



# Advanced Therapies for the Immune Compromised

[WWW.ADMABIOLOGICS.COM](http://WWW.ADMABIOLOGICS.COM)

## 2016 Annual Report

Dear Stockholder,

We hope that you are as excited as we are with the recent announcement of our proposed acquisition of certain assets from Biotest Pharmaceuticals Corporation (BPC), which we believe will rapidly transform ADMA Biologics into a fully vertically integrated manufacturer and provider of commercial hyperimmune globulins and other plasma derived products. Since signing the definitive purchase agreement with BPC, our current contract manufacturer, we have been aggressively working on integration efforts and advancing towards the closing of this transformational transaction.

We are also pleased with the continued year-over-year revenue growth from our plasma collection business segment. We believe that our FDA approved plasma collection centers will serve as a strong foundation and supply resource for a portion of the raw material normal source and hyperimmune plasma required for our anticipated post-transaction commercial production needs on our vertically integrated platform.

We expect 2017 will be a year of hard work, advancement and execution in three core areas: 1. delivering accretive revenues from the acquisition of certain commercial assets from BPC, as well as further penetrating the market for these products; 2. overhauling the quality management system at the BPC facility and ultimately remediating the outstanding inspection issues and addressing the complete response letter received for our lead product candidate, RI-002; and 3. expanding our existing plasma collection center network in anticipation of growing our commercial operations into the future. Upon closing of the transaction, we believe we will be positioned to create significant value for all of our stockholders in the coming years and we are grateful to you, our stockholders, for your continued support and trust, as we embark on this tremendous opportunity.

Additionally, I would like to thank my team members at ADMA Biologics and the employees of BPC who will be soon joining our growing company for their continued loyalty, hard work and dedication in making our company a success and achieving our ultimate goal of positively impacting patient's lives.

Sincerely,



Adam S. Grossman  
Founder, President and Chief Executive Officer

## GROUNDBREAKING IMMUNOTECHNOLOGY, ONE CONNECTION AT A TIME.

### SUPERIOR SOLUTIONS COME FROM SUPERIOR COMMITMENT

ADMA Biologics is a biopharmaceutical company relentlessly committed to creating superior products for immunodeficient patients at risk for infection. It is our devotion to this underserved population that fuels us, and it is our hands-on approach to production and development that sets us apart.

**Why does it matter? Because patients are counting on us.**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2016

or

**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**

\_\_\_\_\_  
(State or Other Jurisdiction of Incorporation or Organization)

**56-2590442**

\_\_\_\_\_  
(I.R.S. Employer Identification No.)

**465 State Route 17, Ramsey, New Jersey**

\_\_\_\_\_  
(Address of Principal Executive Offices)

**07446**

\_\_\_\_\_  
(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

**Common stock, par value \$0.0001 per share**

\_\_\_\_\_  
Name of each exchange on which registered

**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

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

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  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  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) 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.

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

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

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

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates was \$40,899,598 as of June 30, 2016 (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 \$5.95 as reported on the Nasdaq Capital Market on June 30, 2016.

The number of shares of the registrant's common stock, par value \$0.0001 per share, outstanding as of February 24, 2017 was 12,886,741.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement for its 2017 annual meeting of stockholders or annual report on Form 10-K/A, to be filed on or before May 1, 2017, are incorporated by reference into Part III of this annual report on Form 10-K.



**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 consummate and close our proposed acquisition of certain assets from Biotest Pharmaceuticals Corporation, the expected closing date of which is conditioned upon several factors, including stockholder approval;
- our ability to successfully leverage the anticipated benefits and synergies of our proposed acquisition of certain assets from Biotest Pharmaceuticals Corporation, including maximizing the anticipated future combined businesses, operations, products and services, and liquidity, debt repayment and capital return expectations;
- our ability to successfully resubmit to the U.S. Food and Drug Administration, or FDA, our Biologics License Application, or BLA, for our lead product candidate, RI-002, once the deficiencies identified in the July 2016 Complete Response Letter, or CRL, 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, market, launch and build our own commercial infrastructure and commercialize RI-002 and the success of such efforts;
- the expected timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including the timeframe within which we may receive approval from the FDA, if at all, of our BLA 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 one manufacturer for RI-002 and the effect any adverse events on such manufacturer could have on us or our business;
- our dependence upon our third-party contract manufacturers and vendors;
- our ability to obtain adequate quantities of FDA-approved normal source plasma and Respiratory Syncytial Virus, or RSV, high-titer 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 RI-002 for any purpose by physicians, patients or payers;
- concurrence by FDA with our conclusions and the satisfaction by us of its guidance;
- the comparability of results of RI-002 to other comparably run injectable immune globulin clinical trials;
- the potential of RI-002 to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease, or PIDD;
- our intellectual property position, including our expectations of 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 relating to manufacturing, supply and other collaborative agreements;
- our estimates regarding expenses, capital requirements and needs for additional financing;
- possible or likely reimbursement levels, if any, if and when RI-002 is approved for marketing;

- estimates regarding market size, projected growth and sales as well as our expectations of market acceptance of RI-002; 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 of these terms, although some forward-looking statements are expressed differently. 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 expressly disclaim any obligation or undertaking 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.



## 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 subsidiary, ADMA Plasma Biologics, Inc., a Delaware corporation, including its wholly-owned subsidiary, ADMA Bio Centers Georgia Inc., or ADMA BioCenters, a Delaware corporation, taken as a whole.*

### Business of ADMA

#### Overview

ADMA Biologics is a late-stage biopharmaceutical company that develops, manufactures and intends to commercialize specialty plasma-based biologics for the proposed 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. Our 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.

#### *Our Lead Product Candidate – RI-002*

We are currently developing our lead product candidate, RI-002, for the treatment of Primary Immune Deficiency Disease, or PIDD, and have completed a pivotal Phase III clinical study. RI-002 is derived from human plasma blended from normal donors and donors tested to have high levels of neutralizing titers to Respiratory Syncytial Virus, or RSV. RI-002 is manufactured using a process called fractionation, which purifies immune globulins, or IgG, from this blended plasma pool resulting in a final IVIG product enriched with naturally occurring polyclonal anti-pathogen antibodies (e.g., streptococcus pneumonia, H. influenza type B, Cytomegalovirus or CMV, measles, tetanus, etc.). We use our proprietary RSV microneutralization assay to test for standardized levels of neutralizing antibodies to RSV in the final drug product.

In the third quarter of 2015, the U.S. Food and Drug Administration, or FDA, accepted for review our Biologics License Application, or BLA, for RI-002 for the treatment of PIDD. In July 2016, the FDA issued a Complete Response Letter, or CRL. 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 FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies relating to Chemistry, Manufacturing and Controls, or CMC, at our third-party contract manufacturers and vendors and requested documentation of corrections for a number of those issues. The FDA indicated in the CRL that it cannot grant final approval of the BLA until, among other things, these deficiencies are resolved. Since receiving the CRL, we have worked diligently with our contract fill and finisher as well as the contract testing laboratory. We have also continued to work with our third-party contract manufacturer, Biotest Pharmaceuticals Corporation, or Seller or BPC, and on January 23, 2017 we announced the signing of a definitive acquisition agreement to acquire certain manufacturing and therapy-related assets from BPC in Boca Raton, Florida, a wholly-owned subsidiary of Biotest AG, or Biotest, in efforts to address the CRL and remediate the outstanding warning letter and other matters at the manufacturing facility.

We continue to collaborate with our third-party manufacturers and vendors to identify solutions to outstanding issues identified in the CRL. We are currently preparing documentation for an additional submission to the FDA to address the CRL. We, along with our vendors, are awaiting certain feedback from the FDA regarding previous submissions and we intend to provide a timeline for resubmission of our BLA for RI-002 as soon as practicable. If RI-002 is approved by the FDA for PIDD, we intend to commercialize RI-002 for the treatment of PIDD and explore alternative regulatory processes to evaluate and seek approval for RI-002 for additional indications, patient populations and uses.

## *Evaluation of 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, or PK, data collection points including antibody titers for certain agents, including RSV antibody levels at various time points after infusion.

RI-002 demonstrated positive results in the Phase III study in patients with PIDD, meeting its primary endpoint, of no Serious Bacterial Infections, or SBI, reported. RI-002 was administered 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 the BLA, more than meet the requirement specified by FDA guidance of  $\leq 1$  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 in RSV Infected Patients*

RSV is a common virus that ordinarily leads to mild, cold-like symptoms in healthy adults and children. In high-risk groups, such as the PIDD population and the other immune-compromised populations, RSV can lead to a more serious infection and may even cause death. The polyclonal antibodies which are present in RI-002 are expected to prevent infections in immune-compromised patients.

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

From April 2009 through February 2011, RI-001 was also administered to 15 compassionate use patients where physicians requested access to the product for treating their patients with documented lower respiratory tract RSV infections due to the fact that these patients had failed conventional therapeutic interventions. Serum samples were obtained from 13 patients. Samples showed that patients demonstrated a four-fold or greater rise in RSV

antibody titers from baseline. Serum samples were not obtained from two patients that received Palivizumab. All 11 patients who received RI-001 within 4.2 days after the onset of the diagnosis of RSV survived. 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 during 2014, 2015 and 2016.

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.

### *Commercialization*

While we are working towards remediating the Warning Letter and other deficiencies and eventually filing the BLA resubmission for RI-002, we expect to continue our commercialization efforts and plan to increase our initiatives by hiring a small, specialty sales force to market Nabi-HB™ (Hepatitis B Immune Globulin, Human) upon closing the BPC acquisition anticipated during the first half of 2017, and Bivigam™ (Immune Globulin Intravenous, Human) upon its relaunch and RI-002 once approved by the FDA, to hospitals, physician offices/clinics, and other specialty treatment organizations. We anticipate staffing our company with additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, reimbursement, inventory and logistics, human resources, and financial and operational management. If and when we receive FDA approval, we may also use a network of national distributors to assist with order fulfillment for RI-002 for use by healthcare professionals and hospitals.

### *Intellectual Property*

During the second quarter of 2015, we received a notice of allowance from the U.S. Patent Office, or USPTO, for our RI-002 patent filed under U.S. patent application 14/592,721 entitled 'Compositions and Methods for the Treatment of Immunodeficiency,' which extends through January 2035. During the third quarter of 2015, our U.S. Patent 9,107,906 was issued by the USPTO. This patent describes methods by which the blending of plasma obtained from normal donors with plasma obtained from donors selected to have high levels of neutralizing titers to RSV form a unique antibody enriched plasma pool and provide for the standardization of the levels of anti-RSV antibodies in the RI-002 final product. Our proprietary microneutralization assay allows us to effectively identify and isolate donor plasma with high-titer RSV antibodies and to standardize RI-002's antibody profile, which we believe may enable us to garner a premium price.

### *Plasma Collection Facilities*

Our wholly-owned subsidiary, ADMA BioCenters, operates two FDA-licensed, German Health Authority, or GHA, and Korean Ministry of Food and Drug Safety, or MFDS, certified source plasma collection facilities located in Norcross, Georgia and Marietta, Georgia, which provide us with a portion of our blood plasma for the manufacture of RI-002. Our plasma collection center in Marietta, Georgia received FDA approval in the third quarter of 2015. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase, and market conditions at the time of sale. Plasma collected from ADMA BioCenters' two Georgia facilities that is not used for making RI-002 is sold to third-party customers in the U.S., and other locations where we are approved globally under supply agreements or in the open "spot" market. We have entered into long-term manufacturing and licensing agreements with Biotest and its U.S. subsidiary, BPC, that provide for the exclusive manufacture of RI-002. At the same time, we granted Biotest an exclusive, royalty-bearing license to market and sell RSV antibody-enriched IVIG in Europe and in other selected territories in North Africa and the Middle East.

### *Leadership*

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

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

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

## Our Strategy

Our goal is to be a leader in developing and commercializing specialized, targeted, plasma-derived therapeutics 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:

- **Obtain FDA approval of RI-002 as a treatment for PIDD.** In the third quarter of 2015, the FDA accepted for review a BLA for RI-002 for the treatment of PIDD. In July 2016, the FDA issued a CRL. 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 FDA identified in the CRL, among other things, certain outstanding inspection issues and CMC deficiencies at our third-party contract manufacturers and vendors and requested documentation of corrections for a number of those issues. Since receiving the CRL, we have worked diligently with our contract fill and finisher as well as the contract testing laboratory. We have also continued to work with our third-party contract manufacturer, BPC, and on January 23, 2017 we announced the signing of a definitive acquisition agreement to acquire certain manufacturing and therapy-related assets from BPC in Boca Raton, Florida, a wholly-owned subsidiary of Biotest, in efforts to address the CRL and remediate the outstanding Warning Letter and other deficiencies at the manufacturing facility.

We continue to collaborate with our third-party manufacturers and vendors to identify solutions to outstanding issues identified in the CRL. We are currently preparing documentation for an additional submission to the FDA to address the CRL. We, along with our vendors, are awaiting certain feedback from the FDA regarding previous submissions and we intend to provide a timeline for resubmission of our BLA for RI-002 as soon as practicable. If RI-002 is approved by the FDA for PIDD, we intend to commercialize RI-002 for the treatment of PIDD and explore alternative regulatory processes to evaluate and seek approval for RI-002 for additional indications, patient populations and uses. The FDA indicated in the CRL that it cannot grant final approval of the BLA until, among other things, these deficiencies are resolved.

- **Commercialize RI-002 as a treatment for PIDD.** We plan to increase our hiring initiatives of a small, specialty sales force to market RI-002 to hospitals, physician offices/clinics, and other specialty treatment and infusion center organizations. We anticipate staffing our company with additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, reimbursement, inventory and logistics, human resources, and financial and operational management. 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.

- ***Develop additional plasma-derived products.*** Our core competency is in the development 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 patent, which includes 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 in advance of RI-002's commercialization, we formed ADMA BioCenters, a subsidiary that operates plasma collection facilities in Norcross and Marietta, Georgia. The Norcross and Marietta facilities hold FDA licenses, along with GHA and MFDS certifications. Under the FDA licenses, ADMA BioCenters may collect normal source plasma and high-titer RSV plasma. We sell a portion of our normal source plasma to buyers in the open "spot" market. We also plan to use the high-titer RSV plasma collected by ADMA BioCenters in the commercial manufacturing of RI-002. We may initiate other hyperimmune plasma collection programs at the Norcross and Marietta facilities. These programs would be initiated during the normal course of business and are expected to cost approximately \$2 million to implement. We may also consider growth through the creation and licensing of additional ADMA BioCenters facilities in various regions of the U.S. Additional ADMA BioCenters may allow us to cost-effectively secure additional high-titer RSV plasma for RI-002, and potentially increase revenues through the collection and sale of normal source plasma and other hyperimmune plasma to third parties.

### **Summary of Proposed Acquisition of Certain Assets of BPC**

On January 21, 2017, we and our wholly-owned subsidiary, ADMA BioManufacturing, LLC, a Delaware limited liability company ("Buyer"), entered into a definitive Master Purchase and Sale Agreement (as amended, restated, supplemented or otherwise modified from time to time, the "Purchase Agreement") with Seller, and for certain limited purposes set forth in the Purchase Agreement, Biotest and Biotest US Corporation, a Delaware corporation and subsidiary of Biotest (together with Biotest AG, the "Biotest Guarantors"), pursuant to which Buyer has agreed to acquire certain assets and assume certain liabilities constituting the therapy business of Seller (the "Business"). We refer to the foregoing transactions and the other transactions contemplated by the Purchase Agreement collectively as the "Proposed Acquisition." The Business includes (a) a FDA-licensed immune globulin manufacturing and plasma products production facility of two buildings of approximately 126,000 square feet located on approximately 15 acres of land in Boca Raton, Florida, and the associated real property, (b) all exclusive rights to FDA licensed biologics products Nabi-HB®, BIVIGAM® and the investigational product CIVACIR®, (c) in-process inventory with an agreed-upon value of at least \$5.0 million, (d) certain other properties and assets used exclusively in the Business, and (e) certain additional assets which relate to both the Business and Biotest's plasma business, the arrangement with respect to which will be documented in a transition services agreement to be mutually agreed by the parties between the signing of the Purchase Agreement and the closing of the Proposed Acquisition.

Subject to the terms and conditions of the Purchase Agreement, (i) upon the closing, Buyer has agreed to assume certain liabilities of Seller related to the Business, including, without limitation, related to (x) product liabilities, breach of warranty, product complaints, product returns, post-market commitments, recalls, adverse event reporting, product deviation reporting, lookbacks, market withdrawals and field corrections or similar claims for injury to person or property with respect to the Business or any product of the Business to the extent such liabilities relate to products manufactured and sold by Buyer after the closing (other than inventory transferred to us at the closing, which will be allocated 50% to Buyer and 50% to Seller if not traceable to acts or omissions of a particular party); and (y) other regulatory matters, whether related to the pre-closing or post-closing period and including any liabilities related to the products of the Business, the FDA warning letter (the warning letter issued by the FDA to Seller in connection with outstanding issues requiring remediation at the manufacturing facility in Boca Raton, Florida), noncompliance with applicable laws and legal proceedings related to the foregoing, but excluding such liabilities that arise out of any fraud, willful misconduct or intentional misrepresentation by Seller prior to the closing (the "Assumed Liabilities"); (ii) upon the closing, we have agreed to deliver to Seller an aggregate equity interest in us equal to 50%, less one share, of our issued and outstanding capital stock (calculated as of immediately following the closing and on a post-closing issuance basis) (the "Biotest Equity Interest"), consisting of (x) common

stock representing 25% of our issued and outstanding common stock, equal to 4,295,580 common shares and (y) non-voting common stock equal to 8,591,160 shares of our common stock representing the balance of the Biotest Equity Interest which is convertible into our common stock upon the occurrence of certain specified events; (iii) upon the closing, we agreed to issue to Seller warrants, if any, necessary to acquire additional shares of our capital stock equal to the excess, if any, of (x) the number of shares represented by rights, options and warrants issued by us between September 12, 2016 until the closing, over (y) 184,000 shares; and (iv) on January 1, 2019, pursuant to the terms of a separate purchase agreement to be entered into by the parties at the closing, we have agreed to sell, transfer and convey to Seller for no additional consideration, all of our right, title and interest in and to our certain biocenter located in Norcross, Georgia and our certain biocenter located in Marietta, Georgia, 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. As part of the consideration, upon the closing, Seller will also be granted the right to designate one director and one observer to our board of directors, and under certain circumstances, Seller will be granted the right to designate an additional director.

Additionally, on the closing date, Seller has agreed to (i) deliver to us a capital contribution of \$12.5 million in respect of the Biotest Equity Interest, which capital contribution will be contributed by Seller to Buyer; and (ii) fund a \$15.0 million unsecured subordinated loan to us, which (a) will bear interest at a rate of 6% per annum, payable semiannually in arrears, (b) has a term of five years and (c) will not be subject to any prepayment penalty or other breakage costs. Such loan will be subordinated to our existing indebtedness as of the signing of the Purchase Agreement and any additional indebtedness approved by our board of directors which is secured only by a mortgage on the owned real property acquired in connection with the transaction. Such loan will rank *pari passu* with all additional indebtedness approved by our board of directors that is not secured only by a mortgage on such owned real property and if such additional indebtedness is secured, the loan from Seller will be secured on a *pari passu* basis with such additional indebtedness. At any time after the closing, if we undertake an underwritten equity financing or a Private Investment in Public Equity, or PIPE, offering involving at least one unrelated third party, Biotest and/or Seller have agreed to participate *pro rata* in accordance with the Biotest Equity Interest up to an aggregate amount equal to \$12.5 million.

Upon the closing, the parties will also enter into a ten-year plasma supply agreement, pursuant to which (x) Seller will sell to us high titer Hepatitis B plasma at a specified price (indexed by inflation), and (y) we will purchase from Seller all Hepatitis B plasma necessary to produce Nabi-HB® unless we require more than a specified amount, in which case we may use alternative sources for the excess quantity. Additionally, the parties have agreed to 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 Buyer and Seller. The mutual release is effective as of the signing of the Purchase Agreement conditioned on the closing of the Proposed Acquisition at which time the Manufacturing Supply and License Agreement and Master Services Agreement will terminate and the mutual release will no longer be conditional.

The Purchase Agreement contains customary representations and warranties of the parties, including, without limitation, with respect to: organization; power and authority; due authorization; enforceability; capitalization; no conflict; no consents required; no actions; no orders; financial statements; indebtedness; no undisclosed liabilities; absence of certain changes; taxes; contracts; customers and suppliers; intellectual property; title to properties; real property; employee benefit plans; employees; insurance; compliance with laws; environmental; material permits; inventory; affiliate transactions; and no brokers.

The Purchase Agreement also contains customary covenants and agreements, including covenants and agreements of: Seller to conduct the Business in the ordinary course until the Proposed Acquisition is completed or terminated and to not take certain actions relating to the Business during the interim period between signing and closing, without our prior consent not to be unreasonably withheld, conditioned or delayed; our conduct of our business in the ordinary course until the Proposed Acquisition is completed or terminated and to not take certain actions relating to its business during the interim period between signing and closing, without Seller's prior consent not to be unreasonably withheld, conditioned or delayed; Seller not to compete with us in certain lines of business for a period of five years following the closing date; Seller and the Biotest Guarantors not to solicit our employees for one year following the closing date; we and Buyer not to solicit Seller's employees for one year following the closing date; and Seller not to interfere with the our customers for five years following the closing date.

Subject to certain limitations, Buyer or Seller may terminate the Purchase Agreement if the Proposed Acquisition has not been consummated by September 30, 2017. A termination of the Purchase Agreement under certain customary circumstances relating to (i) our board of directors exercising their fiduciary out will entitle Seller to receive from us a termination fee in an amount equal to \$2.5 million; or (ii) our failure to obtain the requisite stockholder approval will entitle Seller to receive expense reimbursement in an amount up to \$2.5 million. In no event will Seller be entitled to both a termination fee and expense reimbursement.

We and Seller will each indemnify the other party after the closing for any losses arising from breaches of its representations, warranties, covenants and agreements in the Purchase Agreement. In addition, Buyer will indemnify Seller after the closing for any assumed liability, and Seller will indemnify us after the closing for any excluded asset or excluded liability. The representations, warranties and pre-closing covenants generally survive for 15 months following the closing of the transaction and each party's indemnification obligations with respect to (a) its representations and warranties (other than its fundamental representations, which include representations related to taxes, organization, due authorization, organizational documents, no conflicts, enforceability, title, sufficiency, the Amended and Restated Product Distribution Agreement, effective as of January 19, 2016, by and between Seller and Kedrion Biopharma Inc., or the Kedrion Contract, brokers, etc. and ownership of our securities) are subject to a \$25,000 mini-basket and \$750,000 true deductible; and (b) its representations and warranties (other than fundamental) and pre-closing covenants are subject to a \$25.0 million cap.

Seller will be entering into a standstill with ADMA, which will limit Seller's ability to control the Company. Seller will also agree to a six (6) month lock-up of the sale of ADMA securities.

The consummation of the Proposed Acquisition is subject to the satisfaction of certain conditions, including approval of the Proposed Acquisition by the stockholders of ADMA and approval of the amended and restated certificate of incorporation of the Company by the stockholders of ADMA. The Proposed Acquisition is not subject to any financing conditions. There can be no assurance as to when the closing conditions will be satisfied, if at all.

Upon consummation and closing of the Proposed Acquisition, we believe we will be uniquely positioned to offer a fully vertically integrated plasma products and immune globulin platform in the U.S.

## **The Plasma Industry**

### *Primary Immunodeficiency Disease*

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

As most patients with PIDD present with infections, the differential diagnosis and initial investigations for an underlying immune defect are typically guided by the clinical presentation. In subjects with PIDD, individual infections are not necessarily more severe than those that occur in a normal host. Rather, the clinical features suggestive of an immune defect may be the recurring and/or chronic nature of infections with common pathogens that may result in end organ damage, such as bronchiectasis. In addition, subjects with PIDD will often respond poorly to standard antimicrobial therapy or they may have repeated infections with the same pathogen. The virulence of the infecting organism should also be considered, and a subject's immune competence should be questioned when invasive infections are caused by low virulence or opportunistic pathogens. For example, infection with the opportunistic pathogens *Pneumocystis jirovecii* (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 (e.g., streptococcus pneumoniae, H. influenza type B, CMV, measles, tetanus, etc.) 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, or 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, or 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.

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, or NAT, for various infectious diseases, such as human immunodeficiency virus, or HIV, and hepatitis C virus, 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 called “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 (e.g., 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, or CBER.

### *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 study for the treatment of Alzheimer’s disease. Additionally, IVIG is also used as therapy in a variety of other diseases that do not involve primary or secondary immune deficiencies, such as multiple sclerosis, skin disease, and asthma. These latter uses are referred to as “off-label” or evidence-based uses because the FDA has not approved their use in these indications and promotion of such uses is not permitted by FDA unless a BLA or BLA supplement with additional data is approved. Among the various IVIG products, there are only 14 labeled indications approved by the FDA. However, medical literature identifies at least 150 evidence based uses for IVIG, of which approximately 60 are currently included on lists of reimbursable uses by Medicare and other healthcare plans. This provides opportunities for new product development and submissions.

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

As of the date of this annual report on Form 10-K, 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.

#### *Our Lead Product Candidate – RI-002*

We are currently developing our lead product candidate, RI-002, for the treatment of PIDD, and have completed a pivotal Phase III clinical study. RI-002 is derived from human plasma blended from normal donors and donors tested to have high levels of neutralizing titers to RSV. RI-002 is manufactured using a process called fractionation, which purifies immune globulins, or IgG, from this blended plasma pool resulting in a final IVIG product enriched with naturally occurring polyclonal anti-pathogen antibodies (e.g., streptococcus pneumonia, H. influenza type B, Cytomegalovirus or CMV, measles, tetanus, etc.). We use our proprietary RSV microneutralization assay to test for standardized levels of neutralizing antibodies to RSV in the final drug product.

In the third quarter of 2015, the FDA accepted for review a BLA for RI-002 for the treatment of PIDD. In July 2016, the FDA issued a CRL. 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 FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies at our third-party contract manufacturers and vendors and requested documentation of corrections for a number of those issues. The FDA indicated in the CRL that it cannot grant final approval of the BLA until, among other things, these deficiencies are resolved.

We continue to collaborate with our third-party manufacturers and vendors to identify solutions to outstanding issues identified in the CRL. We are currently preparing documentation for an additional submission to the FDA to address the CRL. We, along with our vendors, are awaiting certain feedback from the FDA regarding previous submissions and we intend to provide a timeline for resubmission of our BLA for RI-002 as soon as practicable. If RI-002 is approved by the FDA, we intend to commercialize RI-002 for the treatment of PIDD and explore alternative processes to evaluate and seek approval for RI-002 for additional indications, patient populations and uses.

#### *Evaluation of 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, or PK, data collection points including antibody titers for certain agents, including RSV antibody levels at various time points after infusion.

RI-002 demonstrated positive results in the Phase III study in patients with PIDD, meeting its primary endpoint, of no Serious Bacterial Infections, or SBI, reported. RI-002 was administered 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 the BLA, more than meet the requirement specified by FDA guidance of  $\leq 1$  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 in RSV Infected Patients*

RSV is a common virus that ordinarily leads to mild, cold-like symptoms in healthy adults and children. In high-risk groups, such as the PIDD population and the other immune-compromised populations, RSV can lead to a more serious infection and may even cause death. The polyclonal antibodies which are present in RI-002 are expected to prevent infections in immune-compromised patients.

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

From April 2009 through February 2011, RI-001 was also administered to 15 compassionate use patients where physicians requested access to the product for treating their patients with documented lower respiratory tract RSV infections due to the fact that these patients had failed conventional therapeutic interventions. Serum samples were obtained from 13 patients. Samples showed that patients demonstrated a four-fold or greater rise in RSV antibody titers from baseline. Serum samples were not obtained from two patients that received Palivizumab. All 11 patients who received RI-001 within 4.2 days after the onset of the diagnosis of RSV survived. 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 during 2014, 2015 and 2016.

#### **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 two FDA-licensed, GHA and MFDS-certified source plasma collection facilities located in Norcross and Marietta, Georgia, which facilities provide us with a portion of our plasma requirements. By using our patented proprietary assay, we can identify plasma donors with elevated amounts of RSV antibodies and formulate RI-002 with an appropriate RSV titer level to ensure the final product is standardized to contain high levels of RSV antibodies. Once source plasma has been collected, it is then fractionated and purified into specialized therapies, which are used by patients who require them. We have agreements with independent third parties for the sourcing of blood plasma and for the fractionation and purification stages of manufacturing. The contracts are with well-regarded facilities that are fully licensed to manufacture biologics. We are dependent upon our third party suppliers for the manufacture of RI-002. Our principal supplier of source plasma is BPC.

In December 2012, we entered into our Manufacturing, Supply and License Agreement with BPC. Under the agreement, we 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 is for a period of ten years from January 1, 2013, renewable for two additional five year periods at the agreement of both parties. We are

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 is subject to increase at our option. As consideration for BPC's obligations under the agreement, we are 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. The agreement may be terminated by either party (a) by reason of a material breach if the breaching party fails to remedy the breach within 120 days after receiving notice of the breach from the other party, (b) upon bankruptcy, insolvency, dissolution, or winding up of the other party, or (c) if the other party is unable to fulfill its obligations under the agreement for 120 consecutive days or more as a result of (a) or (b) above. Additionally, the parties have agreed to 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 us and BPC. The mutual release is effective as of January 21, 2017 conditioned on the closing of the Proposed Acquisition anticipated during the first half of 2017 at which time the Manufacturing Supply and License Agreement and Master Services Agreement will terminate and the mutual release will no longer be conditional.

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. This volume will increase at the earlier of our receipt of a BLA from the FDA, or March 31, 2016. 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 Proposed Acquisition, we will amend 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 Proposed Acquisition, which is anticipated during the first half of 2017.

On June 22, 2012, we entered into a Plasma Supply Agreement with BPC for the purchase of normal source plasma from our ADMA BioCenters, Norcross, Georgia 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 right or obligations there under 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 relating 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. The Manufacturing, Supply and License Agreement with BPC will be terminated upon the closing the Proposed Acquisition anticipated during the first half of 2017.

For the fiscal year ended December 31, 2016, two of our customers, SK Plasma Co., Ltd., or SK, and BPC, represented greater than 95% of our total revenues, with SK representing approximately 14% of our total revenues and BPC representing approximately 82% of our total revenues. We believe SK will represent approximately less than 10% of our total revenues for 2017.

On June 7, 2012, we entered into a Testing Services Agreement with Quest Diagnostics Clinical Laboratories, Inc., or Quest, in which Quest agreed to provide biomarker testing and related support services for protocol screening and recertification which are exclusive to us. If either party believes the other party is in material breach of any of their obligations under the agreement, the non-breaching party has the right to terminate the agreement by providing the breaching party with written notice specifying the material breach(es) and indicating clearly its intention to terminate the agreement. If the breaching party cures such breach, the non-breaching party's notice is void. In addition, either party can terminate the agreement without cause upon written notice. All data, test results, studies and other information generated by Quest in performing services under the agreement will be our sole property. 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 a small 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 of directors has substantial prior direct marketing, sales and distribution experience with plasma derived drugs, specialty immune globulins and other biological products. We anticipate staffing the company with additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, 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 Proposed Acquisition, our current and anticipated plans and intentions will evolve and change. For a discussion of forward-looking statements, see the section entitled "Special Note Regarding Forward-Looking Statements" on page 1 of this annual report on Form 10-K and the section entitled "Item 1A – Risk Factors" beginning on page 21 of this annual report on Form 10-K.

In our Manufacturing, Supply and License Agreement, we granted BPC an exclusive license to market and sell RSV antibody-enriched IVIG in Europe and in selected countries in North Africa and the Middle East, collectively referred to as 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 BPC seeking regulatory approval for the RSV antibody-enriched IVIG in the Territory. As consideration for the license, BPC agreed to provide us with certain services at no charge and also compensate us with cash payments upon the completion of certain milestones. BPC is also obligated to pay us an adjustable royalty based on a percentage of revenues from the sale of RSV antibody-enriched IVIG in the Territory for 20 years from the date of first commercial sale. Additionally, BPC has agreed to grant us an exclusive license for marketing and sales in the U.S. and Canada for BPC's Varicella Zoster Immune Globulin, or VZIG, of which terms are expected to be terminated upon the closing of the Proposed Acquisition, anticipated during the first of 2017. The mutual release is effective as of January 21, 2017 conditioned on the closing of the Proposed Acquisition anticipated during the first half of 2017 at which time the Manufacturing Supply and License Agreement and Master Services Agreement will terminate and the mutual release will no longer be conditional.

### **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, or 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, direct ownership of manufacturing facilities, 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, we received a notice of allowance from the U.S. Patent Office, or USPTO, for our RI-002 patent filed under U.S. patent application 14/592,721 entitled ‘Compositions and Methods for the Treatment of Immunodeficiency,’ which extends through January 2035. During the third quarter of 2015 our U.S. Patent 9,107,906 was issued by the USPTO. This patent describes methods by which the blending of plasma obtained from normal donors with plasma obtained from donors selected to have high levels of neutralizing titers to RSV form a unique antibody enriched plasma pool and provide for the standardization of the levels of anti-RSV antibodies in the RI-002 final product. Our proprietary microneutralization assay allows us to effectively identify and isolate donor plasma with high-titer RSV antibodies and to standardize RI-002’s antibody profile, which we believe may enable us to garner a premium price.

We also rely on a combination of patents, 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 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 have filed for other provisional patent applications with the U.S. which are pending relating to expanded hyperimmune globulin products.

## Government Regulation and Product Approval

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the testing (preclinical and clinical), manufacturing, labeling, storage, recordkeeping, advertising, promotion, import, export, marketing and distribution, among other things, 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, or FDCA, and related regulations. Our current and anticipated future product candidates are considered “biologics” under the FDA regulatory framework. FDA’s regulatory authority for the approval of biologics resides in the PHS 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):

1. 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;
2. submission to the FDA of an IND application which must become effective before clinical trials may begin;
3. 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;
4. manufacturing (through an FDA-licensed contract manufacturing organization) of product in accordance with current Good Manufacturing Practices, or cGMP, to be used in the clinical trials and providing manufacturing information need in regulatory filings;
5. submission of a BLA to the FDA;
6. 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
7. the FDA review and approval of the 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 the section entitled “Item 1A – Risk Factors” beginning on page 21 of this annual report on Form 10-K.

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, or 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, or GCP, 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):

1. 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.
2. 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.
3. Certain Phase III clinical trials are referred to as pivotal trials. When Phase II clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to provide substantial evidence of reproducibility of clinical efficacy results and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

In addition, under the Pediatric Research Equity Act of 2003 (PREA), 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 are 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 FDASIA 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 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. In a CRL, it 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. 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.

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 relating 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 continuing, 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 relating 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 the 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.

In addition, the distribution of prescription drug products (including biological drug products) is subject to the Prescription Drug Marketing Act (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. Our ADMA BioCenters, located in Norcross and Marietta, Georgia, have completed these requirements and hold FDA licenses along with GHA and MFDS certifications. In order to maintain the license, 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, or CLIA, state licensure, and compliance with industry standards such as the International Quality Plasma Program, or IQPP. 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 obtain, 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 uncertainty exists 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 payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors 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 payor'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.

Third-party payors 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 payors 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, 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 payors 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 \$7.7 million and \$7.0 million for the fiscal years ended December 31, 2016 and 2015, respectively.

## **Employees**

ADMA Biologics, Inc., together with its subsidiaries ADMA Plasma Biologics, Inc. and ADMA BioCenters, Inc., has a total of 92 employees, which include 5 part-time employees, as well as additional full and part-time consultants and temporary staff. 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 ("Former ADMA"). On February 13, 2012, Former ADMA merged into a subsidiary of R&R Acquisition VI, Inc., a Delaware "blank check" company, which had been incorporated in 2006 and which subsequently changed its name to ADMA Biologics, Inc. upon completion of the merger. For accounting purposes, the merger was accounted for as a reverse acquisition, with Former ADMA as the accounting acquiror (legal acquiree) and R&R Acquisition VI, Inc. (now ADMA Biologics, Inc.) as the accounting acquiree (legal acquiror), effectively a recapitalization of Former ADMA.

The Company maintains a website at [www.admabiologics.com](http://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 on Form 10-K and all of the Company's filings under 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, or the SEC. Such filings are also available to the public on the internet at the SEC's website at [www.sec.gov](http://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**

*There are numerous and varied risks that may prevent us from achieving our goals. We believe that the following are the material risks that we face. If any of the following risks actually occurs, our business, financial condition or results of operations may be materially adversely affected. In such case, the trading price of our common stock could decline and investors in our common stock could lose all or part of their investment.*

### **Risks Relating to our Business**

***To date, we have generated limited product revenues, we 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 nearly all of our revenues from our plasma collections facilities derived from the sale of plasma, as well as our other plasma inventory sales. Unless and until we receive approval from the FDA

and other regulatory authorities for our RI-002 product candidate, we do not expect to sell and generate revenue from the commercialization of RI-002 and we will be required to raise additional funds through the sale of equity and/or debt securities or otherwise to, among others, establish a commercial salesforce, infrastructure and recognize any significant sales.

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 during the second half of 2017, we will likely not have sufficient cash flow and liquidity to fund our business operations as we currently operate, forcing us to curtail our activities and potentially significantly reduce, or potentially 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 the our projected revenue and expenditures for 2017, including regulatory and consulting fees for RI-002 associated with third-party manufacturers and ongoing discussions with the FDA, continuing implementation of our commercialization and expansion activities and certain other assumptions, management currently believes that its cash, cash equivalents, short-term investments, projected revenue and accounts receivable are sufficient to fund our operations, as currently conducted, into the second half of 2017. These estimates may change based upon whether or when the FDA approves RI-002, the timing of any required commercial manufacturing scale up activities or if any of our other assumptions change. These estimates may also change based upon the timing of the completion of the Proposed Acquisition which is anticipated during the first half of 2017. Upon the closing of the Proposed Acquisition, BPC will be providing funds to us consisting of: \$12.5 million in funding, \$15.0 million in debt financing and an additional \$12.5 million commitment towards a future equity financing is expected to be sufficient to fund operations into the first quarter of 2018. There is no assurance that we will be able to successfully close on the Proposed Acquisition. Other than the funding to be provided by BPC, 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 trial or commercialization activities, or the approval of any of our potential products. In addition, we could be forced to reduce or forego sales and marketing efforts and forego attractive business opportunities.

***We are not currently 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, 2016 and 2015, we incurred net losses of \$19.5 million and \$18.0 million, respectively, and from our inception in 2004 through December 31, 2016, we have incurred an accumulated deficit of \$106.9 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:

- seek regulatory approval(s);
- initiate commercialization and marketing efforts;
- implement additional internal systems, controls and infrastructure;
- hire additional personnel;
- expand and build out of our plasma center network; and
- integrate the assets which we intend to acquire in the Proposed Acquisition into our business post-closing.

We also expect to experience negative cash flow 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.

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

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

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any;
- third-party manufacturers might be unable to manufacture our products in the volume and of the quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not perform as agreed, and operate their business independently from ADMA. Contract manufacturers are directly responsible for their own FDA cGMP interactions and ADMA may not be privy to all ongoing discussions and information concerning products or process unrelated to ADMA. Additionally, contract manufacturers may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products;
- product manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards and our manufacturers may be found to be in noncompliance with certain regulations, which may impact our ability to manufacture our drug product candidates and may impact the regulatory status of ADMA and its product candidates; and
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation. We may be required to pay fees or other costs for access to such improvements and additional clinical trials or other studies may be required.

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

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

***Although our financial statements have been prepared on a going concern basis, we must raise additional capital during the second half of 2017 to fund our operations in order to continue as a going concern.***

CohnReznick LLP, our independent registered public accounting firm for the fiscal year ended December 31, 2016, has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2016, indicating that our current liquidity position raises 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 licensing partners. 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 in our company.

We anticipate that our principal sources of liquidity will only be sufficient to fund our activities as currently conducted and financial obligations into the second half of 2017. In order to have sufficient cash to fund our operations thereafter, we will need to raise additional equity or debt capital by the end of the second half of 2017 in order to continue as a going concern, and we cannot provide any assurance that we will be successful in doing so. This time frame may change based upon the timing of our commercial manufacturing scale up activities and the timing of the closing of the Proposed Acquisition. If our assumptions underlying our estimated expenses prove to be wrong, we may have to raise additional capital sooner than the second half of 2017. These assumptions may also change based upon the timing of the completion of the Proposed Acquisition, anticipated during the first half of 2017, of which funds received from BPC at the closing of the Proposed Acquisition are expected to be sufficient to fund operations into the first 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 authorized.

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.

***Our lead 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 don't 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. We cannot provide any assurance or certainty

regarding when we might complete the clinical trial process or receive regulatory approval for 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 or repeat clinical trials. The commencement and completion of clinical trials 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 IRB may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. In the event we do not ultimately receive regulatory approval for RI-002, we may be required to terminate development of our only product candidate. Unless we acquire or develop other product candidates that are saleable, our business will be limited to plasma collection and sales.

***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 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.

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

At the present time, our entire focus is obtaining regulatory approval for RI-002, our only product candidate. If we cannot obtain regulatory approval for RI-002, our only source of revenue will be plasma collection and sales. We cannot assure you that we will receive the approvals necessary to commercialize RI-002 or any other product candidate we may acquire or develop in the future. In order to obtain FDA approval of RI-002 or any other 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 submit a BLA. To obtain required FDA approval of any other product candidate generally requires significant research and testing, referred to as preclinical studies, as well as human tests, referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in products that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the product approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. 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. Our BLA is dependent upon our third party manufacturer continuing operations and maintaining compliance with rules and regulations. 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 potential product candidate. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without a saleable product beyond the plasma collected by ADMA BioCenters, and therefore without any source of additional revenues if and until another product candidate can be developed and commercialized. There is no guarantee that we will ever be able to develop or acquire another product candidate. In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any products. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any product candidate for sale outside the 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 FDA to market RI-002 for the treatment of PIDD and, even if approved, we cannot be sure whether we will be able to obtain FDA approval for any desired future indications for RI-002.

While physicians in the U.S. may choose, and are generally permitted to prescribe drugs for uses that are not described in the product’s labeling, and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote our products is narrowly limited to those indications that are specifically approved by the FDA. “Off-label” uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. Although recent court decisions suggest that certain off-label communications (e.g., 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 relating 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 and consultants to conduct our preclinical and clinical trials 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.

***A single customer accounts for a significant amount of our revenues and, together with a second customer represent greater than 95% of our total revenues, and, therefore, the loss of such single customer could have a material adverse effect on our business, results of operations and financial condition.***

A significant amount of our revenues are attributed to a single customer, BPC. For the fiscal year ended December 31, 2016, two of our customers, SK and BPC, represented greater than 95% of our total revenues, with BPC representing approximately 82% of our total revenues and SK representing approximately 14% of our total revenues. We believe SK will represent approximately less than 10% of our total revenues for 2017.

Our relationships with BPC and SK are arm's length commercial relationships. The loss of either or both of BPC and SK as a customer or a material change in the revenue generated by either or both of Biotest and SK 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 prices that are competitive with our competitors;
- 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 either or both of BPC and SK could have a material adverse effect on our business and results of operations.

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

We have limited internal experience in manufacturing operations and have not historically established our own manufacturing facilities. We currently lack the internal resources to manufacture RI-002. Although we have agreements pertaining to the manufacture, testing, supply, storage and distribution of product supplies of RI-002, upon commercialization, it is possible that our manufacturing requirements may exceed the available supply allotments under our existing agreements. We currently rely on one third-party contractor to manufacture RI-002. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any;
- third-party manufacturers might be unable to manufacture our products in the volume and of the quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products;
- product manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with good manufacturing practice (cGMP) and other government regulations and corresponding foreign

standards. We do not have control over third-party manufacturers' compliance with these regulations and standards and our manufacturers may be found to be in noncompliance with certain regulations, which may impact our ability to manufacture our drug product; and

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

Each of these risks could delay the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues. Our contract manufacturer has announced that it received a warning letter from the FDA relating to an inspection at its Boca Raton, Florida location in August 2014 and that the warning letter does not prevent the manufacturing or distribution of any of its products. The receipt of the warning letter has not affected the manufacture or delivery to us of RI-002 by our contract manufacturer.

***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 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 launching new products.

***If physicians and patients do not accept and use our product, our ability to generate revenue from sales will be materially impaired.***

Even if the FDA approves RI-002, physicians and patients may not accept and use it. Acceptance and use of our product will depend on a number of factors including:

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

Because we expect sales of RI-002, if approved, to generate substantially all of our product revenues other than the revenue attainable from the sale of plasma collected by ADMA BioCenters, the failure of this product 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 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 that study represent the independent consultants' own methodologies, assumptions, research, analysis, projections, estimations, 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.

***Our long-term success may depend on our ability to supplement our existing RI-002 product candidate through new product development or the in-license or acquisition of other new products, and if our business development efforts are not successful, our ability to achieve profitability may be negatively impacted.***

Our current product development portfolio consists primarily of RI-002. We intend to seek to expand our current portfolio through new product development efforts or to in-license or acquire additional products. If we are not successful in developing or acquiring additional products, we will have to depend on our ability to raise capital for, and the successful development and commercialization of, RI-002 and the revenue we may generate from the sale of plasma attributable to the operations of ADMA BioCenters.

***Our loan and security agreement with Oxford Finance LLC, or Oxford, is subject to acceleration in specified circumstances, which may result in Oxford taking possession and disposing of any collateral. We became obligated to begin making payments of principal and interest on February 1, 2017, unless accelerated as a result of certain events of default or at our option.***

On June 19, 2015, we entered into a Loan and Security Agreement, or LSA, with Oxford for up to \$21.0 million and refinanced our existing loan with Hercules Technology Growth Capital, Inc. or Hercules. The first tranche of \$16.0 million from the Oxford loan was primarily used to repay our existing facility with Hercules. In May 2016, we amended the LSA with Oxford and we borrowed an additional \$4.0 million, bringing the total principal amount borrowed to \$20.0 million. The LSA bears interest at a rate per annum equal to the greater of (i) 7.80% and (ii) the sum of (a) the three month U.S. LIBOR rate (as reported in *The Wall Street Journal*) on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 7.54% on the outstanding principal balance. We became obligated to begin to repay the principal over 36 months beginning February 1, 2017, unless accelerated as a result of certain events of default. A final payment equal to 8.95% of the funded loan amount is due at the earlier of loan maturity or prepayment. In addition, a facility fee of \$105,000 was paid at closing. In the event we elect to prepay the loan, we are obligated to pay a prepayment charge corresponding to a percentage of the principal amount of the loan, with such percentage being: (i) for a prepayment made on or after the funding date of the applicable term loan through and including the first anniversary of its funding date, an amount equal to 3.00% of the principal amount of the term loan prepaid; (ii) for a prepayment made after the first anniversary of the funding date of the applicable term loan through and including the second anniversary of such funding date, an amount equal to 2.00% of the principal amount of such term loan prepaid; and (iii) for a prepayment of a term loan made after the second anniversary of its funding date and prior to its maturity date, an amount equal to 1.00% of the principal amount of the term loan prepaid. The loan matures no later than January 1, 2020. The loan is secured by our assets, except for our intellectual property (which is subject to a negative pledge). Events of default under the agreement include, but are not limited to: (i) insolvency, liquidation, bankruptcy or similar events; (ii) failure to pay any debts due under the LSA or other loan documents on a timely basis; (iii) failure to observe any covenant or secured obligation under the LSA or other loan documents, which failure, in most cases, is not cured within 10 days of written notice by lender; (iv) occurrence of any default under any other agreement between us and the lender, which is not cured within 10 days; (v) occurrence of an event that could reasonably be expected to have a material adverse effect; (vi) material misrepresentations; (vii) occurrence of any default under any other agreement involving indebtedness or the occurrence of a default under any agreement that could reasonably be expected to have a material adverse effect; and (viii) certain money judgments are entered against us or a certain portion of its assets are attached or seized. Remedies for events of default include acceleration of amounts owing under the LSA and Oxford taking immediate possession of, and selling, any collateral securing the loan.

***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. Should we obtain regulatory approval for RI-002 or any future product we may develop, we will have to compete with existing 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 capital 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.

***If we are unable to protect our patents, trade secrets or other proprietary rights, if our patent is 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 patent may be challenged, found to be over-broad or otherwise invalidated in subsequent proceedings before courts or the U.S. Patent and Trademark Office. Even if enforceable, we cannot provide any assurances that it 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 our only product, 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.

***Continued instability in the credit and financial markets may negatively impact our business, results of operations and financial condition.***

Financial markets in the U.S., Canada, Europe and Asia continue to experience disruption, including, among other things, significant volatility in security prices, declining valuations of certain investments, as well as severely diminished liquidity and credit availability. Business activity across a wide range of industries and regions continues to be greatly reduced and local governments and many businesses are still suffering from the lack of consumer spending and the lack of liquidity in the credit markets. As a clinical-stage biotechnology company, we rely on third parties for several important aspects of our business, including contract manufacturing of drug product, plasma collection supplies, transportation and storage of plasma, and conduct of our clinical trials. These third parties may be unable to satisfy their commitments to us due to tightening of global credit from time to time, which would adversely affect our business. The continued instability in the credit and financial market conditions may also negatively impact our ability to access capital and credit markets and our ability to manage our cash balance. While we are unable to predict the continued duration and severity of the adverse conditions in the U.S. and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flow or cash position.

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

Our success will depend on the expansion of our commercial, manufacturing, 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.

***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, particularly if we close and consummate the Proposed Acquisition. 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 located in Norcross and Marietta, Georgia, and if we cannot maintain FDA approval for these locations we may be adversely affected and potentially may not be able to sell and 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 cGMP, FDA and other government approvals. Failure to comply may result in enforcement action, which may significantly delay or suspend our operations for these locations.

***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, alone or with collaborators.

***Many of our business practices are subject to scrutiny by 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 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. There can be no assurance that our activities will not come under the scrutiny of 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 (e.g., 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.

We may be required to report detailed pricing information, net of included discounts, rebates and other concessions, to the Centers for Medicare & Medicaid Services, or 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 their 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, or FCPA, 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, or 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.

***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 goods sold. 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 profitability.

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 sales and profits. 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, or 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 (e.g., 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.

***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 source plasma to manufacture RI-002. Therefore, we are reliant on purchasing normal source plasma to manufacture RI-002. We can give no assurances that normal source plasma will be available to us on commercially reasonable terms or at all. 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 goods. 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 on 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 depend 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 reimbursement. 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 payors, including Medicare, if payors 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 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.

***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 prepare 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 that may cover the cost of our future products, including Medicaid, Medicare Parts B and D, and these efforts could have a materially adverse impact on our future financial prospects and performance. For example, with respect to Medicaid, 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 this 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, or AMP, or the AMP less Best Price, whichever is greater. Effective January 1, 2010, the healthcare reform law generally increases the size of the Medicaid rebates paid by manufacturers for single source and innovator multiple source (brand name) drug product from a minimum of 15.1% to a minimum of 23.1% of the AMP, subject to certain exceptions, for example, for certain clotting factors, the increase is limited to a minimum of 17.1% of the AMP. 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.

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, or 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.

***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 supply 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. While to date we cannot directly trace any material reduction in demand to the recession, if economic conditions do not improve, the impact may become material.

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

***We are a late stage company with a history of operating losses that are expected to continue and we are unable to predict the extent of future losses, whether we will generate significant revenues or whether we will achieve or sustain profitability.***

We are a late stage company and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by similarly situated companies. We have generated net losses in all periods since our inception in June 2004, including losses of approximately \$19.5 million and \$18.0 million for the years ended December 31, 2016 and 2015, respectively. We have an accumulated deficit of \$106.9 million since inception. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand commercial development, infrastructure, manufacturing and inventory planned requirements and clinical trial activities for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability.

***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. During the years ended December 31, 2016 and 2015, we incurred research and development expenses of approximately \$7.7 million and \$7.0 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 anticipate that, based upon our projected revenue and expenditures, our current cash and cash equivalents, short term investments and accounts receivable will be sufficient to fund our operations, as currently conducted, into the second half of 2017. This time frame may change based upon the timing of the closing of our Proposed Acquisition, and how aggressively we execute on our operational initiatives. If our assumptions underlying our estimated expenses prove to be wrong, we may have to raise additional capital sooner than the second half of 2017. These assumptions may also change based upon the timing of the completion of the Proposed Acquisition, anticipated during the first half of 2017, of which funds received from BPC at the closing of the Proposed Acquisition are expected to be sufficient to fund operations into the first quarter of 2018. We have based this estimate, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings or corporate collaboration and licensing arrangements. If we are unable to raise additional capital, we will have to delay, curtail or eliminate our product development, 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 restrict our operations, including

limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. 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.

***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, or FDIC, insurance limit. While we monitor daily the cash balances in the operating accounts 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 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, or SOX, 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, or the Exchange Act, we have been required to upgrade, and may need to implement further upgrades to our systems, including information technology, 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, 2016, we had Federal and state NOLs of \$87.8 million and \$75.2 million, respectively. The \$87.8 million and \$75.2 million in Federal and state NOLs, respectively, 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 utilize our NOLs fully. 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.

#### **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:

- the closing and consummation, or failure thereof, of our Proposed Acquisition;
- sales or potential sales of substantial amounts of our common stock;
- 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, reimbursement and sales of RI-002;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors or product manufacturers;
- 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.

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

As of December 31, 2016, almost all of our 12,886,741 outstanding shares of common stock, as well as a substantial number of shares of our common stock underlying outstanding warrants, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, or may become available under registration statements we intend to file in the future. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

***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.

***Our affiliates control the majority of our shares of common stock. Provisions in our certificate of incorporation, our by-laws 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 by-laws 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. Our directors and executive officers and their affiliates beneficially own approximately 51% of the outstanding shares of 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; and the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to

institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our board of directors; and

- classification of our board of directors 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.

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 forgoing 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.

***If we fail to adhere to the strict listing requirements of 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 the NASDAQ Capital Market 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 continuing NASDAQ listing requirements could have an adverse impact on the value of and trading activity in our common stock. Although we currently satisfy the listing criteria for NASDAQ, if our stock price declines dramatically, we could be at risk of falling below NASDAQ continuing listing criteria.

***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 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.



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 and our stock price may be more volatile.

### **Risks Related to the Proposed Acquisition of Certain Assets from BPC**

#### ***Failure to complete the Proposed Acquisition could negatively impact our business, financial condition or results of operations or the trading price of our common stock.***

The completion of the Proposed Acquisition is subject to a number of conditions and there can be no assurance that the conditions to the completion of the Proposed Acquisition will be satisfied. If the Proposed Acquisition is not completed, we will be subject to several risks, including:

- the current trading price of our common stock may reflect a market assumption that the Proposed Acquisition will occur, meaning that a failure to complete the Proposed Acquisition could result in a decline in the trading price of our common stock;
- certain of our executive officers and/or directors may seek other employment opportunities, and the departure of any of our executive officers and the possibility that we would be unable to recruit and hire an executive could impact negatively our business and operating result;
- we may be required to pay a termination fee of \$2.5 million to BPC if the Purchase Agreement is terminated by us under certain circumstances;
- we have incurred and are expected to continue to incur substantial transaction costs in connection with the Proposed Acquisition whether or not the Proposed Acquisition is completed;
- we would not realize any of the anticipated benefits of having completed the Proposed Acquisition; and
- pursuant to the Purchase Agreement, we are subject to certain restrictions on the conduct of our business prior to completion of the Proposed Acquisition, which restrictions could adversely affect our ability to realize certain of our business strategies or take advantage of certain business opportunities.

If the Proposed Acquisition is not completed, these risks may materialize and affect materially and adversely our business, financial condition, results of operations, and/or the trading price of our common stock.

#### ***While the Proposed Acquisition is pending, we will be subject to business uncertainties that could adversely affect our businesses.***

Uncertainty about the effect of the Proposed Acquisition on employees, customers, suppliers and other third parties with whom we interact may have an adverse effect on us. These uncertainties may impair our ability to attract, retain and motivate key personnel until the Proposed Acquisition is completed and for a period of time thereafter, and could cause customers, suppliers and others who deal with us to seek to change existing business relationships with us. Employee retention may be challenging during the pendency of the transaction, as certain employees may experience uncertainty about their future roles. If key employees depart because of issues related to the uncertainty and difficulty of integration or a desire not to remain with the business, our business, and the acquired business from BPC, as the case may be, could be materially adversely affected. In addition, the Proposed

Acquisition includes restrictions on our ability to take specified actions until the consummation of the transaction, without the consent of the other party. These restrictions may prevent us from pursuing attractive business opportunities that may arise prior to the completion of the transaction.

***The issuance of shares of our common stock to BPC in connection with the Proposed Acquisition will dilute substantially the voting power of our current stockholders.***

Pursuant to the terms of the Purchase Agreement, it is anticipated that we will issue shares of our capital stock to BPC stockholders representing approximately 50% less one share of the outstanding shares of capital stock of the combined company as of immediately following completion of the Proposed Acquisition, consisting of 25% common stock and the balance non-voting common stock. Accordingly, the issuance of shares of our common stock to BPC in connection with the Proposed Acquisition will reduce significantly the relative voting power of each share of our common stock held by our current stockholders. Consequently, our stockholders as a group will have significantly less influence over the management and policies of the combined company after the completion of the Proposed Acquisition than prior to completion of the Proposed Acquisition.

***The market price of our common stock following the Proposed Acquisition may decline as a result of the Proposed Acquisition.***

The market price of our common stock may decline as a result of the Proposed Acquisition for a number of reasons, including if:

- investors react negatively to the prospects of the combined organization's business and prospects from the Proposed Acquisition;
- third parties may seek to terminate and/or renegotiate their relationships with us as a result of the Proposed Acquisition, whether pursuant to the terms of their existing agreements with us or otherwise;
- the effect of the Proposed Acquisition on the combined organization's business and prospects is not consistent with the expectations of financial or industry analysts; or
- the combined organization does not achieve the perceived benefits of the Proposed Acquisition as rapidly or to the extent anticipated by financial or industry analysts.

***We have incurred and will continue to incur significant direct and indirect transaction costs in connection with the Proposed Acquisition, some of which will be required to be paid even if the Proposed Acquisition is not completed.***

We have incurred and will continue to incur significant transaction costs in connection with the Proposed Acquisition. These costs are primarily associated with the fees of our attorneys, accountants and financial advisors, but also include the diversion of our resources and the attention of our management team from the operation of our business. We will be required to pay most of these costs even if the Proposed Acquisition is not completed. In addition, if the Purchase Agreement is terminated due to certain triggering events specified in the Purchase Agreement, we may be required to pay Biotest a termination fee of \$2.5 million.

***Third party lawsuits may be filed against us in connection with the Proposed Acquisition which may be frivolous but costly to defend.***

Third parties may assert claims against us alleging that the terms of the Proposed Acquisition are somehow unfair or inappropriate. Although our board of directors and management team may disagree, any claims against us, with or without merit, as well as claims initiated by us against third parties, can be time-consuming and expensive to defend or prosecute and resolve. We cannot assure you that litigation asserting claims against us will not be initiated or that we would prevail in any litigation. We cannot assure you that the Proposed Acquisition of certain assets of BPC would close if and to the extent a claim or claims were filed against us in this regard.

## **Risks Related to the Combined Company if the Proposed Acquisition is Completed**

***The success of the Proposed Acquisition will depend, in large part, on the ability of the combined company following completion of the Proposed Acquisition to realize the anticipated benefits from acquiring certain assets of BPC.***

The Proposed Acquisition involves the integration of two businesses that previously have operated independently with principal offices in two distinct locations. Significant management attention and resources will be required to integrate the two companies after completion of the Proposed Acquisition. 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 Proposed Acquisition.

Potential difficulties that may be encountered in the integration process include the following:

- using our cash and other assets efficiently to develop the business on a post-transaction basis;
- appropriately managing the liabilities of our Company on a post-transaction basis;
- potential unknown or currently unquantifiable liabilities associated with the Proposed Acquisition and the operations of our Company on a post-transaction basis;
- potential unknown and unforeseen expenses, delays or regulatory conditions associated with the Proposed Acquisition; 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 Proposed Acquisition and integrating the businesses.

Delays in the integration process could adversely affect the combined company's business, financial results, financial condition and stock price following the Proposed Acquisition. 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 and that these benefits will be achieved within a reasonable period of time.

***Ownership of our common stock on a post-transaction basis will be highly concentrated, and it may prevent our stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the combined company's stock price to decline.***

Upon completion of the Proposed Acquisition, BPC, together with current members of our board of directors, are expected to beneficially own or control a majority of our Company. On a post-transaction basis, BPC will own 12,886,740 shares of our capital stock, consisting of 4,295,580 voting shares of our common stock and 8,591,160 nonvoting shares of our common stock, representing 50% less one share of our common stock outstanding, and the current members of our board of directors will own 5,991,740 voting shares of our common stock. Accordingly, these directors, executive officers and their affiliates and stockholders, acting individually or as a group, will have substantial influence over the outcome of a corporate action of the combined company requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the combined company's assets or any other significant corporate transaction. These stockholders also may exert influence in delaying or preventing a change in control of the combined company, even if such change in control would benefit the other stockholders of the combined company. In addition, the significant concentration of stock ownership may affect adversely the market value of the combined company's common stock due to investors' perception that conflicts of interest may exist or arise.

***Upon closing and consummation of the Proposed Acquisition, BPC will be a significant stockholder. Future sales, or the perception of future sales, of our common stock by this stockholder may negatively impact our stock price and impair our ability to raise capital in the future.***

Upon the closing and consummation of the Proposed Acquisition, we have agreed to deliver to BPC the Biotest Equity Interest, consisting of (x) common stock representing 25% of our issued and outstanding common

stock, equal to 4,295,580 voting shares of our common stock and (y) 8,591,160 nonvoting shares of our common stock, representing the balance of the Biotest Equity Interest which is convertible into common stock upon the occurrence of certain specified events. In addition, upon the closing of the Proposed Acquisition, we have agreed to issue to BPC warrants, if any, necessary to acquire additional shares of our capital stock equal to the excess, if any, of (x) the number of shares represented by rights, options and warrants issued by us between September 12, 2016 until the closing, over (y) 184,000 shares. In connection with the execution of the Purchase Agreement, upon the closing, we and certain Biotest stockholders plan to enter into a Registration Rights Agreement (the “Registration Rights Agreement”), pursuant to which such Biotest stockholders, and certain other of our existing stockholders, will have, among other things, certain registration rights under the Securities Act with respect to their shares of our capital stock. In addition, upon the closing, we and Biotest will also enter into a Stockholders Agreement (the “Stockholders Agreement”), pursuant to which Biotest will be subject to lock-up, volume limitation and standstill provisions for a period of six months. Any sales of substantial amounts of our common stock in the public market, including sales or distributions of shares by Biotest stockholders, including Biotest, or the perception that such sales or distributions might occur, could harm the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

#### **Item 1B. Unresolved Staff Comments**

Not Applicable.

#### **Item 2. Properties**

Our executive offices are located in approximately 4,200 square feet of space at 465 State Route 17, Ramsey, New Jersey. 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. Rent under the shared services agreement is \$16,000 per month.

ADMA BioCenters’ facilities are located in Norcross and Marietta, Georgia. The combined facilities have a total of approximately 28,000 square feet of space for approximately \$30,000 rent per month. The Norcross, Georgia 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, Georgia lease expires on January 31, 2024.

#### **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.

## 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 under the symbol "ADMA" since November 10, 2014. Between October 17, 2013 and November 10, 2014, our common stock was quoted on the OTC Bulletin Board (OTCBB) and the OTC Markets (OTCQB) under the same symbol.

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 the NASDAQ Capital Market:

	Year Ended December 31, 2016		Year Ended December 31, 2015	
	High	Low	High	Low
First Quarter .....	\$ 8.28	\$ 4.15	\$ 11.95	\$ 7.57
Second Quarter .....	\$ 8.85	\$ 5.71	\$ 9.66	\$ 7.51
Third Quarter .....	\$ 8.00	\$ 5.00	\$ 10.28	\$ 8.00
Fourth Quarter .....	\$ 7.34	\$ 4.34	\$ 9.85	\$ 7.74

#### Holder

As of February 7, 2017, there were 6 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.

#### 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 LSA with Oxford precludes us from paying cash dividends without the consent of Oxford. 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, 2016:

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 (excluding securities reflected in column (a))
Equity compensation plans approved by security holders .....	1,535,187	\$ 7.90	368,086
Equity compensation plans not approved by security holders .....	—	\$ —	—
Total.....	1,535,187	\$ 7.90	368,086

## **Stock Performance Graph**

Not applicable.

## **Sale of Unregistered Securities**

During the fiscal year ended December 31, 2016, 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 in the fourth quarter of 2016.

## **Item 6. Selected Financial Data**

Not applicable.

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

*This discussion, which refers to our historical results, should be read in conjunction with the other sections of this annual report, including "Risk Factors," "Business" and the consolidated financial statements and other consolidated financial information included in this report. 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 affected by the uncertainties and risk factors described throughout this report. See "Special Note Regarding Forward-Looking Statements." Our actual results may differ materially.*

### **Financial Operations Overview**

We are a late-stage biopharmaceutical company that develops, manufactures and intends to commercialize specialty plasma-based biologics for the proposed 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. Our 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.

### **Revenues**

Revenue for the year ended December 31, 2016 of \$10,661,037 is primarily comprised of \$10,518,203 from the sale of normal source human plasma through our FDA-licensed, GHA and MFDA certified plasma collection centers segment and \$142,834 of license and other revenue which are recorded as deferred revenue and amortized into income over the terms of the respective agreements. In exchange for the out-licensing of RI-002 to market and sell in Europe and selected countries in North Africa and the Middle East, BPC has provided us with certain services and a financial payment received in accordance with the related license agreement and is obligated to pay us certain amounts in the future if certain milestones are achieved.

A significant amount of our revenues are attributed to a single customer, BPC. For the fiscal year ended December 31, 2016, two of our customers, SK and BPC, represented greater than 95% of our total revenues, with BPC representing approximately 82% of our total revenues and SK representing approximately 14% of our total revenues.

Product revenues from the sale of human plasma collected at our FDA-licensed plasma collection centers are recognized at the time of transfer of title and risk of loss to the customer, which occurs, depending on the agreement with the customer, at the time of shipment or at the time of delivery if we retain the risk of loss during shipment. Revenue from license fees and research and development services rendered are recognized as revenue when the performance obligations under the terms of the license agreement have been completed.

During the third quarter of 2015, we recorded deferred revenue of \$1,500,000 for a milestone payment provided to us from BPC upon filing the BLA for RI-002 with the FDA, in accordance with the terms of the license agreement. Deferred revenue is recognized over the term of the license. Deferred revenue is amortized into income for a period of approximately 20 years, which is the term of the license agreement.

### ***Research and Development Expense***

Research and development, or R&D, expenses, attributable to our R&D segment, consists of clinical research organization costs, clinical trial costs related to our clinical trial, consulting expenses relating to regulatory and medical affairs, quality assurance and control, manufacturing, assay development, ongoing testing costs, drug product manufacturing costs, including the cost of plasma, plasma storage and transportation costs, as well as wages and benefits for employees, including stock-based compensation directly related to the R&D of RI-002. All R&D costs are expensed as incurred.

The process of conducting preclinical studies, clinical trials and regulatory activities necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, regulatory, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, the uncertainties associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. For the year ended December 31, 2016, R&D expenses increased as compared to R&D expenses for the year ended December 31, 2015 due to higher validation, testing and production costs related to RI-002 along with increased regulatory consulting services related to our BLA. We anticipate that 2017 R&D expenses will decrease, as compared to 2016, as a result of reduced testing and validation services related to RI-002 offset by increased costs related to regulatory activities in connection with the CRL. Once we have clarity for the timing of our expected BLA resubmission and anticipated RI-002 approval, we would then expect our R&D costs to increase.

### ***General and Administrative Expense***

General and administrative, or G&A, expenses, consist of wages, stock-based compensation, benefits for senior management and staff unrelated to R&D, legal fees, accounting and auditing fees, commercialization and marketing activities, information technology, investor relations fees, rent, maintenance and utilities, insurance, travel and other expenses related to the general operations of our business. For the year ended December 31, 2016, G&A expenses increased as a result of higher marketing, commercial planning, increased headcount, wages and benefits for employees, including stock-based compensation and consulting expenses associated with commercialization activities as well as additional expenses incurred related to the Proposed Acquisition of certain assets of BPC. We expect that our G&A expenses will decrease as we continue to manage our costs through deferring certain pre-launch and commercial planning activities, while we focus on addressing the CRL. Once we have clarity for the timing of our expected BLA resubmission and anticipated RI-002 approval, we would then expect our G&A costs to increase.

### ***Other Income and Expense***

Interest income consists of interest earned on our cash and cash equivalents and short-term investments. Interest expense consists of interest incurred on our notes payable, as well as the amortization of end of term fees, back end fees, value of warrants issued, facility and financing fees. We anticipate other income and expense to remain consistent throughout 2017 as a result of our current outstanding debt and interest earned on investments.

### ***Segment Reporting***

We are engaged in the development and commercialization of human plasma and plasma-derived therapeutics. We also operate two FDA-licensed source plasma collection facilities located in Norcross, Georgia and Marietta, Georgia. We define our segments as those business units whose operating results are regularly reviewed by the chief operating decision maker ("CODM") to analyze performance and allocate resources. Our CODM is our President and Chief Executive Officer.

The plasma collection center segment includes our operations in Georgia. The research and development segment includes our plasma development operations in New Jersey.

Summarized financial information concerning reportable segments is included in Note 11 of the consolidated financial statements.

## Results of Operations

### Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

#### Summary Table

The following table presents a summary of our results of operations for the year ended December 31, 2016 compared to the year ended December 31, 2015.

	<b>Years Ended December 31,</b>	
	<b>2016</b>	<b>2015</b>
Product revenue .....	\$ 10,518,203	\$ 7,050,283
License and other revenue .....	142,834	127,350
Total revenues .....	<u>10,661,037</u>	<u>7,177,633</u>
Cost of product revenue .....	6,360,761	4,311,461
Research and development .....	7,688,238	7,015,946
Plasma centers .....	5,447,691	4,618,065
General and administrative .....	8,494,742	6,745,968
Total operating expenses .....	<u>27,991,432</u>	<u>22,691,440</u>
Loss from operations .....	(17,330,395)	(15,513,807)
Interest income .....	50,317	37,830
Interest expense .....	(2,239,569)	(1,842,716)
Other income .....	4,496	—
Change in fair value of stock warrants .....	—	67,860
Loss on extinguishment of debt .....	—	(719,097)
Net loss .....	<u>\$ (19,515,151)</u>	<u>\$ (17,969,930)</u>

#### Revenue

We recorded total revenue of \$10,661,037 during the year ended December 31, 2016 compared to \$7,177,633 during the year ended December 31, 2015. Product revenue was \$10,518,203 for the year ended December 31, 2016, which is attributable to our ADMA BioCenters plasma collection centers segment and derived from the sale of human source plasma collected in our FDA-licensed, GHA and MFDS-certified Georgia-based blood plasma collection centers, compared to product revenue of \$7,050,283 for the year ended December 31, 2015. The increase in product revenue of \$3,467,920 was primarily attributable to increased plasma collections and sales from our Marietta, Georgia plasma center which received FDA approval to sell human source plasma within the U.S. during the third quarter of 2015. Product revenue for the year ended December 31, 2016 was primarily attributable to sales made pursuant to our plasma supply agreement with BPC under which BPC purchases normal source plasma from ADMA BioCenters for their manufacturing, in addition to selling increased quantities of normal source plasma to a second customer. We sold a majority of the normal source plasma collected from our plasma centers throughout 2016. The normal source plasma and high-titer RSV plasma we did not sell was allocated to inventory in anticipation of commercial manufacturing. For the years ended December 31, 2016 and 2015, license and other revenue was \$142,834 and \$127,350, respectively, which relates to services and financial payments provided by BPC and Biotest in accordance with our license agreement. We have not generated any revenue from our therapeutics research and development business.



### ***Cost of Product Revenue***

Cost of product revenue was \$6,360,761 for the year ended December 31, 2016 and \$4,311,461 for the year ended December 31, 2015. The increased cost of product revenues of \$2,049,300 for the year ended December 31, 2016 was directly related to the increase in 2016 product revenues primarily related to our second plasma center.

### ***Research and Development Expenses***

R&D expenses, which are attributable to our R&D segment, were \$7,688,238 for the year ended December 31, 2016, an increase of \$672,292 as compared to \$7,015,946 for the year ended December 31, 2015. R&D expenses consist of clinical research organization costs, consulting expenses relating to regulatory affairs, quality control and manufacturing, assay development and ongoing testing costs, clinical trial costs and fees, drug product manufacturing including the cost of plasma, plasma storage and transportation costs, as well as wages and benefits for staff directly related to the research and development of RI-002. R&D expenses increased for the year ended December 31, 2016, as compared to the year ended December 31, 2015, primarily as a result of an increase in validation, testing and production costs related to RI-002 and an increase in regulatory consulting fees.

### ***Plasma Center Operating Expenses***

Plasma center operating expenses were \$5,447,691 for the year ended December 31, 2016, an increase of \$829,626 as compared to \$4,618,065 for the year ended December 31, 2015. Plasma center operating expenses consist of: general and administrative plasma center costs; overhead comprised of rent, maintenance, utilities, wages, stock-based compensation and benefits for center staff, plasma collection supplies, plasma transportation and storage (off-site); advertising and promotion expenses; and computer software fees related to donor collections. The increase in expenses was primarily the result of increased plasma collections at our ADMA BioCenters Marietta collection facility, which received FDA approval during the third quarter of 2015. The increased expenses include higher costs in wages, rent, maintenance and plasma collection supplies for the year ended December 31, 2016 as compared to the year ended December 31, 2015. We expect that as plasma collection increases, our operating expenses will also increase accordingly.

### ***General and Administrative Expenses***

G&A expenses were \$8,494,742 for the year ended December 31, 2016, an increase of \$1,748,774 from \$6,745,968 for the year ended December 31, 2015. General and administrative expenses consist of Proposed Acquisition fees, wages and stock-based compensation for our senior management and staff unrelated to research and development, professional fees for commercialization and marketing consulting, attorneys, accountants and auditors, investor relations, maintenance and utilities, insurance, information technology, travel and other expenses related to the general operations of the business. G&A expenses primarily increased as a result of fees incurred for the Proposed Acquisition fees paid for legal, accounting and financial advisors. The increase was also attributed to consulting services provided to us related to pre-launch, commercial planning, and market research, along with increased rent expense, higher wages and benefits for employees and consulting fees.

### ***Other Income (Expense)***

Other expense, net, was \$2,184,756 for the year ended December 31, 2016, as compared to \$2,456,123 for the year ended December 31, 2015. The decrease of \$271,367 is primarily related to a loss on extinguishment of debt of \$719,097, which was recorded in the second quarter of 2015 for the refinancing of an existing loan with our new lender, Oxford Finance LLC, or Oxford. Such expenses are comprised of a write-off of deferred financing costs, end of term fees and prepayment penalties for the repayment of debt to our prior lender, offset by increased interest expense due to an increase of \$4,000,000 to our current debt in the second quarter of 2016, which includes debt discounts amortization for our new lender's end of term fees, back end fees, value of warrants issued, facility and financing fees.

### ***Net Loss***

Net loss increased to \$19,515,151 for the year ended December 31, 2016 as compared to \$17,969,930 for the year ended December 31, 2015, for the reasons previously stated.

### ***Net Cash Used in Operating Activities***

Net cash used in operating activities was \$18,268,973 for the year ended December 31, 2016. The net loss for this period was higher than net cash used in operating activities by \$1,246,178, which was primarily attributable to stock-based compensation of \$1,250,074, depreciation and amortization of \$469,576 and amortization of debt discount of \$676,943, offset by an increase of inventories of \$1,574,373 related to collection and purchases of RSV plasma and normal source plasma, an increase in accounts payable of \$476,826 and accrued expenses of \$416,972 primarily related to fees associated to the Proposed Acquisition.

Net cash used in operating activities was \$15,418,404 for the year ended December 31, 2015. The net loss for this period was higher than net cash used in operating activities by \$2,551,526, which was primarily attributable to increases in inventories of \$1,737,010 related to allocating additional plasma to inventory in preparation for commercial manufacturing activities anticipated in 2016, increased deferred revenue of \$1,525,000 from a milestone payment received from BPC resulting from the BLA filing of RI-002, increases in accounts receivable of \$540,507 related to sales of our normal source plasma, offset by stock-based compensation of \$1,711,047, a loss on extinguishment of debt of \$719,097 attributable to the refinancing of previous debt with a new venture debt lender and depreciation and amortization of \$469,821.

### ***Net Cash Provided by (Used in) Investing Activities***

Net cash provided by investing activities was \$904,583 for the year ended December 31, 2016, which was related to the purchases and redemptions of short-term investments of \$977,993 and purchases of computers and equipment of \$73,410, primarily related to our second plasma centers which received FDA approval in September 2015.

Net cash used in investing activities was \$1,741,575 for the year ended December 31, 2015, which was related to the purchases and redemptions of short-term investments of \$1,715,502 and \$26,073 in purchases of computers and equipment.

### ***Net Cash Provided by Financing Activities***

Net cash provided by financing activities totaled \$16,838,298 for the year ended December 31, 2016, which primarily consisted of \$14,145,000 received from the issuance of common stock during the second quarter of 2016 offset by equity issuance costs of \$1,244,459, proceeds of \$4,000,000 received from Oxford during the second quarter of 2016, offset by payment of debt issue costs to Oxford of \$47,104 in addition to amortization of our leasehold improvement loan for our ADMA BioCenters subsidiary.

Net cash provided by financing activities totaled \$10,401,908 for the year ended December 31, 2015, which primarily consisted of \$16,000,000 received from the loan from Oxford during the second quarter of 2015, and \$10,257,380 received from the issuance of common stock during the first quarter of 2015, offset by the \$15,300,781 related to the repayment of a pre-existing loan with Hercules, prepayment premium to Hercules of \$229,512, debt issue costs to Oxford of \$228,065 and an end of term fee payment of \$132,500 to Hercules in addition to amortization of our leasehold improvement loan for our ADMA BioCenters wholly-owned subsidiary.

## **Liquidity and Capital Resources**

### ***Overview***

As of December 31, 2016, we had working capital of \$10.4 million, consisting primarily of \$9.9 million of cash and cash equivalents, \$5.4 million of short term investments, \$5.0 million of inventories, \$1.0 million of accounts receivable and \$0.3 million of prepaid expenses, offset by \$11.2 million of current liabilities, which are mainly comprised of the current portion of our note payable due to Oxford and accounts payable and accrued expenses.

We have had limited revenue from operations and we have incurred cumulative losses of \$106.9 million since inception. We have funded our operations to date primarily from equity investments, loans from venture debt lenders and loans from our primary stockholders. In May 2016, we completed an underwritten public offering of our common stock and we received net proceeds of approximately \$12.9 million. In May 2016, we amended our Loan and Security Agreement, or LSA, with Oxford and borrowed an additional \$4.0 million. In March 2015, we received net cash proceeds of approximately \$10.2 million from an underwritten public offering from the sale of our common stock. In October 2013, we received net cash proceeds of approximately \$26.6 million from our initial public offering, or IPO. In various financings since 2012, we received a total of \$20.0 million from venture debt lenders. In February 2012, we received net cash proceeds of approximately \$15.3 million from a private placement of our common stock. Our funds are being used and have been used: to conduct clinical trials; to manufacture drug products; to collect and procure plasma; to test plasma donors for RSV titers; to file our BLA for RI-002; to conduct pre-launch activities; for commercialization and marketing activities; for the buildout and expansion of our first plasma center and the buildout of our second plasma center; for our Proposed Acquisition of certain assets of BPC and the remainder for payment of existing accounts payable; for general and administrative, research and development expenses; and for other business activities and general corporate purposes.

We expect to continue to spend substantial amounts of capital on product development, including commercialization activities, procuring raw material plasma, manufacturing activities, regulatory activities, consulting fees in connection with our BLA and the potential approval of RI-002, conducting potential future studies and/or clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. Based upon our projected revenue and expenditures for 2017, including the ongoing regulatory activities associated with pursuing the BLA for RI-002, implementation of our planned potential commercialization and expansion activities, we currently believe that our cash, cash equivalents, short-term investments and accounts receivable as of February 24, 2017 are sufficient to fund our operations, as currently conducted, into the second half of 2017. 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 capital by the end of the second half of 2017, and we cannot provide any assurance that we will be successful in fundraising. This time frame may change based upon the timing of the closing of our Proposed Acquisition of certain assets of BPC, our interactions with FDA, potential timing of our commercial manufacturing scale up activities, our generation of future revenue, how aggressively we execute on our regulatory strategy and/or commercial initiatives and when the FDA approves our BLA for RI-002, if at all. This timing may also change based upon the timing of the completion of the Proposed Acquisition, anticipated during the first half of 2017. Upon the closing of the Proposed Acquisition, BPC will be providing us funds consisting of: \$12.5 million in funding, \$15.0 million in debt financing and an additional \$12.5 million commitment towards a future equity financing is expected to be sufficient to fund operations into this first quarter of 2018. Other than the funding to be provided by BPC we currently do not have arrangements to obtain additional financing. There is no assurance that we will be able to successfully close on the Proposed Acquisition. Any such financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution of stockholders' interests. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan and financial performance and, as a result, we could be forced to delay, discontinue or prevent product development, clinical trial or commercialization activities, delay or discontinue the approval of any of our potential products, curtail our activities and potentially significantly reduce, or potentially cease operations. In addition, we could be forced to reduce or forego sales and marketing efforts and forego attractive business opportunities.

We believe that we will incur net losses and negative net cash flows from operating activities for the foreseeable future, which raises substantial doubt about our ability to continue as a going concern. As there are numerous risks and uncertainties associated with the research, development and future commercialization of our product candidate RI-002, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our anticipated development and commercialization activities. Our current estimates may be subject to change as circumstances and requirements further develop. We may decide to raise capital through public or private equity offerings, debt financings, grants or corporate collaboration and licensing arrangements. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations or other financing alternatives.

## ***Loan and Security Agreement***

In June 2015, we entered into the LSA with Oxford, as collateral agent and lender, pursuant to which we were provided an initial term loan in the aggregate principal amount of \$16.0 million, of which \$15.7 million was used to repay an existing loan balance of \$15.0 million, along with \$0.4 million of interest and \$0.3 million of prepayment premium and other fees, under our prior loan and security agreement, dated December 21, 2012, with Hercules (the “Prior Loan Agreement”), as amended on February 24, 2014 (the “Prior Loan Amendment”). In May 2016, we amended the LSA with Oxford (the “Amended LSA”) which provided us with an additional \$4.0 million term loan, bringing the total principal amount borrowed to \$20.0 million. The LSA bears interest at a rate per annum equal to the greater of (i) 7.80% and (ii) the sum of (a) the three month U.S. LIBOR rate (as reported in *The Wall Street Journal*) on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 7.54% on the outstanding principal balance. We are obligated to begin to repay the principal over 36 months beginning February 1, 2017, unless accelerated as a result of certain events of default. At our option, if we receive BLA approval for RI-002 within the initial 18-month interest only period, the interest only period may be extended for an additional six months. A final payment equal to 8.95% of the funded loan amount is due at the earlier of loan maturity or prepayment. In the event of the six-month interest only extension, the final payment will be 9.95% of the funded loan, which shall also be due at the earlier of loan maturity or prepayment. In addition, a facility fee of \$105,000 was paid at closing. In the event we elect to prepay the loan, we are obligated to pay a prepayment charge corresponding to a percentage of the principal amount of the loan, with such percentage being: (i) for a prepayment made on or after the funding date of the applicable term loan through and including the first anniversary of its funding date, an amount equal to 3.00% of the principal amount of the term loan prepaid; (ii) for a prepayment made after the first anniversary of the funding date of the applicable term loan through and including the second anniversary of such funding date, an amount equal to 2.00% of the principal amount of such term loan prepaid; and (iii) for a prepayment of a term loan made after the second anniversary of its funding date and prior to its maturity date, an amount equal to 1.00% of the principal amount of the term loan prepaid. The loan matures no later than January 1, 2020. The loan is secured by our assets, except for our intellectual property (which is subject to a negative pledge). The LSA contains customary representations, warranties and covenants, including limitations on incurring indebtedness, engaging in mergers or acquisitions and making investments, distributions or transfers. The representations, warranties and covenants contained in the LSA were made only for purposes of such agreement and as of a specific date or specific dates, were solely for the benefit of the parties to such agreement, and may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures exchanged between the parties in connection with the execution of the LSA. Events of default under the agreement include, but are not limited to: (i) insolvency, liquidation, bankruptcy or similar events; (ii) failure to pay any debts due under the LSA or other loan documents on a timely basis; (iii) failure to observe any covenant or secured obligation under the LSA or other loan documents, which failure, in most cases, is not cured within 10 days of written notice by lender; (iv) occurrence of any default under any other agreement between us and the lender, which is not cured within 10 days; (v) occurrence of an event that could reasonably be expected to have a material adverse effect; (vi) material misrepresentations; (vii) occurrence of any default under any other agreement involving indebtedness or the occurrence of a default under any agreement that could reasonably be expected to have a material adverse effect; and (viii) certain money judgments are entered against us or a certain portion of our assets are attached or seized. Remedies for events of default include acceleration of amounts owing under the LSA and taking immediate possession of, and selling, any collateral securing the loan.

In connection with the LSA, on June 19, 2015, we issued Oxford a seven-year warrant, expiring on June 19, 2022, to purchase 74,309 shares of common stock at an exercise price of \$8.51 per share. We recorded \$367,700 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included: (i) volatility of 57% on our common stock based upon a pro rata percentage of our common stock’s volatility and similar public companies’ volatilities for comparison; (ii) an expected dividend yield of 0.0%; (iii) a risk-free interest rate of 1.99%; and (iv) a term of seven years. As a result of prepaying the Hercules loan prior to maturity, we incurred a loss on extinguishment of debt of \$0.7 million comprised of unamortized debt issuance costs, unamortized debt discount related to the warrants issued to Hercules, along with a prepayment penalty.

Pursuant to the Amended LSA, (i) we paid a total facility fee of \$125,000, consisting of \$105,000 previously paid and an additional \$20,000 paid on the date the Term B Loan was funded; (ii) certain adjustments were made to the time periods for any applicable prepayment fees; and (iii) certain defined terms were adjusted,

including a new Amortization Date that is defined as (a) February 17, 2017, if the Term C Loan is not made and (b) August 1, 2017 if the Term C Loan is made. The Amended LSA further provides for customary representations, warranties and covenants for us. Except as otherwise amended, the Amended LSA does not alter the terms of the LSA. In addition, on May 13, 2016, pursuant to the terms and conditions of the LSA as modified by the Amended LSA, we agreed to issue to the lenders warrants to purchase shares of our common stock, upon our draw of each term loan tranche. The aggregate number of shares of common stock issuable upon exercise of the warrants is equal to 3.95% of the amount drawn of such tranche, divided by the average reported closing price per share of common stock for the consecutive 10 trading days prior to the applicable draw.

In connection with the Amended LSA, on May 13, 2016, we issued to Oxford a seven-year warrant, expiring on May 23, 2023, to purchase 24,800 shares of common stock at an exercise price of \$6.37 per share, equal to 3.95% of the amount drawn of such tranche, divided by the average reported closing price per share of common stock for the consecutive 10 trading days prior to the applicable draw, in accordance with our drawdown of the Term B Loan. We recorded \$86,300 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included: volatility of 53.5% on our common stock based upon a pro rata percentage of our common stock's volatility and similar public companies' volatilities for comparison, an expected dividend yield of 0.0%, a risk-free interest rate of 1.51% and a term of seven years.

In connection with our Prior Loan Agreement with Hercules, we borrowed a total of \$15.0 million, which was repaid and terminated in June 2015 through a new loan with Oxford. We recorded a loss on extinguishment of \$0.7 million comprised of an early prepayment penalty and the remaining unamortized debt issuance costs and end of term fee. The loan's interest at a rate per annum was equal to the greater of (i) 8.75% and (ii) the sum of (a) 8.75% plus (b) the Prime Rate (as reported in *The Wall Street Journal*) minus (c) 5.75%. Payment-in-kind interest accrues on the outstanding principal balance of the loan compounded monthly at 1.95% per annum. Such accrued and unpaid interest is added to the principal balance of the loan on the first day of each month beginning on the month after the closing. In connection with the Prior Loan Agreement and Prior Loan Amendment with Hercules, we issued to Hercules a warrant to purchase 31,750 shares of common stock in December 2012, with an exercise price of \$7.56 and in connection with the Prior Loan Agreement and Prior Loan Amendment, we issued to Hercules a warrant to purchase an additional 58,000 shares of our common stock, comprised of a warrant to purchase 23,200 shares of common stock issued in February 2014 and a warrant to purchase 34,800 shares of common stock issued in December 2014, each warrant issued under the Prior Loan Amendment and Prior Loan Agreement having an exercise price of \$7.50. The warrants expire after 10 years and have piggyback registration rights with respect to the shares of common stock underlying the warrant. The fair value of the Prior Loan Agreement and Prior Loan Amendment warrants were calculated using a lattice-based option model in order to account for features in the warrant that could cause the exercise price to reset ("down round protection") as a result of the next issuance of our common stock ("the next round of equity financing"). We initially recorded the fair value of the warrant of \$219,588 as warrant liability and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included the expected date of the next round of equity financing, volatility of 59% for our common stock based upon similar public companies' volatilities for comparison, an expected dividend yield of 0.0%, a risk-free interest rate of 2.53% and a term of 10 years. As of December 31, 2014, we recorded \$476,760 as the fair value of the warrant for the purchase of 58,000 shares of common stock. As a result of the increase in warrant liability, we recorded an expense of \$74,356 from the change in the fair value of warrant liability. During the first quarter ended March 31, 2015, we recorded \$408,900 as the fair value of the warrant for the purchase of 58,000 shares of common stock. As a result of the decrease in warrant liability, we recorded a change in the fair value of stock warrants of \$67,860 from the December 31, 2014 balance. The key assumptions used to value the warrants included the expected date of the next round of equity financing, volatility of 58% based upon a pro rata percentage of our common stock and similar public companies' volatilities, an expected dividend yield of 0.0%, a risk-free rate of 1.99% and a term of 10 years. This warrant liability was adjusted from the date of the Prior Loan Agreement on February 24, 2014 to fair value each reporting period using a lattice-based option model and the debt discount will be amortized to interest expense over the term of the loan. The down round warrant protection feature resulting in the warrant liability's quarterly "mark-to-market" valuation has terminated as of February 24, 2015, which was the end of the one-year period following the amended loan closing on February 24, 2014 and as a result the warrant liability of \$408,900 was reclassified to additional paid-in capital.

### *Future Financing Needs*

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 anticipate that, based upon our projected revenue and expenditures, our current cash and cash equivalents, short-term investments and accounts receivable will be sufficient to fund our operations into the second half of 2017. In order to have sufficient cash to fund our operations thereafter, we will need to raise additional equity or debt capital by the end of the second half of 2017 in order to continue as a going concern, and we cannot provide any assurance that we will be successful in doing so. Upon the closing of the Proposed Acquisition, BPC will be providing us funds consisting of: \$12.5 million in funding, \$15.0 million in debt financing and an additional \$12.5 million commitment towards a future equity financing is expected to be sufficient to fund operations into this first quarter of 2018. Other than the funding to be provided by BPC we currently do not have arrangements to obtain additional financing. There is no assurance that we will be able to successfully close on the Proposed Acquisition. This time frame may change based upon the timing of our commercial manufacturing scale up activities, how aggressively we execute on our commercial initiatives and when the FDA approves our BLA, if at all. 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 of stockholders' interests. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan and financial performance and we could be forced to delay, discontinue or prevent product development, clinical trial or commercialization activities, delay or discontinue the approval of any of our potential products, or potentially cease operations. In addition, we could be forced to reduce or forego sales and marketing efforts and forego attractive business opportunities.

We cannot predict with certainty that we will not need to raise additional funds in the future or when we will reach profitability, if at all. Furthermore, if our assumptions underlying our estimated expenses, the timing of FDA resubmission or approval for RI-002 and generation of revenues from RI-002 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 candidate, 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, 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, or we may decide to obtain debt financings or a bank credit facility 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 indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations or other future financing alternatives. Additional equity or debt financing, grants, or corporate collaboration and potential licensing arrangements may not be available on acceptable terms, if at all.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned clinical trials and delay or abandon potential commercialization efforts of our lead product candidate or other product candidates.

Our long-term liquidity depends on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. We have reported losses since inception in June 2004 through December 31, 2016, and we have as of December 31, 2016, an accumulated deficit of \$106.9 million. We believe that we will continue to incur losses and negative cash flows from operating activities to fund our research and development, commercial programs and meet our obligations on a timely basis through the foreseeable future. As such, these conditions raise substantial doubt about our ability to continue as a going concern. If we are unable to successfully raise sufficient additional capital, we will likely not have sufficient cash flow and liquidity to fund our business operations as we currently operate, which may force us to delay, discontinue or prevent product development and clinical trial activities or the approval of any of our potential products, curtail our activities and potentially significantly reduce, or potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution to stockholders and, in such event, the value and potential future market price of our common stock may decline.

Financial markets in the U.S., Canada, Europe and Asia continue to experience disruption, including, among other things, significant volatility in security prices, declining valuations of certain investments, as well as severely diminished liquidity and credit availability. Business activity across a wide range of industries and regions continues to be greatly reduced and local governments and many businesses are still suffering from the lack of consumer spending and the lack of liquidity in the credit markets. Instability in the credit and financial market conditions may negatively impact our ability to access capital and credit markets and our ability to manage our cash balance. While we are unable to predict the continued duration and severity of the adverse conditions in the U.S. and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flows or cash position.

### **Effect of Inflation**

Inflation did not have a significant impact on ADMA's net sales, revenues or income from continuing operations in 2014, 2015 or 2016.

### **Summary of Proposed Acquisition of Certain Assets of BPC**

On January 21, 2017, we and Buyer entered into the Purchase Agreement with Seller, and for certain limited purposes set forth in the Purchase Agreement, the Biotest Guarantors, pursuant to which Buyer has agreed to acquire certain assets and assume certain liabilities constituting the Business. The Business includes (a) a FDA-licensed immune globulin manufacturing and plasma products production facility of two commercial buildings of approximately 126,000 square feet located on approximately 15 acres of land in Boca Raton, Florida, and the associated real property, (b) all exclusive rights to FDA licensed biologics products Nabi-HB®, BIVIGAM® and the investigational product CIVACIR®, (c) in-process inventory with an agreed-upon value of at least \$5.0 million, (d) certain other properties and assets used exclusively in the Business, and (e) certain additional assets which relate to both the Business and Seller's plasma business, the arrangement with respect to which will be documented in a transition services agreement to be mutually agreed by the parties between the signing of the Purchase Agreement and the closing of the Proposed Acquisition.

Subject to the terms and conditions of the Purchase Agreement, (i) upon the closing, Buyer has agreed to assume the Assumed Liabilities; (ii) upon the closing, we have agreed to deliver to Seller the Biotest Equity Interest, consisting of (x) common stock representing 25% of our issued and outstanding common stock, equal to 4,295,580 common shares and (y) non-voting common stock equal to 8,591,160 shares of our non-voting common stock representing the balance of the Biotest Equity Interest which is convertible into our common stock upon the occurrence of certain specified events; (iii) upon the closing, we agreed to issue to Seller warrants, if any, necessary to acquire additional shares of our capital stock equal to the excess, if any, of (x) the number of shares represented by rights, options and warrants issued by us between September 12, 2016 until the closing, over (y) 184,000 shares; and (iv) on January 1, 2019, pursuant to the terms of a separate purchase agreement to be entered into by the parties at the closing, we will agree to sell, transfer and convey to Seller for no additional consideration, all of our right, title and interest in and to our certain biocenter located in Norcross, Georgia and our certain biocenter located in Marietta, Georgia, 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. As part of the consideration, upon the closing, Seller will also be granted the right to designate one director and one observer to our board of directors, and under certain circumstances, Seller will be granted the right to designate an additional director.

Additionally, on the closing date, Seller has agreed to (i) deliver to us a capital contribution of \$12.5 million in respect of the Biotest Equity Interest, which capital contribution will be contributed by Seller to Buyer; and (ii) fund a \$15.0 million unsecured subordinated loan to us, which (a) will bear interest at a rate of 6% per annum, payable semiannually in arrears, (b) has a term of five years and (c) will not be subject to any prepayment penalty or other breakage costs. Such loan will be subordinated to our existing indebtedness as of the signing of the Purchase Agreement and any additional indebtedness approved by our board of directors which is secured only by a mortgage on the owned real property acquired in connection with the transaction. Such loan will rank *pari passu* with all additional indebtedness approved by our board of directors that is not secured only by a mortgage on such owned real property and if such additional indebtedness is secured, the loan from Seller will be secured on a *pari passu* basis with such additional indebtedness. At any time after the closing, if we undertake an underwritten equity

financing or a Private Investment in Public Equity, or PIPE, offering involving at least one unrelated third party, Biotest and/or Seller have agreed to participate pro rata in accordance with the Biotest Equity Interest up to an aggregate amount equal to \$12.5 million.

Upon the closing, the parties will also enter into a ten-year plasma supply agreement, pursuant to which (x) Seller will sell to us high titer Hepatitis B plasma at a specified price (indexed by inflation), and (y) we will purchase from Seller all Hepatitis B plasma necessary to produce Nabi-HB® unless we require more than a specified amount, in which case we may use alternative sources for the excess quantity. Additionally, the parties have agreed to a mutual release with respect to any claims relating to or arising from any breach or default under the Manufacturing Supply and License Agreement and Master Services Agreement between Buyer and Seller. The mutual release is effective as of the signing of the Purchase Agreement conditioned on the closing of the Proposed Acquisition at which time the Manufacturing Supply and License Agreement and Master Services Agreement will terminate and the mutual release will no longer be conditional.

The Purchase Agreement contains customary representations and warranties of the parties, including, without limitation, with respect to: organization; power and authority; due authorization; enforceability; capitalization; no conflict; no consents required; no actions; no orders; financial statements; indebtedness; no undisclosed liabilities; absence of certain changes; taxes; contracts; customers and suppliers; intellectual property; title to properties; real property; employee benefit plans; employees; insurance; compliance with laws; environmental; material permits; inventory; affiliate transactions; and no brokers.

The Purchase Agreement also contains customary covenants and agreements, including covenants and agreements of: Seller to conduct the Business in the ordinary course until the Proposed Acquisition is completed or terminated and to not take certain actions relating to the Business during the interim period between signing and closing, without our prior consent not to be unreasonably withheld, conditioned or delayed; our ability to conduct our business in the ordinary course until the Proposed Acquisition is completed or terminated and to not take certain actions relating to our business during the interim period between signing and closing, without Seller's prior consent not to be unreasonably withheld, conditioned or delayed; Seller not to compete with us in certain lines of business for a period of five years following the closing date; Seller and the Biotest Guarantors not to solicit our employees for one year following the closing date; we and Buyer not to solicit Seller's employees for one year following the closing date; and Seller not to interfere with our customers for five years following the closing date.

Subject to certain limitations, Buyer or Seller may terminate the Purchase Agreement if the Proposed Acquisition has not been consummated by September 30, 2017. A termination of the Purchase Agreement under certain customary circumstances relating to (i) our board of directors exercising their fiduciary out will entitle Seller to receive from us a termination fee in an amount equal to \$2.5 million; or (ii) our failure to obtain the requisite stockholder approval will entitle Seller to receive expense reimbursement in an amount up to \$2.5 million. In no event will Seller be entitled to both a termination fee and expense reimbursement.

We and Seller will each indemnify the other party after the closing for any losses arising from breaches of its representations, warranties, covenants and agreements in the Purchase Agreement. In addition, Buyer will indemnify Seller after the closing for any assumed liability, and Seller will indemnify us after the closing for any excluded asset or excluded liability. The representations, warranties and pre-closing covenants generally survive for 15 months following the closing of the transaction and each party's indemnification obligations with respect to (a) its representations and warranties (other than its fundamental representations, which include representations related to taxes, organization, due authorization, organizational documents, no conflicts; enforceability, title; sufficiency, the Kedrion Contract, brokers, etc. and ownership of our securities) are subject to a \$25,000 mini-basket and \$750,000 true deductible; and (b) its representations and warranties (other than fundamental) and pre-closing covenants are subject to a \$25.0 million cap.

Seller will be entering into a standstill with ADMA, which will limit Seller's ability to control us. Seller will also agree to a six (6) month lock-up of the sale of ADMA securities.

The consummation of the Proposed Acquisition is subject to the satisfaction of certain conditions, including approval of the Proposed Acquisition by the stockholders of ADMA and approval of the amended and restated certificate of incorporation of the Company by the stockholders of ADMA. The Proposed Acquisition is not subject to any financing conditions. There can be no assurance as to when the closing conditions will be satisfied, if at all.



Upon consummation and closing of the Proposed Acquisition, we believe we will be uniquely positioned to offer a fully vertically integrated plasma products and immune globulin platform in the U.S.

### **Recent Accounting Pronouncements**

In January 2017, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or 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 do not expect this new guidance to have a material impact on our consolidated financial statements.

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. ASU 2016-09 will be effective for us in the first quarter of 2017 and will be applied either prospectively, retrospectively or using a modified retrospective transition approach depending on the area covered in this update. The adoption of this ASU is not expected to have a material impact on our consolidated financial statements and related disclosures.

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 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 do not expect this new guidance to 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 do not expect this new guidance to have a material impact on our consolidated financial statements.

In July 2015, the FASB issued ASU No. 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 standard is effective for us prospectively beginning January 1, 2017. The adoption of ASU 2015-11 is not expected to have a material impact on our consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest—Imputation of Interest*, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. The update requires retrospective application and represents a change in accounting principle. The update is effective for fiscal years beginning after December 15, 2015. Early adoption is permitted for financial statements that have not been previously issued. We have early adopted ASU 2015-03 in the second quarter 2015 consolidated financial statements and recast the prior period balances to conform to the current period presentation.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date of issuance of the entity’s financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is “substantial doubt about the entity’s ability to continue as a going concern.” The FASB believes that requiring management to perform the assessment will enhance the timeliness, clarity, and consistency of related disclosures and improve convergence with International Financial Reporting Standards (“IFRS”) (which emphasize management’s responsibility for performing the going-concern assessment). However, the time horizon for the assessment (look-forward period) and the disclosure thresholds under GAAP and IFRSs will continue to differ. This guidance is effective for annual reporting periods ending after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption permitted. We have adopted this standard which has not had a material impact on its consolidated financial statements.

In May 2014, FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which requires that an entity recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to its customers. In order to achieve this core principle, an entity should apply the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. This update will replace existing revenue recognition guidance under Accounting Principles Generally Accepted in the U.S., or GAAP, when it becomes effective for us beginning January 1, 2018, with early adoption permitted in the first quarter of 2017. The updated standard will permit the use of either the retrospective or cumulative effect transition method. We are currently assessing the impact of the new guidance on our results of operations. Based on our procedures performed to date, nothing has come to our attention that would indicate that the adoption of ASU 2014-09 will have a material impact on our financial statements, however, we will continue to evaluate this assessment. We have not yet selected a transition method. We are still evaluating disclosure requirements under the new standard. We will continue to evaluate the standard as well as additional changes, modifications or interpretations which may impact our current conclusions.

### **Critical Accounting Policies and Estimates**

On April 5, 2012, the Jumpstart Our Business Startups Act, or 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. 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 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 auditors provide an attestation report on our internal control over financial reporting.

This Management’s Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S., or GAAP. The preparation of these 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 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 summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition and results of operations.

### ***Stock-Based Compensation***

Stock-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as expense over the employee’s requisite service period on a straight-line basis.

We account for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing method. The noncash charge to operations for non-employee options with vesting are revalued at the end of each reporting period based upon the change in the fair value of the options and amortized to consulting expense over the related contract service period.

For purposes of valuing stock options granted to our employees, non-employees and directors and officers during the year ended December 31, 2016, we used the Black-Scholes option pricing model. We granted options to purchase an aggregate of 100,984 shares of common stock during the year ended December 31, 2016. 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, which 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. We have not experienced any material forfeitures of stock options and, as such, have not established a forfeiture rate since the stock options currently outstanding are primarily held by our senior management and directors. We will continue to evaluate the effects of such future potential forfeitures, as they may arise, to evaluate our estimated forfeiture rate.

### **Research and Development Costs**

Our R&D costs are expensed as incurred, including costs associated with (i) planning and conducting clinical trials, (ii) drug product manufacturing, 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.

### **Revenue Recognition**

Depending on the agreement with the customer, revenue from the sale of human plasma collected by ADMA BioCenters is recognized at the time of transfer of title and risk of loss to the customer, which usually occurs at the time of shipment. Product revenue is recognized at the time of delivery if we retain the risk of loss during shipment. Our product revenues are substantially attributable to two customers. One customer accounts for greater than 80% and another customer accounts for greater than 10% of our product revenues for the year ended December 31, 2016. Revenue from license fees and research and development services rendered are recognized as revenue when the performance obligations under the terms of the license agreement with Biotest have been completed. During the third quarter 2015, we recorded deferred revenue of \$1.5 million in accordance with a license agreement payment we received related to the filing of our BLA with the FDA. Deferred revenue of \$1.7 million was recorded in 2013 as a result of certain research and development services provided in accordance with a license agreement. Deferred revenue is recognized over the term of the license. Deferred revenue is amortized into income for a period of approximately 20 years, the term of the license agreement.

### **Accounting for Loan and Security Agreement**

On June 19, 2015, we entered into a LSA with Oxford for up to \$21.0 million and refinanced our then existing debt. The first tranche of \$16.0 million from the Oxford loan was primarily used to repay our existing debt and the remaining \$5.0 million was available at our option upon RI-002's BLA being approved from the FDA no later than January 31, 2017, which funding would have also extended our interest only period for an additional six months pursuant to the May 2016 amendment to the LSA. The LSA bears interest at a rate per annum equal to the greater of (i) 7.80% and (ii) the sum of (a) the three month U.S. LIBOR rate (as reported in *The Wall Street Journal*) on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 7.54% on the outstanding principal balance. We are obligated to begin to repay the principal over 36 months beginning February 1, 2017, unless accelerated as a result of certain events of default. A final payment equal to 8.95% of the funded loan amount is due at the earlier of loan maturity or prepayment. In the event of the six-month interest only extension, the final payment will be 9.95% of the funded loan, which shall also be due at the earlier of loan maturity or prepayment. In the event we elect to prepay the loan, we are obligated to pay a prepayment charge corresponding to a percentage of the principal amount of the loan, with such percentage being: (i) for a prepayment made on or after the funding date of the applicable term loan through and including the first anniversary of its funding date, an amount equal to 3.00% of the principal amount of the term loan prepaid; (ii) for a prepayment made after the first anniversary of the funding date of the applicable term loan through and including the second anniversary of such funding date, an amount equal to 2.00% of the principal amount of such term loan prepaid; and (iii) for a prepayment of a term loan made after the second anniversary of its funding date and prior to its maturity date, an amount equal to 1.00% of the principal amount of the term loan prepaid. All term loans mature no later than January 1, 2020. The loans are secured by our assets, except for our intellectual property (which is subject to a negative pledge). The LSA contains customary representations, warranties and covenants, including limitations on incurring indebtedness, engaging in mergers or acquisitions and making investments, distributions or transfers.

In connection with the LSA, on June 19, 2015, we issued to Oxford a seven-year warrant, expiring on June 19, 2022, to purchase 74,309 shares of common stock at an exercise price of \$8.51 per share. We recorded \$367,700 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included: (i) volatility of 57% on our common stock based upon a pro rata percentage of our common stock's volatility and similar public companies' volatilities for comparison; (ii) an expected dividend yield of 0.0%; (iii) a risk-free interest rate of 1.99%; and (iv) a term of seven years. As a result of prepaying our prior loan before maturity, we incurred a loss on extinguishment of debt of \$0.7 million comprised of debt issuance costs, debt discount related to the warrants issued to our prior lender, and a prepayment penalty.

In May 2016, we entered into an amendment to our LSA with Oxford, pursuant to which we borrowed an additional \$4.0 million, as an extension to the original LSA entered into on June 19, 2015, which brings the total principal borrowed to \$20.0 million. In connection therewith, we issued warrants to purchase an aggregate of up to 24,800 shares of our common stock at an exercise price equal to \$6.37, which will expire seven years after their issuance on May 13, 2023. We paid a total facility fee of \$125,000, consisting of \$105,000 previously paid and an additional \$20,000 paid on the date the \$4.0 million loan was funded.

### **Off-Balance Sheet Arrangements**

We have entered into leases for our ADMA BioCenters' facilities in Norcross, Georgia and Marietta, Georgia. The Norcross, Georgia 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, Georgia lease expires on January 31, 2024. There is a total minimum aggregate rent due under these leases of \$2.6 million through the end of the respective lease terms.

### **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.

### **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, 2016. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures as of December 31, 2016 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 chief executive officer and chief 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, 2016. 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, 2016, the Company's internal control over financial reporting is effective.

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.

### **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, 2016 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**

On February 17, 2017, ADMA BioCenters, entered into a lease (the "Lease") with Home Center Properties, LLC, a Georgia limited liability company ("Landlord"), for approximately 12,167 square feet located at 166 Earnest W. Barrett Parkway, Marietta, Georgia 30066 (the "Premises"). Pursuant to the Lease, ADMA BioCenters will utilize the Premises as a facility specializing in the collection of human plasma and blood, general office administration and any other related use.

The Lease has an initial term of approximately eight years and nine months (the "Initial Term"), commencing upon substantial completion of "Landlord's Work" (as defined in the Lease) (the "Lease Commencement Date"), with rent payments commencing 150 days after the Lease Commencement Date. ADMA BioCenters' total monthly cost of the Premises (inclusive of Landlord's "Operating Costs", "Taxes" and "Insurance Charges" (as such terms are defined in the Lease)) will range from approximately \$20,000 to \$27,000 during the Initial Term; *provided, however, that*, provided ADMA BioCenters is not in default of the Lease beyond the expiration of any applicable notice and cure period, ADMA BioCenters shall not be obligated to make any rent payments for the first five calendar months of the Initial Term beginning on the Lease Commencement Date and the last four months of the Initial Term beginning on the 102<sup>nd</sup> month after the Lease Commencement Date. Provided that the Lease is in full force and effect and provided there has been no "Event of Default" (as defined in the Lease) beyond the expiration of any applicable notice and cure period, ADMA BioCenters shall have the option to extend the term of the Lease for two additional periods of five years each (each, an "Extension Term"), each Extension Term on the same terms, covenants and conditions as the Lease, with the rent for each Extension Term to equal the mutually agreed fair market value of the Premises on the commencement of such Extension Term. The Lease also contains customary default provisions, representations, warranties and covenants.

The foregoing summary of the material terms of the Lease is qualified in its entirety by reference to the full text of the Lease, which is attached hereto as Exhibit 10.22 and incorporated herein by reference.

## **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 in 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 2017 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year.

Information required to be disclosed by this Item about our board of directors is incorporated in 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 2017 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year.

Information required to be disclosed by this Item about the Section 16(a) compliance of our directors and executive officers is incorporated in 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 2017 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year.

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

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 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 in 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 2017 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year.

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

Information required to be disclosed by this Item is incorporated in 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 2017 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year.

#### **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 2017 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year.

#### **Item 14. Principal Accountant Fees and Services**

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 “Audit and Other Fees” contained in our definitive proxy statement for our 2017 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year.

**Part IV**

**Item 15. Exhibits and 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.

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(2) Financial Statement Schedules.

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

(3) Exhibits.

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

**Exhibit 16. Form 10-K Summary**

None.



## 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: February 24, 2017

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:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Adam S. Grossman</u> Adam S. Grossman	President and Chief Executive Officer (Principal Executive Officer)	February 24, 2017
<u>/s/ Brian Lenz</u> Brian Lenz	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 24, 2017
<u>/s/ Steven A. Elms</u> Steven A. Elms	Chairman of the Board of Directors and Director	February 24, 2017
<u>/s/ Dr. Jerrold B. Grossman</u> Dr. Jerrold B. Grossman	Vice Chairman of the Board of Directors and Director	February 24, 2017
<u>/s/ Bryant E. Fong</u> Bryant E. Fong	Director	February 24, 2017
<u>/s/ Dov A. Goldstein, M.D.</u> Dov A. Goldstein, M.D.	Director	February 24, 2017
<u>/s/ Lawrence P. Guiheen</u> Lawrence P. Guiheen	Director	February 24, 2017
<u>/s/ Eric I. Richman</u> Eric I. Richman	Director	February 24, 2017

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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

ADMA Biologics, Inc.

We have audited the accompanying consolidated balance sheets of ADMA Biologics, Inc. and Subsidiaries as of December 31, 2016 and 2015, and the related consolidated statements of operations, changes in stockholders' (deficiency) equity, and cash flows for the years then ended. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ADMA Biologics, Inc. and Subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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.

/s/ CohnReznick LLP

Roseland, New Jersey  
February 24, 2017

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**December 31, 2016 and 2015**

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents.....	\$ 9,914,867	\$ 10,440,959
Short-Term Investments .....	5,390,184	6,368,177
Accounts Receivable .....	1,018,027	924,468
Inventories .....	5,020,146	3,445,773
Prepaid Expenses.....	313,914	111,027
Total Current Assets.....	<u>21,657,138</u>	<u>21,290,404</u>
Property and Equipment at Cost, Net.....	<u>2,000,784</u>	<u>2,396,950</u>
Other Assets:		
Deposits .....	<u>27,163</u>	<u>27,163</u>
Total Other Assets.....	<u>27,163</u>	<u>27,163</u>
<b>TOTAL ASSETS</b> .....	<u><u>\$ 23,685,085</u></u>	<u><u>\$ 23,714,517</u></u>
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIENCY) EQUITY</b>		
Current Liabilities:		
Accounts Payable .....	\$ 2,564,681	\$ 2,087,855
Accrued Expenses .....	2,385,356	1,968,384
Current Portion of Note Payable.....	6,111,111	—
Current Portion of Deferred Revenue.....	145,154	145,154
Current Portion of Leasehold Improvement Loan.....	16,559	15,139
Total Current Liabilities.....	<u>11,222,861</u>	<u>4,216,532</u>
Notes Payable, Net of Debt Discount.....	12,321,640	14,247,212
End of Term Liability, Notes Payable.....	1,790,000	1,432,000
Deferred Revenue, Net of Current Portion.....	2,690,033	2,832,867
Deferred Rent Liability .....	98,116	128,676
Leasehold Improvement Loan, Net of Current Portion.....	19,697	36,256
<b>TOTAL LIABILITIES</b> .....	<u>28,142,347</u>	<u>22,893,543</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' (DEFICIENCY) EQUITY</b>		
Common Stock \$0.0001 par value 75,000,000 shares authorized, and 12,886,741 and 10,713,087 shares issued and outstanding as of December 31, 2016 and December 31, 2015, respectively.....	1,289	1,072
Additional Paid-In Capital.....	102,476,267	88,239,569
Accumulated Deficit.....	(106,934,818)	(87,419,667)
<b>TOTAL STOCKHOLDERS' (DEFICIENCY) EQUITY</b> .....	<u>(4,457,262)</u>	<u>820,974</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIENCY) EQUITY</b> .....	<u><u>\$ 23,685,085</u></u>	<u><u>\$ 23,714,517</u></u>

See notes to consolidated financial statements

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**Years Ended December 31, 2016 and 2015**

	<u>2016</u>	<u>2015</u>
<b>REVENUES:</b>		
Product revenue .....	\$ 10,518,203	\$ 7,050,283
License and other revenue .....	142,834	127,350
<b>Total Revenues</b> .....	<u>10,661,037</u>	<u>7,177,633</u>
<b>OPERATING EXPENSES:</b>		
Cost of product revenue .....	6,360,761	4,311,461
Research and development .....	7,688,238	7,015,946
Plasma centers .....	5,447,691	4,618,065
General and administrative .....	8,494,742	6,745,968
<b>TOTAL OPERATING EXPENSES</b> .....	<u>27,991,432</u>	<u>22,691,440</u>
<b>LOSS FROM OPERATIONS</b> .....	<u>(17,330,395)</u>	<u>(15,513,807)</u>
<b>OTHER INCOME (EXPENSE):</b>		
Interest income .....	50,317	37,830
Interest expense .....	(2,239,569)	(1,842,716)
Other income .....	4,496	—
Change in fair value of stock warrants .....	—	67,860
Loss on extinguishment of debt .....	—	(719,097)
<b>OTHER EXPENSE, NET</b> .....	<u>(2,184,756)</u>	<u>(2,456,123)</u>
<b>NET LOSS</b> .....	<u>\$ (19,515,151)</u>	<u>\$ (17,969,930)</u>
<b>NET LOSS PER COMMON SHARE,</b>		
<b>Basic and Diluted</b> .....	<u>\$ (1.61)</u>	<u>\$ (1.73)</u>
<b>WEIGHTED AVERAGE SHARES</b>		
<b>OUTSTANDING, Basic and Diluted</b> .....	<u>12,153,407</u>	<u>10,412,305</u>

See notes to consolidated financial statements

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' (DEFICIENCY) EQUITY**  
**Years Ended December 31, 2016 and 2015**

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>			
Balance - December 31, 2014.....	9,291,823	\$ 929	\$ 75,457,458	\$ (69,449,737)	\$ 6,008,650
Stock-based compensation.....	—	—	1,711,047	—	1,711,047
Issuance of common stock, net.....	1,408,750	141	10,245,239	—	10,245,380
Stock issued in connection with stock options exercised.....	7,514	1	49,226	—	49,227
Restricted stock.....	5,000	1	(1)	—	—
Elimination of warrant liability.....	—	—	408,900	—	408,900
Warrants issued in connection with note payable.....	—	—	367,700	—	367,700
Net loss.....	—	—	—	(17,969,930)	(17,969,930)
	<u>10,713,087</u>	<u>1,072</u>	<u>88,239,569</u>	<u>(87,419,667)</u>	<u>820,974</u>
Balance - December 31, 2015.....	10,713,087	1,072	88,239,569	(87,419,667)	820,974
Stock-based compensation.....	—	—	1,250,074	—	1,250,074
Issuance of common stock, net.....	2,176,154	217	12,900,324	—	12,900,541
Restricted stock.....	(2,500)	—	—	—	—
Warrants issued in connection with note payable.....	—	—	86,300	—	86,300
Net loss.....	—	—	—	(19,515,151)	(19,515,151)
	<u>12,886,741</u>	<u>\$ 1,289</u>	<u>\$102,476,267</u>	<u>\$(106,934,818)</u>	<u>\$ (4,457,262)</u>
Balance - December 31, 2016.....	12,886,741	\$ 1,289	\$102,476,267	\$(106,934,818)	\$ (4,457,262)

See notes to consolidated financial statements

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**Years Ended December 31, 2016 and 2015**

	<b>2016</b>	<b>2015</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss .....	\$ (19,515,151)	\$ (17,969,930)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization .....	469,576	469,821
Stock-based compensation .....	1,250,074	1,711,047
Warrant liability .....	—	(67,860)
Amortization of debt discount .....	676,943	353,635
Amortization of deferred financing costs .....	—	39,717
Payment-in-kind interest .....	—	124,536
Amortization of license and other revenue .....	(142,834)	(127,350)
Loss on extinguishment of debt .....	—	719,097
Changes in operating assets and liabilities:		
Accounts receivable .....	(93,559)	(540,507)
Inventories .....	(1,574,373)	(1,737,010)
Prepaid expenses .....	(202,887)	32,559
Accounts payable .....	476,826	202,994
Accrued expenses .....	416,972	(199,615)
Deferred revenue .....	—	1,525,000
Deferred rent liability .....	(30,560)	45,462
Net cash used in operating activities .....	(18,268,973)	(15,418,404)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of short-term investments .....	(15,680,000)	(18,130,000)
Redemptions of short-term investments .....	16,657,993	16,414,498
Purchase of property and equipment .....	(73,410)	(26,073)
Net cash provided by (used in) investing activities .....	904,583	(1,741,575)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from Oxford note payable .....	4,000,000	16,000,000
Proceeds from issuance of common stock .....	14,145,000	10,257,380
Proceeds from stock options exercised .....	—	49,227
Repayment of Hercules note payable .....	—	(15,300,781)
Prepayment penalty of early extinguishment of note payable .....	—	(229,512)
Payment of debt issuance costs .....	(47,104)	(228,065)
Payment of Hercules end of term fee .....	—	(132,500)
Equity issuance costs .....	(1,244,459)	—
Payments of leasehold improvement loan .....	(15,139)	(13,841)
Net cash provided by financing activities .....	16,838,298	10,401,908
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS .....</b>	<b>(526,092)</b>	<b>(6,758,071)</b>
<b>CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR .....</b>	<b>10,440,959</b>	<b>17,199,030</b>
<b>CASH AND CASH EQUIVALENTS - END OF YEAR .....</b>	<b>\$ 9,914,867</b>	<b>\$ 10,440,959</b>
<b>SUPPLEMENTAL INFORMATION:</b>		
Cash paid for interest .....	\$ 1,530,235	\$ 1,326,788
<b>Supplemental Disclosure of Noncash Financing Activities:</b>		
Reclassification of equity issuance costs to additional paid-in capital .....	\$ —	\$ 12,000
Warrants issued in connection with note payable .....	\$ 86,300	\$ 367,700
End of term liability in connection with note payable .....	\$ 358,000	\$ 1,432,000
Elimination of warrant liability .....	\$ —	\$ 408,900

See notes to consolidated financial statements



**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2016 AND 2015**

**1. ORGANIZATION AND BUSINESS**

ADMA Biologics, Inc. (“ADMA” or the “Company”) is a late stage biopharmaceutical company that develops, manufactures, and intends to commercialize specialty plasma-based biologics for the proposed 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 disease or who may be immune-suppressed for medical reasons. ADMA also operates through its wholly-owned subsidiary, ADMA Bio Centers Georgia Inc., (“ADMA BioCenters”), a source plasma collection business with U.S. Food and Drug Administration (“FDA”) approved facilities in Norcross, Georgia and Marietta, Georgia. Each facility holds certifications from the German Health Authority (“GHA”) and the Korean Ministry of Food and Drug Safety (“MFDS”). ADMA BioCenters supplies ADMA with a portion of its raw material plasma for the manufacture of RI-002, ADMA’s lead product candidate, which the Company is currently developing for the treatment of Primary Immune Deficiency Disease (“PID”). A Biologics License Application (“BLA”) for RI-002 was submitted to the FDA and accepted for review during the third quarter of 2015 for the treatment of PID. In July 2016, the FDA issued a Complete Response Letter (“CRL”) to the Company for its BLA for RI-002. 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 FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies at the Company’s third-party contract manufacturers and vendors and requested documentation of corrections for a number of those issues. The FDA indicated in the CRL that it cannot grant final approval of the BLA until, among other things, these deficiencies are resolved. Since receiving the CRL, the Company has worked diligently with its contract fill and finisher as well as the contract testing laboratory. The Company has also continued to work with its third-party contract manufacturer, Biotest Pharmaceuticals Corporation (“BPC” or “Seller”), and on January 21, 2017, the Company signed a definitive acquisition agreement to acquire certain manufacturing and therapy-related assets from Biotest in Boca Raton, Florida, a wholly-owned subsidiary of Biotest Aktiengesellschaft (“Biotest”) in efforts to address the CRL and remediate the outstanding warning letter at the manufacturing facility. The acquisition of certain manufacturing and therapy-related assets of Biotest (the “Proposed Acquisition”) is anticipated to close during the first half of 2017. The Company and its vendors are awaiting certain feedback from the agency on submissions already made and the Company intends to provide a timeline for resubmission of the BLA for RI-002 as soon as practicable.

The Company has experienced net losses and negative cash flows from operations since inception in 2004 and expects these conditions to continue for the foreseeable future. Since inception, the Company has needed to raise capital from the sales of its equity securities and debt financings to sustain operations. In May 2016, the Company completed an underwritten public offering of its common stock, raising gross proceeds of approximately \$14.1 million, and subsequently borrowed an additional \$4.0 million under its Loan and Security Agreement (“LSA”) with Oxford Finance LLC (“Oxford”), which brought the total principal borrowed to \$20.0 million (see Note 5). In February and December 2014, the Company borrowed a total of \$15 million from Hercules Technology Growth Capital, Inc. (“Hercules”) and subsequently refinanced its borrowings of \$16 million with Oxford (see Note 5). In March 2015, ADMA completed an underwritten public offering of its common stock, raising gross proceeds of \$11.3 million. In June 2015, ADMA entered into the LSA with Oxford, as collateral agent and lender, pursuant to which ADMA accessed an initial term loan in the aggregate principal amount of \$16.0 million, of which \$15.7 million was used to repay the Hercules loan balance of \$15.0 million, along with \$0.4 million of interest, and \$0.3 million of prepayment premium and other fees, (the “Prior Loan Agreement”).

As of December 31, 2016, the Company had working capital of \$10.4 million, consisting primarily of \$9.9 million of cash and cash equivalents, \$5.4 million of short-term investments, \$1.0 million of accounts receivable, \$5.0 million of inventories, and \$0.3 million of prepaid expenses, offset primarily by the current portion of note payable due to Oxford of \$6.1 million, \$2.6 million of accounts payable, \$2.4 million of accrued expenses and \$0.2 million of deferred revenue. Based upon the Company’s projected revenue and expenditures for 2017, including the fees associated to the Proposed Acquisition of certain BPC assets, regulatory and consulting fees for RI-002 associated with third-party manufacturers and ongoing discussions with the FDA, continuing implementation of the Company’s commercialization and expansion activities and certain other assumptions, management currently believes that its cash, cash equivalents, short-term investments, projected revenue and accounts receivable are sufficient to fund ADMA’s operations, as currently conducted, into the second half of 2017. These estimates may change based upon the timing of the closing of the Proposed Acquisition of certain BPC assets, whether or when the

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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FDA approves RI-002, the timing of any required commercial manufacturing scale up activities or if any other assumptions of the Company change. This timing may also change based upon the timing of the completion of the Proposed Acquisition, anticipated during the first half of 2017. Upon the closing of the Proposed Acquisition, BPC will be providing funds to ADMA consisting of: \$12.5 million in funding, \$15.0 million in debt financing and an additional \$12.5 million commitment towards a future equity financing is expected to be sufficient to fund operations into the first quarter of 2018. There is no assurance that we will be able to successfully close on the Proposed Acquisition. Other than the funding to be provided by BPC, the Company does not currently have arrangements to obtain additional financing. Furthermore, if the Company's assumptions underlying its estimated expenses and revenues are incorrect, it may have to raise additional capital sooner than anticipated. Due to numerous risks and uncertainties associated with the research and development and potential future commercialization of its product candidate, 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 Company does not have any existing commitments for future external funding. The sale of additional equity or debt securities, if convertible, could result in dilution to the Company's stockholders. 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. Additional equity or debt financing, grants, or corporate collaboration and potential licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, the Company may be required to delay, reduce the scope of or eliminate the Company's research and development programs, reduce the Company's planned clinical trials and delay or abandon potential commercialization efforts of the Company's lead or other product candidates. The Company has reported losses since inception in June 2004 through December 31, 2016 of \$106.9 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 relating to the recoverability and classification of asset carrying amounts and the classification of liabilities that might be necessary from the outcome of this uncertainty.

ADMA's long-term liquidity will be dependent upon on its ability to raise additional capital, to fund its research and development and commercial programs and meet its obligations on a timely basis. If ADMA is unable to successfully raise sufficient additional capital, it will likely not have sufficient cash flow and liquidity to fund its business operations, forcing ADMA to curtail activities and, potentially significantly reduce, or potentially cease operations. Even if ADMA is 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 its common stock may decline.

There can be no assurance that the Company's research and development will be successfully completed or that any product will be approved or commercially viable. The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with FDA and other governmental regulations and approval requirements.

## **2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The following comprises the Company's significant accounting policies:

### **Basis of presentation**

The accompanying consolidated financial statements include the accounts of ADMA Biologics, Inc. and its wholly-owned subsidiaries. All significant intercompany transactions and balances have been eliminated in consolidation.

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
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Cash and cash equivalents

The Company considers all highly-liquid instruments purchased with a maturity of three months or less to be cash equivalents. 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.

Inventories

Plasma inventories (both plasma intended for resale and plasma intended for internal use in the Company's research and development and future anticipated commercialization activities of which certain quantities are labeled as normal source and Respiratory Syncytial Virus, ("RSV") high titer) 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 was processed to a finished product and subsequently expensed to research and development. Inventory at December 31, 2016 and 2015 consists of high titer RSV plasma and normal source plasma.

Revenue recognition

Depending on the agreement with the customer, product revenues from the sale of human plasma collected at the Company's FDA-licensed plasma collection centers are recognized at the time of transfer of title and risk of loss to the customer, which 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 fiscal year ended December 31, 2016, two of the Company's customers, SK Plasma Co., Ltd., "SK", and BPC, represented greater than 95% of our total revenues, with BPC representing approximately 82% of our total revenues and SK representing approximately 14% of our total revenues.

Revenue from license fees and research and development services rendered are recognized as revenue when the performance obligations under the terms of the license agreement have been completed.

Revenues for the year ended December 31, 2016 are comprised of product revenues from the sale of normal source human plasma collected from the Company's plasma collection centers segment and license and other revenues are primarily attributable to the out-licensing of RI-002 to Biotest AG to market and sell in Europe and selected countries in North Africa and the Middle East. Biotest and BPC, a subsidiary of Biotest, have 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. During the third quarter of 2015, the Company recorded deferred revenue of \$1.5 million for a milestone payment provided to the Company after the BLA for RI-002 was filed with the FDA, in accordance with the terms of the Biotest license agreement. Deferred revenue is recognized over the term of the Biotest AG license. Deferred revenue is amortized into income for a period of approximately 20 years, the term of the Biotest license agreement.

Concentration of significant customers and accounts receivable

As of and for the years ended December 31, 2016 and 2015, the Company's trade receivable balance and revenues were substantially attributable to two customers.

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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Research and development costs

The Company expenses all research and development costs as incurred, of which such expenses include costs associated with planning and conducting clinical trials, manufacturing, quality, testing, validation, regulatory consulting and filing fees and employees' compensation expenses directly related to R&D activities.

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 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.

Concentration of credit risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents and short-term investments.

Property and equipment

Fixed assets are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the asset's estimated useful life, which is five to ten years. Leasehold improvements are amortized over the lesser of the lease term or their estimated useful lives.

Income taxes

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") 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.

The Company has no unrecognized tax benefits at December 31, 2016 and 2015. The Company's U.S. Federal and state income tax returns prior to fiscal year 2013 are closed and management continually evaluates expiring statutes of limitations, audits, proposed settlements, changes in tax law and new authoritative rulings.

The Company will recognize interest and penalties associated with tax matters as income tax expense.

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.

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 common stock and dilutive common stock outstanding during the period. Potential common stock includes the shares of common stock issuable upon the exercise of outstanding stock options and warrants (using the treasury stock method). Potential 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. The aggregate number of potentially dilutive securities upon the exercise of outstanding warrants and stock options was 1.8 million and 1.7 million as of December 31, 2016 and 2015, respectively.

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
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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. The estimated fair value of stock options granted under the Company's 2007 Employee Stock Option Plan (the "Plan") and the 2014 Omnibus Incentive Compensation Plan (the "2014 Plan") is recognized as compensation expense over the option-vesting period.

During the years ended December 31, 2016 and 2015, stock options to purchase 100,984 and 432,500 shares of common stock, respectively, were issued to employees and non-employee directors. During the year ended December 31, 2016, options to purchase 21,334 shares of common stock were forfeited and options to purchase 8,666 shares of common stock expired. During the year ended December 31, 2015, options to purchase 7,514 shares of common stock were exercised by an employee and options to purchase 9,710 shares of common stock were forfeited.

On June 19, 2014, at the Annual Meeting of Stockholders (the "Annual Meeting"), the stockholders approved the 2014 Plan, which was approved by the Board of Directors of ADMA (the "Board") on February 21, 2014. The maximum number of shares reserved for grant under the 2014 Plan is: (a) 800,000 shares; plus (b) an annual increase as of the first day of the Company's fiscal year, beginning in 2015 and occurring each year thereafter through 2020, equal to the least of (i) 200,000 shares, (ii) 1% of the outstanding shares of common stock as of the end of the Company's immediately preceding fiscal year, and (iii) any lesser number of shares determined by the Board; provided, however, that the aggregate number of shares available for issuance pursuant to such increases shall not exceed a total of 800,000 shares.

During the years ended December 31, 2016 and 2015, the Company recorded stock-based compensation expense to employees of \$1,250,074 and \$1,711,047, 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. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. The Company's employee stock options have characteristics significantly different from those of traded options, and changes in the subjective input 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 Company has not experienced any material forfeitures of stock options and, as such, has not established a forfeiture rate since the stock options currently outstanding are primarily held by the Company's senior management and directors. The Company will continue to evaluate the effects of such future potential forfeitures, as they may arise, to evaluate the Company's estimated forfeiture rate.

The Company records compensation expense associated with stock options and other forms of equity compensation using the Black-Scholes option-pricing model and the following assumptions:

	<b>Year Ended December 31, 2016</b>	<b>Year Ended December 31, 2015</b>
Expected term.....	5.8-6.3 years	5.8-6.3 years
Volatility.....	51-52%	51-58%
Dividend yield .....	0.0	0.0
Risk-free interest rate.....	1.54-1.79%	1.49-2.14%

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
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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.

Recent Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or 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 does not expect this new guidance to have a material impact on its consolidated financial statements.

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. ASU 2016-09 will be effective for the Company in the first quarter of 2017 and will be applied either prospectively, retrospectively or using a modified retrospective transition approach depending on the area covered in this update. The adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

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 adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

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 adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

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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 standard is effective for the Company prospectively beginning January 1, 2017. The adoption of ASU 2015-11 is not expected to have a material impact on the Company’s consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, *Interest—Imputation of Interest*, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. The update requires retrospective application and represents a change in accounting principle. The update is effective for fiscal years beginning after December 15, 2015. The Company adopted ASU 2015-03 in its second quarter 2015 consolidated financial statements and recast the prior period balances to conform to the current period presentation.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date of issuance of the entity’s financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is “substantial doubt about the entity’s ability to continue as a going concern.” The FASB believes that requiring management to perform the assessment will enhance the timeliness, clarity, and consistency of related disclosures and improve convergence with International Financial Reporting Standards (“IFRS”) (which emphasize management’s responsibility for performing the going-concern assessment). However, the time horizon for the assessment (look-forward period) and the disclosure thresholds under GAAP and IFRS will continue to differ. This guidance is effective for annual reporting periods ending after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption permitted. The Company has adopted this standard which has not had a material impact on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, which requires that an entity recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to its customers. In order to achieve this core principle, an entity should apply the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. This update will replace existing revenue recognition guidance under GAAP, when it becomes effective for us beginning January 1, 2018, with early adoption permitted in the first quarter of 2017. The updated standard will permit the use of either the retrospective or cumulative effect transition method. The Company is currently assessing the impact of the new guidance on its results of operations. Based on its procedures performed to date, nothing has come to the Company’s attention that would indicate that the adoption of ASU 2014-09 will have a material impact on its consolidated financial statements, however, the Company will continue to evaluate this assessment. The Company has not yet selected a transition method. The Company is still evaluating disclosure requirements under the new standard. The Company will continue to evaluate the standard as well as additional changes, modifications or interpretations which may impact its current conclusions.

**3. PROPERTY AND EQUIPMENT**

Property and equipment consist of the following at December 31,

	<u>2016</u>	<u>2015</u>
Lab and office equipment .....	\$ 1,336,668	\$ 1,272,042
Computer software .....	188,277	188,277
Leasehold improvements .....	2,699,104	2,690,320
	<u>4,224,049</u>	<u>4,150,639</u>
Less: Accumulated depreciation and amortization .....	(2,223,265)	(1,753,689)
	<u>\$ 2,000,784</u>	<u>\$ 2,396,950</u>

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The Company recorded depreciation and amortization expense of \$469,576 and \$469,821 for the years ended December 31, 2016 and 2015, respectively.

**4. LEASEHOLD IMPROVEMENT LOAN**

In connection with the lease of commercial real estate by the Company's wholly-owned subsidiary for the operation of the plasma collection center, the Company borrowed \$125,980 from the lessor to pay for leasehold improvement costs in excess of the allowance provided for in the lease agreement. The loan bears interest at 9% and is payable in 120 monthly installments of \$1,596 maturing January 2019. Principal maturities under the loan are as follows:

2017 .....	\$	16,559
2018 .....		18,113
2019 .....		1,584
		\$ 36,256

**5. DEBT**

Loan and Security Agreement

On June 19, 2015, the Company entered into an LSA with Oxford for up to \$21.0 million of debt financing in two term loan tranches. The first term loan tranche of \$16.0 million from the LSA (the "Term A Loan") was primarily used to repay the Company's previous debt facility with Hercules dated December 2012. As a result of prepaying the Hercules loan prior to maturity, the Company incurred a loss on extinguishment of debt of \$0.7 million comprised of unamortized debt issuance costs, unamortized debt discount related to the warrants issued to Hercules, along with a prepayment penalty.

The outstanding term loans bear interest at a rate per annum equal to the greater of (i) 7.80% and (ii) the sum of (a) the three month U.S. LIBOR rate (as reported in *The Wall Street Journal*) on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 7.54% on the outstanding principal balance. The Company became obligated to begin to repay the principal over 36 months beginning on February 1, 2017, unless accelerated as a result of certain events of default. A final payment equal to 8.95% of the funded loan amount is due at the earlier of loan maturity or prepayment. All term loans mature no later than January 1, 2020. The loans are secured by the Company's assets, except for its intellectual property (which is subject to a negative pledge). The LSA contains customary representations, warranties and covenants, including limitations on incurring indebtedness, engaging in mergers or acquisitions and making investments, distributions or transfers.

In connection with the entry into the LSA, on June 19, 2015, the Company issued to Oxford a seven-year warrant, expiring on June 19, 2022, to purchase 74,309 shares of common stock at an exercise price of \$8.51 per share. The Company recorded \$367,700 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included: (i) volatility of 57% on our common stock based upon a pro rata percentage of our common stock's volatility and similar public companies' volatilities for comparison; (ii) an expected dividend yield of 0.0%; (iii) a risk-free interest rate of 1.99%; and (iv) a term of seven years. As a result of prepaying the Company's prior loan before maturity, the Company incurred a loss on extinguishment of debt of \$0.7 million comprised of unamortized debt issuance costs and unamortized debt discount related to the warrants issued to the Company's prior lender, along with a prepayment penalty.

In May 2016, the Company amended the LSA with Oxford (the "Amended LSA") which provided ADMA with an additional \$4.0 million term loan (the "Term B Loan"), the availability of which was conditioned on completing an equity financing of its common stock of at least \$10.0 million in gross proceeds no later than May 31, 2016. On May 3, 2016, the Company completed an underwritten public offering of its common stock, raising gross proceeds of approximately \$14.1 million and subsequently borrowed the additional \$4.0 million from Oxford under the Amended LSA, which brings the total principal amount borrowed to \$20.0 million.



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In the event the Company prepays a term loan for any reason, the Company is obligated to pay a prepayment charge corresponding to a percentage of the principal amount of the applicable term loan prepaid. The Amended LSA further modified the fees payable by the Company on mandatory or voluntary prepayment of a term loan prior to its maturity date as follows: (i) for a prepayment made on or after the funding date of the applicable term loan through and including the first anniversary of its funding date, an amount equal to 3.00% of the principal amount of the term loan prepaid; (ii) for a prepayment made after the first anniversary of the funding date of the applicable term loan through and including the second anniversary of such funding date, an amount equal to 2.00% of the principal amount of such term loan prepaid; and (iii) for a prepayment of a term loan made after the second anniversary of its funding date and prior to its maturity date, an amount equal to 1.00% of the principal amount of the term loan prepaid.

Pursuant to the Amended LSA, (i) the Company paid a total facility fee of \$125,000, consisting of \$105,000 previously paid and an additional \$20,000 paid on the date the Term B Loan was funded; (ii) certain adjustments were made to the time periods for any applicable prepayment fees; and (iii) certain defined terms were adjusted, including a new Amortization Date that is defined as (a) February 17, 2017, if the Term C Loan is not made and (b) August 1, 2017 if the Term C Loan is made. The Amended LSA further provides for customary representations, warranties and covenants for the Company. Except as otherwise amended, the Amended LSA does not alter the terms of the LSA.

In connection with the Amended LSA, on May 13, 2016, the Company issued to Oxford a seven-year warrant, expiring on May 23, 2023, to purchase 24,800 shares of common stock at an exercise price of \$6.37 per share, equal to 3.95% of the amount drawn of such tranche, divided by the average reported closing price per share of common stock for the consecutive 10 trading days prior to the applicable draw in accordance with the Company's drawdown of the Term B Loan. The Company recorded \$86,300 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included: volatility of 53.5% on the Company's common stock based upon a pro rata percentage of the Company's common stock's volatility and similar public companies' volatilities for comparison, an expected dividend yield of 0.0%, a risk-free interest rate of 1.51% and a term of seven years.

A summary of the Oxford loan balance is as follows:

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
Gross proceeds .....	\$ 20,000,000	\$ 16,000,000
<u>Less: debt discount, net</u>		
End of term fee .....	(1,155,157)	(1,250,194)
Warrants .....	(257,201)	(310,196)
Financing fees .....	(154,891)	(192,398)
Note payable.....	<u>\$ 18,432,751</u>	<u>\$ 14,247,212</u>

Future amortization of financing fees for each of the years subsequent to December 31, 2016 are as follows:

2017 .....	\$ 708,720
2018 .....	529,888
2019 .....	328,641
	<u>\$ 1,567,249</u>

**6. STOCKHOLDERS' EQUITY**

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 approximately \$13.0 million, after payment of underwriting discounts and offering expenses of approximately \$1.1 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-200638) that was declared effective by the SEC on December 23, 2014.

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On March 18, 2015, the Company closed an underwritten sale of 1,225,000 shares of its common stock, as well as 183,750 additional shares of its common stock pursuant to the full exercise of the over-allotment option granted to the underwriters, for gross proceeds of approximately \$11.3 million. Net proceeds from this offering were approximately \$10.2 million, net of underwriting discounts and offering expenses of approximately \$1.1 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-200638) that was declared effective by the SEC on December 23, 2014.

Oxford and Hercules Debt Financing Warrant Issuance

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. In connection with the LSA with Oxford, on June 19, 2015, the Company issued to Oxford a seven year warrant, expiring on June 19, 2022, to purchase 74,309 shares of common stock at an exercise price of \$8.51 per share. In connection with the Prior Loan Agreement with Hercules, on December 21, 2012, the Company issued to Hercules a warrant to purchase 31,750 shares of common stock with an exercise price of \$7.56, subject to customary anti-dilution adjustments. In connection with the Loan Amendment, the Company issued to Hercules a warrant to purchase 23,200 and 34,800 shares of common stock of the Company in February and December 2014, respectively, with an exercise price set at the lower of (i) \$7.50 per share or (ii) the price per share of the next round of financing from the expiration of the exercise price adjustment, subject to customary anti-dilution adjustments. The warrant expires after 10 years and has piggyback registration rights with respect to the shares of common stock underlying the warrant. The down round warrant protection feature resulting in the warrant liability's quarterly "mark-to-market" valuation has terminated as of the end of the one-year period following the amended Loan Closing on February 24, 2014 (see Note 5).

**7. RELATED PARTY TRANSACTIONS**

The Company leases an office building and equipment from an entity owned by related parties on a month-to-month basis of which terms were amended by the Company's Board of Directors in June 2016. Rent expense amounted to \$192,000 and \$96,448 for the years ended December 31, 2016 and 2015, respectively. The Company also reimburses its landlord and affiliates for office and building related (common area) expenses, equipment and certain other operational expenses, which have been insignificant to the consolidated financial statements for the years ended December 31, 2016 and 2015. The Company maintains deposits and other accounts at a bank which was less than 5%-owned by related parties through January 2016, and where a stockholder and Company director was previously a member of the bank's board of directors through January 2016, and is now a member of its Corporate Advisory Council.

**8. COMMITMENTS AND CONTINGENCIES**

Lease commitments

The Company has entered into leases for its ADMA BioCenters' facilities located in Norcross, Georgia and in Marietta, Georgia. The Norcross, Georgia 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, Georgia lease expires on January 31, 2024. Total rent expense for its New Jersey and Georgia facilities during the years ended 2016 and 2015 was approximately \$535,000 and \$420,000, respectively.

Future minimum lease payments for both leases, for each of the five years ending December 31 and thereafter are as follows:

2017 .....	\$	359,059
2018 .....		362,774
2019 .....		375,198
2020 .....		376,812
2021 .....		381,329
Thereafter .....		732,079
	\$	<u>2,587,251</u>

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Vendor and Licensor Commitments

On December 31, 2012, the Company entered into a Manufacturing, Supply and License Agreement with BPC, which replaces a prior agreement that expired on December 31, 2012. Under the agreement, the Company agreed to purchase exclusively from BPC its worldwide requirements of RSV immune globulin manufactured from human plasma containing RSV antibodies. The term of the agreement is for a period of ten years from January 1, 2013, renewable for two additional five-year periods at the agreement of both parties. The Company is 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 is subject to increase at the Company's option. As consideration for BPC's obligations under the agreement, the Company is 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. The agreement may be terminated by either party (a) by reason of a material breach if the breaching party fails to remedy the breach within 120 days after receiving notice of the breach from the other party, (b) upon bankruptcy, insolvency, dissolution, or winding up of the other party, or (c) if the other party is unable to fulfill its obligations under the agreement for 120 consecutive days or more as a result of (a) or (b) above. The parties have agreed to 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 the Company and BPC.

In a separate license agreement effective December 31, 2012, the Company granted BPC an exclusive license to market and sell RSV antibody-enriched Immune Globulin Intravenous ("IVIG") in Europe and in selected countries in North Africa and the Middle East, collectively referred to as 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 BPC seeking regulatory approval for the RSV antibody-enriched IVIG in the Territory. As consideration for the license, BPC agreed to provide the Company with certain services at no charge and also compensate us with cash payments upon the completion of certain milestones. Such services have been accounted for as deferred revenue which were recorded in 2013 as a result of certain research and development services as provided for in accordance with a license agreement. Deferred revenue is recognized over the term of the license and is amortized into income for a period of approximately 20 years, the term of the license agreement. BPC is also obligated to pay the Company an adjustable royalty based on a percentage of revenues from the sale of RSV antibody-enriched IVIG in the Territory for 20 years from the date of first commercial sale. Additionally, BPC has agreed to grant the Company an exclusive license for marketing and sales in the U.S. and Canada for BPC's Varicella Zoster Immune Globulin ("VZIG"); however, as a result of the Proposed Acquisition the terms associated to VZIG will be terminated upon the closing of the Proposed Acquisition during the first half of 2017.

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. This volume will increase at the earlier of the Company's receipt of a BLA from the FDA, or March 31, 2016. The Company 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 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. 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. The Company may also terminate the agreement upon written notice if the clinical development of its 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, 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. As part of the acquisition of certain assets of BPC, BPC and

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ADMA amended the Plasma Purchase Agreement, to extend the purchase from BPC an annual minimum of plasma containing antibodies to RSV for ten years through the closing date of the transaction which is anticipated during the first half of 2017.

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.

General legal matters

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

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, 2016. The Company does not anticipate recognizing any significant losses relating to these arrangements.

**9. STOCK OPTIONS**

The Company has adopted two stock option plans. On July 16, 2007 (the "Effective Date"), the Company's Board and stockholders adopted the 2007 Plan. On July 17, 2012, the Company's Board and stockholders amended the 2007 Plan to increase the aggregate number of options available for grant to 903,224. On February 21, 2014 the Board approved the 2014 Plan, which was approved by stockholders at the Annual Meeting of Stockholders (the "Annual Meeting") on June 19, 2014. Additionally, the Board also, approved subject to stockholder approval at the Annual Meeting under the Prospective Plan, 800,000 shares of common stock plus an annual increase to be added as of the first day of the Company's fiscal year, beginning in 2015 and occurring each year thereafter through 2020, equal to the lower of 200,000, or 1% of the outstanding shares of common stock as of the end of the Company's immediately preceding fiscal year and any lesser number of shares determined by the Board, provided that the aggregate number of shares available for issuance pursuant to such increases shall not exceed a total of 800,000 shares reserved for issuance under the terms of the 2014 Plan. As of December 31, 2016, the aggregate options approved in the 2007 Plan and 2014 Plan are 1,903,273 with 1,535,187 outstanding and expected to vest and 368,086 available for future issuance. During the year ended December 31, 2016, there were 21,334 options forfeited and 8,666 options expired; such options were included in the stock option plans.

The 2007 and 2014 Plans provides 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, 2016 and 2015:

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	Year Ended December 31, 2016		Year Ended December 31, 2015	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period .....	1,464,203	\$ 8.02	1,048,927	\$ 7.24
Forfeited .....	(21,334)	8.02	(9,710)	9.16
Expired .....	(8,666)	7.88	(7,514)	6.55
Granted .....	100,984	6.20	432,500	9.92
Outstanding at end of period and expected to vest.....	<u>1,535,187</u>	<u>7.90</u>	<u>1,464,203</u>	<u>8.02</u>
Options exercisable.....	<u>1,179,143</u>	<u>\$ 7.64</u>	<u>880,457</u>	<u>\$ 7.19</u>
Weighted average fair value of options granted during the year .....		<u>\$ —</u>		<u>\$ 5.25</u>

The weighted average remaining contractual term of stock options outstanding and expected to vest at December 31, 2016 is 6.4 years. The weighted average remaining contractual term of stock options exercisable at December 31, 2016 is 5.8 years.

Stock-based compensation expense for the years ended December 31, 2016 and 2015 was:

	2016	2015
Research and development .....	\$ 439,982	\$ 724,776
Plasma centers .....	52,973	48,386
General and administrative.....	757,119	937,885
Total stock-based compensation expense .....	<u>\$ 1,250,074</u>	<u>\$ 1,711,047</u>

As of December 31, 2016, the total unrecognized compensation expense related to unvested options totaled \$1,616,337. The weighted-average vesting period over which the total compensation expense will be recorded related to unvested options at December 31, 2016 was approximately 2.2 years.

The aggregate intrinsic value is calculated as the difference between (i) the closing price of the common stock at December 31, 2016 and (ii) the exercise price of the underlying awards, multiplied by the number of options that had an exercise price less than the closing price on the last trading day. The Company's outstanding and exercisable options had an intrinsic value of \$260,974 as of December 31, 2016.

## 10. 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,	
	2016	2015
Benefit at U.S. Federal statutory rate .....	\$ (6,635,151)	\$ (6,109,776)
State taxes – deferred .....	(266,312)	(124,874)
Increase in valuation allowance, inclusive of true-ups.....	5,755,413	6,021,614
Research and development credits .....	(322,499)	(389,355)
Other .....	1,468,549	602,391
Benefit for income taxes .....	<u>\$ —</u>	<u>\$ —</u>

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

	December 31,	
	2016	2015
Federal and state net operating loss carryforwards .....	\$ 30,843,479	\$ 25,834,860
Federal and state research credits.....	4,099,249	4,353,534
Transaction costs.....	652,695	—
Deferred revenue.....	972,345	1,020,872
Accrued expenses and other.....	747,586	350,675
Total gross deferred tax assets .....	37,315,354	31,559,941
Less: valuation allowance for deferred tax assets .....	(37,315,354)	(31,559,941)
Net deferred tax assets .....	\$ —	\$ —

We have incurred substantial losses during our history. As of December 31, 2016, we had Federal and state Net Operating Losses, (“NOLs”) of \$87.8 million and \$75.2 million, respectively, as well as Federal research and development tax credit carryforwards of approximately \$4.1 million. The \$87.8 million and \$75.2 million in Federal and state NOLs, respectively, 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 utilize our NOLs fully. 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.

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.

**11. SEGMENTS**

The Company is engaged in the development and commercialization of human plasma and plasma-derived therapeutics. The Company also operates two FDA-licensed source plasma collection facilities located in Norcross, Georgia and Marietta, Georgia. 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.

The plasma collection center segment includes the Company's operations in Georgia. The research and development segment includes the Company's plasma development operations in New Jersey.

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Summarized financial information concerning reportable segments is shown in the following tables:

<b>Year Ended December 31, 2016</b>	<b>Plasma Collection Centers</b>	<b>Research and Development</b>	<b>Corporate</b>	<b>Consolidated</b>
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)	(7,688,238)	(8,351,908)	(17,330,395)
Other expense .....	—	—	(2,184,756)	(2,184,756)
Loss before income taxes.....	(1,290,249)	(7,688,238)	(10,536,664)	(19,515,151)
Total assets .....	2,421,535	—	21,263,550	23,685,085
Depreciation and amortization expense .....	414,464	—	55,112	469,576

<b>Year Ended December 31, 2015</b>	<b>Plasma Collection Centers</b>	<b>Research and Development</b>	<b>Corporate</b>	<b>Consolidated</b>
Revenues.....	\$ 7,050,283	\$ —	\$ 127,350	\$ 7,177,633
Cost of product revenue.....	4,311,461	—	—	4,311,461
Gross profit.....	2,738,822	—	127,350	2,866,172
Loss from operations .....	(1,879,243)	(7,015,946)	(6,618,618)	(15,513,807)
Other expense .....	—	—	(2,456,123)	(2,456,123)
Loss before income taxes.....	(1,879,243)	(7,015,946)	(9,074,741)	(17,969,930)
Total assets .....	2,719,641	—	20,994,876	23,714,517
Depreciation and amortization expense .....	419,301	—	50,520	469,821

The “Corporate” column includes general and administrative overhead expenses. Total assets included in the “Corporate” column above includes assets related to corporate and support functions.

**12. 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 approximately \$0.2 million and \$0.1 million of related compensation expense for the years ended December 31, 2016 and 2015, respectively.

**13. SUBSEQUENT EVENTS**

**Summary of Proposed Acquisition of Certain Assets of BPC**

On January 21, 2017, the Company and its wholly-owned subsidiary, ADMA BioManufacturing, LLC, a Delaware limited liability company (“Buyer”), entered into a definitive Master Purchase and Sale Agreement (as amended, restated, supplemented, or otherwise modified from time to time (the “Purchase Agreement”) with Seller, and for certain limited purposes set forth in the Purchase Agreement, Biotest, and Biotest US Corporation, a Delaware corporation and subsidiary of Biotest (together with Biotest, the “Biotest Guarantors”), pursuant to which Buyer has agreed to acquire certain assets and assume certain liabilities constituting the therapy business of Seller (the “Business”). The foregoing transactions and the other transactions contemplated by the Purchase Agreement are collectively referred to as the “Proposed Acquisition.” The Business includes (a) a FDA-licensed immune globulin manufacturing and plasma products production facility of two buildings in Boca Raton, Florida, and the associated real property, (b) all exclusive rights to FDA licensed biologics products Nabi-HB®, BIVIGAM® and the

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
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investigational product CIVACIR®, (c) in-process inventory with an agreed-upon value of at least \$5.0 million, (d) certain other properties and assets used exclusively in the Business, and (e) certain additional assets which relate to both the Business and Seller's plasma business the arrangement with respect to which will be documented in a transition services agreement to be mutually agreed by the parties between the signing of the Purchase Agreement and the closing of the Proposed Acquisition.

Subject to the terms and conditions of the Purchase Agreement, (i) upon the closing, the Company has agreed to assume certain liabilities of Seller related to the Business, including, without limitation, related to (x) product liabilities, breach of warranty, product complaints, product returns, post-market commitments, recalls, adverse event reporting, product deviation reporting, lookbacks, market withdrawals and field corrections or similar claims for injury to person or property with respect to the Business or any product of the Business to the extent such liabilities relate to products manufactured and sold by Buyer after the closing (other than inventory transferred to the Company at the closing, which will be allocated 50% to Buyer and 50% to Seller if not traceable to acts or omissions of a particular party); and (y) other regulatory matters, whether related to the pre-closing or post-closing period and including any liabilities related to the products of the Business, the FDA warning letter (the warning letter issued by the FDA to Seller in connection with outstanding issues requiring remediation at the manufacturing facility in Boca Raton, Florida), noncompliance with applicable laws and legal proceedings related to the foregoing, but excluding such liabilities that arise out of any fraud, willful misconduct or intentional misrepresentation by Seller prior to the closing (the "Assumed Liabilities"); (ii) upon the closing, the Company has agreed to deliver to Seller an aggregate equity interest in the Company equal to 50%, less one share, of its issued and outstanding capital stock (calculated as of immediately following the closing and on a post-closing issuance basis) (the "Biotest Equity Interest"), consisting of (x) common stock representing 25% of the Company's issued and outstanding common stock, equal to 4,295,580 common shares and (y) non-voting common stock equal to 8,591,160 shares of the Company's non-voting common stock representing the balance of the Biotest Equity Interest which is convertible into common stock of the Company upon the occurrence of certain specified events; (iii) upon the closing, the Company agreed to issue to Seller warrants, if any, necessary to acquire additional shares of the Company's capital stock equal to the excess, if any, of (x) the number of shares represented by rights, options and warrants issued by the Company between September 12, 2016 until the closing, over (y) 184,000 shares; and (iv) on January 1, 2019, pursuant to the terms of a separate purchase agreement to be entered into by the parties at the closing, the Company has agreed to sell, transfer and convey to Seller for no additional consideration, all of its right, title and interest in and to the Company's certain biocenter located in Norcross, Georgia and the Company's certain biocenter located in Marietta, Georgia, which are subject to a repurchase right in favor of the Company if within five years after January 1, 2019, the Biotest stockholders and its related entities own less than 20% of the Company's issued and outstanding capital stock. As part of the consideration, upon the closing, Seller will also be granted the right to designate one director and one observer to the Company's board of directors, and under certain circumstances, Seller will be granted the right to designate an additional director.

Additionally, on the closing date, Seller has agreed to (i) deliver to the Company a capital contribution of \$12.5 million in respect of the Biotest Equity Interest, which capital contribution will be contributed by Seller to Buyer; and (ii) fund a \$15.0 million unsecured subordinated loan to the Company, which (a) will bear interest at a rate of 6% per annum, payable semiannually in arrears, (b) has a term of five years and (c) will not be subject to any prepayment penalty or other breakage costs. Such loan will be subordinated to the Company's existing indebtedness as of the signing of the Purchase Agreement and any additional indebtedness approved by the Company's board of directors which is secured only by a mortgage on the owned real property acquired in connection with the transaction. Such loan will rank pari passu with all additional indebtedness approved by the Company's board of directors that is not secured only by a mortgage on such owned real property and if such additional indebtedness is secured, the loan from Seller will be secured on a pari passu basis with such additional indebtedness. At any time after the closing, if the Company undertakes an underwritten equity financing or a Private Investment in Public Equity, or PIPE, offering involving at least one unrelated third party, Biotest and/or Seller have agreed to participate pro rata in accordance with the Biotest Equity Interest up to an aggregate amount equal to \$12.5 million.

Upon the closing, the parties will also enter into a ten-year plasma supply agreement, pursuant to which (x) Seller will sell to the Company high titer Hepatitis B plasma at a specified price (indexed by inflation), and (y) the Company will purchase from Seller all Hepatitis B plasma necessary to produce Nabi-HB® unless the Company requires more than a specified amount, in which case the Company may use alternative sources for the excess



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quantity. Additionally, the parties have agreed to a mutual release with respect to any claims relating to or arising from any breach or default under the Manufacturing Supply and License Agreement and Master Services Agreement between the Company and Seller. The mutual release is effective as of the signing of the Purchase Agreement conditioned on the closing of the Proposed Acquisition at which time the Manufacturing Supply and License Agreement and Master Services Agreement will terminate and the mutual release will no longer be conditional.

The Purchase Agreement contains customary representations and warranties of the parties, including, without limitation, with respect to: organization; power and authority; due authorization; enforceability; capitalization; no conflict; no consents required; no actions; no orders; financial statements; indebtedness; no undisclosed liabilities; absence of certain changes; taxes; contracts; customers and suppliers; intellectual property; title to properties; real property; employee benefit plans; employees; insurance; compliance with laws; environmental; material permits; inventory; affiliate transactions; and no brokers.

The Purchase Agreement also contains customary covenants and agreements, including covenants and agreements of: Seller to conduct the Business in the ordinary course until the Proposed Acquisition is completed or terminated and to not take certain actions relating to the Business during the interim period between signing and closing, without the Company's prior consent not to be unreasonably withheld, conditioned or delayed; the Company to conduct its business in the ordinary course until the Proposed Acquisition is completed or terminated and to not take certain actions relating to its business during the interim period between signing and closing, without Seller's prior consent not to be unreasonably withheld, conditioned or delayed; Seller not to compete with the Company in certain lines of business for a period of five years following the closing date; Seller and the Biotest Guarantors not to solicit the Company's employees for one year following the closing date; the Company not to solicit Seller's employees for one year following the closing date; and Seller not to interfere with the Company's customers for five years following the closing date.

Subject to certain limitations, the Company or Seller may terminate the Purchase Agreement if the Proposed Acquisition has not been consummated by September 30, 2017. A termination of the Purchase Agreement under certain customary circumstances relating to (i) the Company's board of directors exercising their fiduciary out will entitle Seller to receive from the Company a termination fee in an amount equal to \$2.5 million; or (ii) the Company's failure to obtain the requisite stockholder approval will entitle Seller to receive expense reimbursement in an amount up to \$2.5 million. In no event will Seller be entitled to both a termination fee and expense reimbursement.

Seller and the Company will each indemnify the other party after the closing for any losses arising from breaches of its representations, warranties, covenants and agreements in the Purchase Agreement. In addition, the Company will indemnify Seller after the closing for any assumed liability, and Seller will indemnify the Company after the closing for any excluded asset or excluded liability. The representations, warranties and pre-closing covenants generally survive for 15 months following the closing of the transaction and each party's indemnification obligations with respect to (a) its representations and warranties (other than its fundamental representations, which include representations related to taxes, organization, due authorization, organizational documents, no conflicts; enforceability, title; sufficiency, the Amended and Restated Product Distribution Agreement, effective as of January 19, 2016, by and between Seller and Kedrion Biopharma Inc., or the Kedrion Contract, brokers, etc. and ownership of the Company's securities) are subject to a \$25,000 mini-basket and \$750,000 true deductible; and (b) its representations and warranties (other than fundamental) and pre-closing covenants are subject to a \$25.0 million cap.

Seller will be entering into a standstill with the Company, which will limit Seller's ability to control the Company. Seller will also agree to a six (6) month lock-up of the sale of the Company's securities.

The consummation of the Proposed Acquisition is subject to the satisfaction of certain conditions, including approval of the Proposed Acquisition by the stockholders of ADMA and approval of the amended and restated certificate of incorporation of the Company by the stockholders of ADMA. The Proposed Acquisition is not subject to any financing conditions. There can be no assurance as to when the closing conditions will be satisfied, if at all.

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Upon consummation and closing of the Proposed Acquisition, the Company believes it will be uniquely positioned to offer a fully vertically integrated plasma products and immune globulin platform in the U.S.

**Summary of Lease with Home Center Properties, LLC**

On February 17, 2017, ADMA Bio Centers Georgia Inc. (“ADMA BioCenters”), a Delaware corporation and a wholly owned subsidiary of the Company, entered into a lease (the “Lease”) with Home Center Properties, LLC, a Georgia limited liability company (“Landlord”), for approximately 12,167 square feet located at 166 Earnest W. Barrett Parkway, Marietta, Georgia 30066 (the “Premises”). Pursuant to the Lease, ADMA BioCenters will utilize the Premises as a facility specializing in the collection of human plasma and blood, general office administration and any other related use.

The Lease has an initial term of approximately eight years and nine months (the “Initial Term”), commencing upon substantial completion of “Landlord’s Work” (as defined in the Lease) (the “Lease Commencement Date”), with rent payments commencing 150 days after the Lease Commencement Date. ADMA BioCenters’ total monthly cost of the Premises (inclusive of Landlord’s “Operating Costs”, “Taxes” and “Insurance Charges” (as such terms are defined in the Lease)) will range from approximately \$20,000 to \$27,000 during the Initial Term; *provided, however, that*, provided ADMA BioCenters is not in default of the Lease beyond the expiration of any applicable notice and cure period, ADMA BioCenters shall not be obligated to make any rent payments for the first five calendar months of the Initial Term beginning on the Lease Commencement Date and the last four months of the Initial Term beginning on the 102<sup>nd</sup> month after the Lease Commencement Date. Provided that the Lease is in full force and effect and provided there has been no “Event of Default” (as defined in the Lease) beyond the expiration of any applicable notice and cure period, ADMA BioCenters shall have the option to extend the term of the Lease for two additional periods of five years each (each, an “Extension Term”), each Extension Term on the same terms, covenants and conditions as the Lease, with the rent for each Extension Term to equal the mutually agreed fair market value of the Premises on the commencement of such Extension Term. The Lease also contains customary default provisions, representations, warranties and covenants.

The foregoing summary of the material terms of the Lease is qualified in its entirety by reference to the full text of the Lease, which is attached hereto as Exhibit 10.22 and incorporated herein by reference.

## EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description</b>
2.1 (16)	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.
3.1 (1)	Certificate of Incorporation, as amended.
3.2 (2)	Certificate of Amendment of Certificate of Incorporation.
3.3 (3)	Amended and Restated Bylaws.
4.1 (4)	Specimen Common Stock Certificate.
4.2 (1)	Form of Placement Agent Warrant.
4.3 (5)	Form of Warrant Agreement with Hercules Technology Growth Capital, Inc.
4.4 (13)	Form of Warrant Agreement with Oxford Finance LLC.
4.5 (5)	Form of Secured Term Loan Promissory Note issued to Hercules Technology Growth Capital, Inc.
4.6 (13)	Form of Secured Term B Loan Promissory Note issued to Oxford Finance LLC.
10.1† (6)	2007 Employee Stock Option Plan, as amended by Amendment No. 3.
10.2 (1)	Amended and Restated Placement Agency Agreement, dated February 12, 2012, between ADMA Biologics, Inc. and Rodman & Renshaw, LLC.
10.3†(12)	Amended and Restated Employment Agreement, dated January 28, 2016, by and between ADMA Biologics, Inc. and Adam Grossman.
10.4+ (7)	Manufacturing Agreement, dated as of October 23, 2006, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc., as amended as of October 23, 2011 and as of December 2, 2011.
10.5+ (7)	Plasma Purchase Agreement, dated as of November 17, 2011, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc., as amended as of December 1, 2011.
10.5.1+(12)	Second Amendment to Plasma Purchase Agreement, dated as of December 18, 2015, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc.
10.5.2 (13)	Third Amendment to Plasma Purchase Agreement, dated as of April 8, 2016, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc.
10.6 (15)	Amended and Restated Agreement for Services, effective as of January 1, 2016, by and between ADMA Biologics, LLC and Areth LLC.
10.7 (1)	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.
10.8+ (11)	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.
10.9 (1)	Form of Indemnification Agreement.
10.10 †(12)	Amended and Restated Employment Agreement, dated January 28, 2016, by and between ADMA Biologics, Inc. and Brian Lenz.
10.11 (8)	Placement Agency Modification and Release Agreement, dated as of June 15, 2012, by and between ADMA Biologics, Inc. and Rodman & Renshaw, LLC.
10.12+(9)	Testing Services Agreement, dated as of June 8, 2012, by and between ADMA Biologics, Inc. and Quest Diagnostics Clinical Laboratories, Inc.
10.13+ (12)	Amended and Restated Plasma Supply Agreement, dated as of March 23, 2016, by and between ADMA Biologics, Inc. and Biotest Pharmaceuticals Corporation.
10.14†(12)	Amended and Restated Employment Agreement, dated January 28, 2016, by and between ADMA Biologics, Inc. and James Mond, M.D., Ph.D.

- 10.15 (5) Loan and Security Agreement, dated as of December 21, 2012, by and among ADMA Biologics, Inc., ADMA Plasma Biologics, Inc., ADMA Bio Centers Georgia Inc. and Hercules Technology Growth Capital, Inc.
- 10.15.1 (11) First Amendment to Loan and Security Agreement, dated as of February 24, 2014, by and among ADMA Biologics, Inc., ADMA Plasma Biologics, Inc., ADMA Bio Centers Georgia Inc. and Hercules Technology Growth Capital, Inc.
- 10.16 (14) 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.
- 10.16.1 (14) 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.
- 10.17 (5) Equity Rights Letter, dated December 21, 2012, from ADMA Biologics, Inc. to Hercules Technology Growth Capital, Inc.
- 10.18+ (5) Manufacturing, Supply and License Agreement, dated as of December 31, 2012, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc.
- 10.19+ (5) License Agreement, effective as of December 31, 2012, by and between ADMA Biologics, Inc. and Biotest Aktiengesellschaft.
- 10.20 (16) 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.
- 10.21† (10) ADMA Biologics, Inc. 2014 Omnibus Incentive Compensation Plan.
- 10.22\* Lease, effective as of February 17, 2017, by and between Home Center Properties, LLC and ADMA Bio Centers Georgia Inc.
- 21.1 (4) Subsidiaries of Registrant.
- 23.1\* CohnReznick LLP Consent.
- 24.1\* Power of Attorney (included on signature page).
- 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.
- 101\* The following materials from ADMA Biologics, Inc. Form 10-K for the year ended December 31, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at December 31, 2016 and December 31, 2015, (ii) Consolidated Statements of Operations for the years ended December 31, 2016 and 2015 (iii) Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2016 and 2015, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015 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.

# Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

\* Filed herewith.

\*\* Furnished herewith.

† Management compensatory plan, contract or arrangement.

- (1) Incorporated herein by reference to the Company's Current Report on Form 8-K, filed with the SEC on February 13, 2012.
- (2) Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on August 26, 2013.
- (3) 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) Incorporated herein by reference to Amendment No. 1 to the Company's Current Report on Form 8-K/A, filed with the SEC on March 29, 2012.
- (5) Incorporated herein by reference to the Company's Registration Statement on Form S-1, filed with the SEC on February 11, 2013.
- (6) Incorporated herein by reference to Exhibit A to the Information Statement on Schedule 14C, filed with the SEC on October 29, 2012.
- (7) Incorporated herein by reference to Amendment No. 3 to the Company's Current Report on Form 8-K/A, filed with the SEC on June 22, 2012.
- (8) Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 21, 2012.
- (9) Incorporated herein by reference to Amendment No. 4 to the Company's Registration Statement on Form S-1, filed with the SEC on August 10, 2012.
- (10) Incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement filed with the SEC on April 29, 2014.
- (11) Incorporated by reference to the Company's annual report on Form 10-K, filed with the SEC on March 28, 2014.
- (12) Incorporated by reference to the Company's annual report on Form 10-K, filed with the SEC on March 23, 2016.
- (13) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2016.
- (14) Incorporated by reference to Exhibit 10.23 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2015.
- (15) Incorporated by reference to Exhibit 10.18 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 12, 2016.
- (16) Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 23, 2017.



## Corporate Information

### Board of Directors

**Steven A. Elms**

Chairman of the Board

**Dr. Jerrold B. Grossman**

Founder and Vice Chairman

**Bryant E. Fong**

Director

**Dov A. Goldstein, M.D.**

Director

**Lawrence P. Guiheen**

Director

**Eric I. Richman**

Director

**Adam S. Grossman**

Founder, Director

### Management Team

**Adam S. Grossman**

President and CEO

**Brian Lenz, CPA**

Vice President, CFO

**James Mond, M.D., Ph.D.**

Executive Vice President, CSO & CMO

### Code of Ethics

ADMA Biologics, Inc. has adopted a corporate Code of Ethics and Business Conduct Standards that applies to all of its directors, officers (including our chief executive officer and chief financial and accounting officer) and employees. ADMA requires that all of its directors, officers and employees certify compliance with the Code of Ethics and Business Conduct Standards on an annual basis. A copy of the Code of Ethics and Business Conduct Standards is accessible through the "Investors-Corporate Governance-Governance Documents" section of the ADMA Biologics, Inc. website at [www.admabiologics.com](http://www.admabiologics.com).

### Corporate Headquarters

465 Route 17 South

Ramsey, NJ 07446

Phone: (201) 478-5552

Fax: (201) 478-5553

Email: [info@admabiologics.com](mailto:info@admabiologics.com)

[www.admabiologics.com](http://www.admabiologics.com)

### Common Stock Trading

The Company's common stock trades on the NASDAQ Capital Market under the symbol "ADMA".

### Annual Meeting of Stockholders

The Company's Annual Meeting of Stockholders will be held on May 25, 2017, at the offices of Paul, Weiss, Rifkind, Wharton & Garrison LLP at 1285 Avenue of the Americas, New York, NY 10019.

### Investor Relations

For additional information, please contact our Investor Relations Department at (201) 478-5552 or via email at: [info@admabiologics.com](mailto:info@admabiologics.com)

### Independent Auditors

CohnReznick LLP

4 Becker Farm Road

Roseland, NJ 07068

Phone: (973) 228-3500

### Transfer Agent

Continental Stock Transfer & Trust Company

17 Battery Place

New York, NY 10004

Phone: (800) 509-5586

[www.continentalstock.com](http://www.continentalstock.com)

### Legal Counsel

DLA Piper LLP (US)

51 John F. Kennedy Parkway, Suite 120

Short Hills, NJ 07078

Phone: (973) 520-2550

# OUR VALUES

**Our superior commitment to patients is anchored to our core values:**



## HUMAN

We make human connection a priority in our products, our patients, and our people.



## COURAGEOUS

We take on the challenges others won't by embracing rare diseases and the underserved populations.



## DYNAMIC

We are relentless in transforming groundbreaking science into meaningful action.



## TENACIOUS

We are tireless in our pursuit of perfection because people's lives are in our hands.

**Through our relentless commitment to improving people's lives, we are changing the future with our immunotechnology.**

### Company Profile

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

ADMA also operates ADMA BioCenters, FDA-licensed and GHA-certified source plasma collection facilities, which provides a portion of blood plasma for the manufacture of our lead product candidate, RI-002.

RI-002 targets the unmet needs of immune deficient patients. RI-002 demonstrated positive Phase III results and successfully achieved its primary endpoint of preventing serious bacterial infections such as bacterial pneumonia, osteomyelitis and bacterial sepsis in immune-compromised PIDD patients.

### Cautionary Statement regarding forward-looking information

This annual report contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Reference is made in particular to statements regarding the description of the plans for product development, announcement of results, submissions to regulatory authorities, possible approvals thereof, FDA action and commercial sales, expectations, objectives, and other forward-looking statements included in the Letter to the Stockholders and Annual Report on Form 10-K for the fiscal year ended December 31, 2016, which is included herein. Such statements are based on management's current expectations and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. In particular, careful consideration should be given to cautionary statements made in the company's filings with the SEC, specifically those statements found in its Annual Report on Form 10-K for the fiscal year ended December 31, 2016 under the caption "Risk Factors" in Item 1A. Therefore, current and prospective security holders are cautioned that there can be no assurance that the forward-looking statements contained in this annual report will prove to be accurate. Except as required by law, ADMA undertakes no responsibility to update any forward-looking statements or announce revisions to any forward-looking statements.



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