PARTY TRANSACTIONS

The Company leases an office building and equipment from Areth, LLC ("Areth") pursuant to a shared services agreement on a month-to-month basis of which terms had been amended by the Company's Board of Directors in June 2016. Effective October 1, 2017, monthly rent on this facility was reduced to $10,000. Rent expense amounted to $0.2 million for the years December 31, 2017 and 2016. Areth is a company controlled by Dr. Jerrold B. Grossman, the Company's Vice Chairman, and Adam S. Grossman, the Company's President and Chief Executive Officer. The Company pays Areth monthly fees for the use of such office space and for other information technology, general warehousing and administrative services. The Company also reimburses Areth for office and building related (common area) expenses, equipment and certain other operational expenses, which were not material to the consolidated financial statements for the years ended December 31, 2017 and 2016.

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During the years ended December 31, 2017 and 2016, the Company maintained deposits and other accounts at Lakeland Bankcorp, Inc., formerly Pascack Bankcorp, a bank of which Dr. Grossman served as a director through January 2016, and which was approximately 5%-owned by members of the Grossman family. Pascack Bankcorp was acquired by Lakeland Bancorp, Inc. in January 2016 and Dr. Grossman is currently a member of the Corporate Advisory Council of Lakeland Bancorp Inc.

As of December 31, 2017, the Company has a $15.0 million subordinated note payable to BPC (see Note 7), and the Company recognized interest expense on this note for the year ended December 31, 2017 in the amount of $0.5 million.

For the years ended December 31, 2017 and 2016, the Company recognized revenues under its out-licensing agreement with Biotest of $0.1 million. Deferred revenue of $2.7 million and $2.8 million as of December 31, 2017 and 2016, respectively, is related to this agreement.

Biotest is the Company’s largest customer for the sale of normal source plasma. Plasma sales to Biotest for the years ended December 31, 2017 and 2016 were $10.7 million and $8.7 million, respectively. Accounts receivable includes $1.2 million and $1.0 million due from Biotest as of December 31, 2017 and 2016, respectively. Additionally, Biotest is a supplier of plasma to ADMA, with the Company purchasing approximately $2.8 million and $1.6 million of plasma in the years ended December 31, 2017 and 2016, respectively. Included in accounts payable is approximately $0.1 million due to Biotest as of December 31, 2017 and 2016. The following table summarizes the related party balances with Biotest:

	Year Ended December 31,	
	2017	2016
Sale and purchase of plasma		
Product revenue	$10,664,456	$8,745,844
Purchases	2,776,959	1,606,573
License revenue	142,834	142,834
Interest expense	520,000	—

	December 31, 2017	December 31, 2016
Accounts receivable	$1,245,677	$969,675
Accounts payable	139,939	82,427
Accrued expenses	314,820	—
Note payable, net of discount	14,842,396	—

Accrued interest	65,000	—
Deferred revenue	2,690,033	2,832,867

In connection with the acquisition of the Biotest Assets, the Company entered into a Transition Services Agreement with BPC pursuant to which each of the Company and BPC agreed to provide transition services to the other party, including services related to finance, human resources, information technologies, leasing of equipment and clinical and regulatory services for a period of up to 24 months after the June 6, 2017 closing date, as well as agreements to lease certain laboratory space within the Boca Facility to BPC for a period of up to 24 months after the closing date of the acquisition transaction. As of December 31, 2017, $0.3 million was payable by the Company to BPC for expenses incurred on behalf of the Company and services related to these agreements. This amount is reflected in accrued expenses in the accompanying consolidated balance sheet. The services component of amounts billed to the Company by BPC for the year ended December 31, 2017 was not material to the Company’s consolidated financial statements.

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Under the terms of the Biotest Transaction, the Company will transfer ownership of two plasma collection centers to BPC on January 1, 2019. The Company has estimated the fair value of these assets to be $12.6 million, and the obligation to transfer these assets to Biotest is reflected in non-current liabilities in the accompanying consolidated balance sheet as of December 31, 2017.

10. COMMITMENTS AND CONTINGENCIES

Lease commitments

The Company has entered into various non-cancelable operating lease agreements for its three ADMA BioCenters facilities in Georgia, as well as for certain operating equipment and warehouse space. Total rent expense for the Company's leased facilities and equipment was $0.6 million and $0.5 million, respectively. Future minimum lease payments for both leases, for each of the next five years ending December 31, and thereafter are as follows:

2018	$701,494
2019	680,509
2020	679,166
2021	670,814
2022	680,317
Thereafter	1,260,718
	$4,673,018

Vendor and Licensor Commitments

In a license agreement effective December 31, 2012, the Company 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 the Company's testing services for testing of BPC's plasma samples using the Company's proprietary RSV assay, and to reference (but not access) the Company's proprietary information for the purpose of Biotest seeking regulatory approval for RI-002 in the Territory. As consideration for the license, Biotest agreed to provide the Company with certain services at no charge and also compensate the Company with cash payments upon the completion of certain milestones. Such services have been accounted for as deferred revenue which was recognized in 2013 as a result of certain research and development services as provided for in accordance with the license agreement. Deferred revenue is recognized over the term of the license and is amortized into income for a period of approximately 22 years, the term of the license agreement. Biotest is also obligated to pay the Company 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.

Pursuant to the terms of a Plasma Purchase Agreement with BPC, the Company has 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. The agreement does not provide for any penalties in the event the Company does not purchase the agreed-upon annual minimum volume from BPC. In addition, the Company may also collect high-titer RSV plasma from up to five wholly-owned ADMA BioCenters. During 2015, BPC and ADMA amended their Plasma Purchase Agreement to allow ADMA the ability to collect its raw material RSV high-titer plasma from other third party collection organizations, thus allowing ADMA to expand its reach for raw material supply as the Company approaches commercialization for RI-002. In connection with the Biotest Transaction, BPC and ADMA amended the Plasma Purchase Agreement to extend the term for ten years from the June 6, 2017 closing date of the Biotest Transaction. Either party may terminate the agreement if the other party fails to remedy any material default in the performance of any material condition or obligation under the agreement following notice. The Company may also terminate the agreement upon written notice if the clinical development of RI-002 is halted or terminated, whether by the FDA, a Data Safety Monitoring Board, or any other regulatory authority. Upon termination of the agreement, the Company must pay for any source plasma already delivered to the Company and for any source plasma collected under the terms of the agreement.

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Employment contracts

The Company has entered into employment agreements with its executive management team consisting of its President and Chief Executive Officer, Chief Medical and Scientific Officer and Chief Financial Officer.

Contract Manufacturing Agreement

In connection with the acquisition of the Biotest Assets, the Company acquired all of the rights and assumed all of the obligations under an existing agreement with a third party related to the fractionation of plasma provided by the third party. As more fully described in Note 6, the contract was amended on December 22, 2017 with reduced production requirements. The contract maintains minimum production requirements as well as a payment due to the counterparty to the contract of $1.5 million per year if the minimum volume is not manufactured in that year and no other breach or default under the contract has occurred.

General legal matters

From time to time the Company is or may become subject to certain legal proceedings and claims arising in connection with the normal course of its business. Management does not expect that the outcome of any such claims or actions will have a material effect on the Company’s liquidity, results of operations or financial condition.

Other commitments

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company’s request in such capacities. The Company’s maximum exposure under these arrangements is unknown as of December 31, 2017. The Company does not anticipate recognizing any significant losses relating to these arrangements.

11. INCOME TAXES

A reconciliation of income taxes at the U.S. Federal statutory rate to the benefit for income taxes is as follows:

	Year Ended December 31,	
	2017	2016
Benefit at U.S. federal statutory rate	$(14,758,443)	$(6,635,151)
State taxes - deferred	(1,581,844)	(266,312)
Increase in valuation allowance	(751,505)	5,755,413
Research and development credits	(272,262)	(322,499)
Federal tax reform rate change	17,263,248	—
Other	100,806	1,468,549
Benefit for income taxes	$—	$—

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A summary of the Company's deferred tax assets is as follows:

	Year Ended December 31,	
	2017	2016
Federal and state net operating loss carryforwards	$29,137,918	$30,843,479
Federal and state research credits	4,526,201	4,099,249
Transaction costs	1,269,443	652,695
Deferred revenue	679,068	972,345
Accrued expenses and other	951,219	747,586
Total gross deferred tax assets	36,563,849	37,315,354
Less: valuation allowance for deferred tax assets	(36,563,849)	(37,315,354)
Net deferred tax assets	$—	$—

As of December 31, 2017, the Company had federal and state Net Operating Losses ("NOLs") of $125.3 million and $201.5 million, respectively, as well as federal research and development tax credit carryforwards of approximately $4.5 million. The NOLs will begin to expire at various dates beginning in 2027, if not limited by triggering events prior to such time. Under the provisions of the Internal Revenue Code, changes in our ownership, in certain circumstances, will limit the amount of federal NOLs that can be utilized annually in the future to offset taxable income. In particular, section 382 of the Internal Revenue Code imposes limitations on a company's ability to use NOLs upon certain changes in ownership. If the Company is limited in its ability to use its NOLs in future years in which it has taxable income, then the Company will pay more taxes than if it were otherwise able to fully utilize its NOLs. The Company may experience ownership changes in the future as a result of subsequent shifts in ownership of the Company's capital stock that the Company cannot predict or control that could result in further limitations being placed on the Company's ability to utilize its federal NOLs.

A valuation allowance, if needed, reduces deferred tax assets to the amount expected to be realized. When determining the amount of net deferred tax assets that are more likely than not to be realized, the Company assesses all available positive and negative evidence. This evidence includes, but is not limited to, prior earnings history, expected future earnings, carry-back and carry-forward periods and the feasibility of ongoing tax strategies that could potentially enhance the likelihood of the realization of a deferred tax asset. The weight given to the positive and negative evidence is commensurate with the extent the evidence may be objectively verified. As such, it is generally difficult for positive evidence regarding projected future taxable income exclusive of reversing taxable temporary differences to outweigh objective negative evidence of recent financial reporting losses. Based on these criteria and the relative weighting of both the positive and negative evidence available, management continues to maintain a full valuation allowance against its net deferred tax assets.

On December 22, 2017, the U.S. Government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "TCJA"). The TCJA makes broad changes to the U.S. tax code, including, but not limited to, (1) reducing the U.S federal corporate tax rate from 35% to 21%; (2) eliminating the corporate alternative minimum tax;

(3) creating a new limitation on deductible interest expense; (4) creating the base erosion and anti-abuse tax, a new minimum tax; (5) limitation on the deductibility of certain executive compensation; (6) enhancing the option to claim accelerated depreciation deductions on qualified property, and (7) changing the rules related to uses and limitations of NOLs in tax years beginning after December 31, 2017.

The TCJA reduces the corporate tax rate to 21%, effective January 1, 2018. The accounting for this portion of the TCJA has caused a reduction to the net deferred tax assets before valuation allowance of $17.3 million for the year ended December 31, 2017. However, as discussed above, the Company maintains a full valuation allowance against its deferred tax assets. As a result, the $17.3 million reduction to the Company's deferred tax assets is offset by a corresponding $17.3 million reduction in the Company's valuation allowance, resulting in no net impact to the Company's tax provision.

The Company has not completed its determination of the accounting implications of the TCJA on its tax accruals. However, the Company has estimated the effects of the TCJA as described above as of December 31, 2017, which is primarily comprised of the re-measurement of federal net deferred tax assets resulting from the permanent reduction in the U.S. statutory corporate tax rate to 21% from 35%. As the Company completes its analysis of the TCJA, collects and prepares necessary data and interprets any additional guidance issued by the U.S. Treasury Department, the IRS, and other standard-setting bodies, it may make adjustments to the provisional amounts recorded as of December 31, 2017. However, those adjustments are not anticipated to have a material impact on the Company's tax provision for the year ended December 31, 2017.

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The Company recognizes a tax benefit from any uncertain tax positions only if they are more likely than not to be sustained upon examination based on the technical merits of the position. The amount of the accrual for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position. The Company does not have any unrecognized tax benefits as of December 31, 2017, and does not anticipate a significant change in unrecognized tax benefits during the next 12 months.

12. SEGMENTS

The Company is engaged in the manufacture, marketing and development of specialty plasma-derived biologics. The Company's operating segments reflect the consummation of the Biotest Transaction on June 6, 2017 (see Notes 1 and 3), and the nature of its operations subsequent to the close of the transaction. The Company's ADMA BioManufacturing segment reflects the Company's immune globulin manufacturing and development operations in Florida, acquired on June 6, 2017 (see Note 3). The Plasma Collection Centers segment consists of two FDA-licensed source plasma collection facilities located in Georgia, with a third collection center that opened in December 2017 for which a BLA is pending. The Corporate segment includes general and administrative overhead expenses. The Company defines its segments as those business units whose operating results are regularly reviewed by the chief operating decision maker ("CODM") to analyze performance and allocate resources. The Company's CODM is its President and Chief Executive Officer. Summarized financial information concerning reportable segments is shown in the following tables:

Year Ended December 31, 2017

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 10,980,987	$11,636,739	$142,834	$22,760,560
Cost of product revenue	21,862,140	7,302,181	—	29,164,321
Gross (loss) profit	(10,881,153)	4,334,558	142,834	(6,403,761)
Loss from operations	(19,801,455)	(2,169,192)	(17,339,349)	(39,309,996)
Interest and other expense, net	(537,235)	(6,885)	(3,904,859)	(4,448,979)
Net loss	(20,338,690)	(2,176,077)	(21,244,208)	(43,758,975)
Capital expenditures	747,402	1,913,663	15,263	2,676,328
Depreciation and amortization expense	2,204,772	436,687	50,842	2,692,301

Total Assets	54,004,696	3,933,673	50,080,464	108,018,833

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Year Ended December 31, 2016

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ —	$10,518,203	$142,834	$10,661,037
Cost of product revenue	—	6,360,761	—	6,360,761
Gross profit	—	4,157,442	142,834	4,300,276
Loss from operations	—	(1,290,249)	(16,040,146)	(17,330,395)
Other expense, net	—	—	(2,184,756)	(2,184,756)
Net loss	—	(1,290,249)	(18,224,902)	(19,515,151)
Capital expenditures	—	56,328	17,082	73,410
Depreciation and amortization expense	—	414,464	55,112	469,576
Total Assets		2,421,535	21,263,550	23,685,085

13. OTHER EMPLOYEE BENEFITS

The Company sponsors a 401(k) savings plan. Under the plan, employees may make contributions which are eligible for a Company discretionary percentage contribution as defined in the plan and determined by the Board of Directors. The Company recognized $0.5 million and $0.2 million of related compensation expense for the years ended December 31, 2017 and 2016, respectively. Compensation expense for the year ended December 31, 2017 includes expense attributable to ADMA BioManufacturing effective as of June 6, 2017.

14. SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Supplemental cash flow information for the years ended December 31, 2017 and 2016 is as follows:

	2017	2016
SUPPLEMENTAL CASH FLOW INFORMATION:		

Cash paid for interest	$2,293,590	$1,530,235
Noncash Financing and Investing Activities:		
Assets acquired through the issuance of common stock and liabilities assumed	$60,161,629	$—
Equipment acquired reflected in accounts payable and accrued liabilities	$544,125	$—
End of term liability for senior notes payable	$2,760,000	$358,000
Warrants issued in connection with notes payable	$614,513	$86,300

15. CONCENTRATIONS

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents and accounts receivable. At December 31, 2017, two customers accounted for 79% of the Company's total accounts receivable. At December 31, 2016, a single customer accounted for 95% of the Company's total accounts receivable.

For the year ended December 31, 2017, BPC represented 47% of the Company's consolidated revenues, and another customer represented 31% of the Company's consolidated revenues. For the year ended December 31, 2016, BPC and another customer represented approximately 82% and 14%, respectively, of the Company's consolidated revenues.

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16. SUBSEQUENT EVENTS

On February 9, 2018, the Board approved grants of options to purchase an aggregate of 650,000 shares of the Company's common stock to the Company's executive officers. The options were granted under the 2014 Plan (see Note 8), and the estimated fair value of the options granted was approximately $1.4 million.

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EXHIBIT INDEX

Exhibit No.	Description
2.1	Master Purchase and Sale Agreement, dated as of January 21, 2017, by and among Biotest Pharmaceuticals Corporation, ADMA BioManufacturing, LLC, ADMA Biologics, Inc., Biotest AG and Biotest US Corporation (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 23, 2017).
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 12, 2017).
3.2	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 7, 2016).
4.1	Specimen Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Current Report on Form 8-K/A, filed with the SEC on March 29, 2012).
4.2	Form of Warrant Agreement with Hercules Technology Growth Capital, Inc. (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1, filed with the SEC on February 11, 2013).
4.3	Form of Warrant Agreement with Oxford Finance LLC (incorporated herein by reference to Exhibit 4.6 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2016).
4.4	Warrant to Purchase Stock, dated October 10, 2017, issued by the Company to Marathon Healthcare Finance Fund, L.P. (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on October 11, 2017).
4.5	Form of Secured Term Loan Promissory Note issued to Hercules Technology Growth Capital, Inc. (incorporated herein by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-1, filed with the SEC on February 11, 2013).
4.6	Form of Secured Term B Loan Promissory Note issued to Oxford Finance LLC (incorporated herein by reference to Exhibit 4.7 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2016).

4.7	Tranche One Term Note, dated October 10, 2017, issued by the Company to Marathon Healthcare Finance Fund, L.P. (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 11, 2017).
10.1†	2007 Employee Stock Option Plan, as amended by Amendment No. 3 (incorporated herein by reference to Exhibit A to the Information Statement on Schedule 14C, filed with the SEC on October 29, 2012).
10.2†	Amended and Restated ADMA Biologics, Inc. 2014 Omnibus Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8 filed on August 18, 2017).
10.3†	Amended and Restated Employment Agreement, dated January 28, 2016, by and between ADMA Biologics, Inc. and Adam Grossman (incorporated herein by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K, filed with the SEC on March 23, 2016).

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10.4†	Amended and Restated Employment Agreement, dated January 28, 2016, by and between ADMA Biologics, Inc. and Brian Lenz (incorporated herein by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K, filed with the SEC on March 23, 2016).
10.5†	Amended and Restated Employment Agreement, dated January 28, 2016, by and between ADMA Biologics, Inc. and James Mond, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K, filed with the SEC on March 23, 2016).
10.6+	Plasma Purchase Agreement, dated as of November 17, 2011, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc., as amended by First Amendment to Plasma Purchase Agreement, dated as of December 1, 2011, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc. (incorporated herein by reference to Exhibit 10.9 to Amendment No. 3 to the Company's Current Report on Form 8-K/A, filed with the SEC on June 22, 2012).
10.6.1+	Second Amendment to Plasma Purchase Agreement, dated as of December 18, 2015, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc. (incorporated herein by reference to Exhibit 10.3.1 to the Company's Annual Report on Form 10-K, filed with the SEC on March 23, 2016).
10.6.2	Third Amendment to Plasma Purchase Agreement, dated as of April 8, 2016, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc. (incorporated herein by reference to Exhibit 10.3.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2016).
10.6.3	Fourth Amendment to Plasma Purchase Agreement, dated as of June 6, 2017, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc. (incorporated herein by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).
10.7+	Amended and Restated Plasma Supply Agreement, dated as of March 23, 2016, by and between ADMA Biologics, Inc. and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K, filed with the SEC on March 23, 2016).
10.8+	Plasma Supply Agreement, dated as of June 6, 2017, by and between ADMA BioManufacturing, LLC and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).
10.9+	Plasma Purchase Agreement, dated as of June 6, 2017, by and between ADMA BioManufacturing, LLC and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).

10.10	Amended and Restated Agreement for Services, effective as of January 1, 2016, by and between ADMA Biologics, LLC and Areth LLC (incorporated herein by reference to Exhibit 10.18 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 12, 2016).
10.11	Agreement of Lease, effective June 1, 2008 and confirmed on November 13, 2008, by and among ADMA Bio Centers Georgia Inc., ADMA Biologics, Inc. and C1VF I-GA1W15-W23, LLC (DCT Holdings), as amended on January 20, 2011, May 24, 2012 and January 1, 2014 (incorporated herein by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K, filed with the SEC on February 13, 2012).

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10.12+	Lease, dated as of January 20, 2014, by and between ADMA Bio Centers Georgia Inc. and U.S. Bank National Association, effective February 1, 2014, as amended on December 18, 2014 and July 9, 2015 (incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K, filed with the SEC on March 28, 2014).
10.13	Lease, effective as of February 17, 2017, by and between Home Center Properties, LLC and ADMA Bio Centers Georgia Inc. (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K, filed with the SEC on February 24, 2017).
10.14	Purchase Agreement, dated as of June 6, 2017, by and among the Company, Biotest Pharmaceuticals Corporation and ADMA Bio Centers Georgia, Inc. (incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).
10.15	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K, filed with the SEC on February 13, 2012).
10.16+	Testing Services Agreement, dated as of June 8, 2012, by and between ADMA Biologics, Inc. and Quest Diagnostics Clinical Laboratories, Inc. (incorporated herein by reference to Exhibit 10.16 to Amendment No. 4 to the Company's Registration Statement on Form S-1, filed with the SEC on August 10, 2012).
10.17	Loan and Security Agreement, dated as of June 19, 2015, by and among Oxford Finance LLC, the lenders party thereto, ADMA Biologics, Inc., ADMA Plasma Biologics, Inc. and ADMA Bio Centers Georgia Inc. (incorporated herein by reference to Exhibit 10.23 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2015).
10.17.1	First Amendment to Loan and Security Agreement, dated as of May 13, 2016, by and among Oxford Finance LLC, the lenders party thereto, ADMA Biologics, Inc., ADMA Plasma Biologics, Inc. and ADMA Bio Centers Georgia Inc. (incorporated herein by reference to Exhibit 10.17.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2016).
10.18	Subordinated Loan Agreement, dated as of June 6, 2017, by and among the Company, ADMA BioManufacturing, LLC and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 12, 2017).
10.19	Credit Agreement, dated as of October 10, 2017, by and among the Company, ADMA Plasma Biologics, Inc., ADMA Bio Centers Georgia Inc., ADMA BioManufacturing, LLC, Marathon Healthcare Finance Fund, L.P. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 11, 2017).

10.20	Security Agreement, dated as of October 10, 2017, by and among the Company, ADMA Plasma Biologics, Inc., ADMA Bio Centers Georgia Inc., ADMA BioManufacturing, LLC and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on October 11, 2017).
10.21	Intellectual Property Security Agreement, dated as of October 10, 2017, by and among the Company, ADMA Plasma Biologics, Inc., ADMA Bio Centers Georgia Inc., ADMA BioManufacturing, LLC and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on October 11, 2017).
10.22	Pledge Agreement, dated as of October 10, 2017, by and between the Company and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed with the SEC on October 11, 2017).

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10.23+	License Agreement, effective as of December 31, 2012, by and between ADMA Biologics, Inc. and Biotest Aktiengesellschaft (incorporated herein by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1, filed with the SEC on February 11, 2013).
10.23.1	First Amendment to License Agreement, dated as of June 6, 2017, by and between the Company and Biotest Aktiengesellschaft (incorporated herein by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).
10.24++ *	Manufacturing Agreement, dated as of September 30, 2011, by and between ADMA BioManufacturing, LLC (as successor-in-interest to Biotest Pharmaceuticals Corporation) and Sanofi Pasteur S.A.
10.24.1++ *	Amendment #2 to the Manufacturing Agreement, effective as of August 1, 2016, by and between ADMA BioManufacturing, LLC (as successor-in-interest to Biotest Pharmaceuticals Corporation) and Sanofi Pasteur S.A.
10.24.2++ *	Amendment #3 to the Manufacturing Agreement, effective as of December 21, 2017, by and between ADMA BioManufacturing, LLC and Sanofi Pasteur S.A.
10.25	Stockholders Agreement, dated as of June 6, 2017, by and between the Company and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on June 12, 2017).
10.26	Registration Rights Agreement, dated as of June 6, 2017, by and between the Company and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on June 12, 2017).
10.27+	Transition Services Agreement, dated as of June 6, 2017, by and between ADMA BioManufacturing, LLC and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).
10.28	Termination Agreement (Manufacturing, Supply and License Agreement and Master Services Agreement), dated as of June 6, 2017, by and between the Company and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).
21.1	Subsidiaries of the Company (incorporated herein by reference to Exhibit 21.1 to the Company's Registration Statement on Form S-1, filed with the SEC on October 11, 2018).

23.1*	Consent of CohnReznick LLP.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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101*	The following materials from ADMA Biologics, Inc. Form 10-K for the year ended December 31, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at December 31, 2017 and December 31, 2016, (ii) Consolidated Statements of Operations for the years ended December 31, 2017 and 2016 (iii) Consolidated Statements of Changes in Stockholders' (Deficiency) Equity for the years ended December 31, 2017 and 2016, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2017 and 2016 and (v) Notes to Consolidated Financial Statements.

+ Confidential treatment has been granted with respect as to certain portions of this exhibit. Such portions have been redacted and submitted separately to the SEC.

++ Confidential treatment has been requested with respect as to certain portions of this exhibit. Such portions have been redacted and submitted separately to the SEC.

* Filed herewith.

** Furnished herewith.

† Management compensatory plan, contract or arrangement.