

ADMA BIOLOGICS, INC.  
Form 10-K  
March 23, 2016

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, 2015

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

465 State Route 17, Ramsey, New Jersey 07446  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (201) 478-5552

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

Title of each class: Name of each exchange on which registered:  
Common stock, par value \$0.0001 per share NASDAQ Capital Market

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

Edgar Filing: ADMA BIOLOGICS, INC. - Form 10-K

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 x Smaller Reporting Company

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

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates was \$40,940,784, as of June 30, 2015 (the last business day of the registrant's most recently completed second fiscal quarter), based on a total of 4,421,251 shares of common stock held by non-affiliates and on a closing price of \$9.26 as reported on the Nasdaq Capital Market on June 30, 2015.

The number of shares of the registrant's Common Stock, par value \$0.0001 per share, outstanding as of March 23, 2016 was 10,713,087.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2016 Annual Meeting of Stockholders or annual report on Form 10-K/A, to be filed on or before April 29, 2016, are incorporated by reference into Part III of this annual report on Form 10-K.

---

ADMA BIOLOGICS, INC.

PART I	
<u>Item 1.</u>	<u>Business</u> 5
<u>Item 1A.</u>	<u>Risk Factors</u> 19
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u> 37
<u>Item 2.</u>	<u>Properties</u> 37
<u>Item 3.</u>	<u>Legal Proceedings</u> 37
<u>Item 4.</u>	<u>Mine Safety Disclosures</u> 38
PART II	
<u>Item 5.</u>	<u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> 38
<u>Item 6.</u>	<u>Selected Financial Data</u> 39
<u>Item 7.</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> 39
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 51
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u> 51
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u> 51
<u>Item 9A.</u>	<u>Controls and Procedures</u> 51
<u>Item 9B.</u>	<u>Other Information</u> 52
PART III	
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u> 52
<u>Item 11.</u>	<u>Executive Compensation</u> 52

<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	52
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	52
<u>Item 14. Principal Accounting Fees and Services</u>	52
PART IV	
<u>Item 15. Exhibits, Financial Statement Schedules</u>	52

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 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, and the labeling or nature of any such approvals,
  - the expected timing, progress and results of clinical development and trials,
    - 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,
- the comparability of results of RI-002 to other comparably run injectable immune globulin trials,
- the potential of RI-002 to provide meaningful clinical improvement for patients living with primary immune deficiency disease,
  - our intellectual property position,
  - our manufacturing 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,
  - the achievement of clinical and regulatory milestones,
  - expectations for future capital requirements,
- expectations of the scope of patent protection with respect to RI-002.

These statements may be found under “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” 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,” “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.

You should also consider carefully the statements under “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 BioCenters 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 market specialty plasma-based biologics for the treatment and prevention of certain infectious diseases. Our targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons. Our product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients at risk of contracting infectious diseases.

Our lead product candidate, RI-002, is intended for the treatment of Primary Immune Deficiency Disease, or PIDD, and has completed a pivotal Phase III clinical study. In the third quarter of 2015, we submitted and the U.S. Food and Drug Administration, or FDA, accepted for review, a Biologics License Application, or BLA, for RI-002 for the treatment of PIDD. The FDA could approve this BLA within approximately one year of its filing, in which case potential first commercial sales could occur as early as the fourth quarter of 2016. As part of our currently ongoing commercialization efforts, we plan to increase our initiatives by hiring a small, specialty sales force to market RI-002 to hospitals, physician offices/clinics, and other specialty treatment organizations. We anticipate staffing our company with additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, reimbursement, inventory and logistics, human resources, and financial and operational management. If and when we receive FDA approval, we may also use a network of national distributors to assist with order fulfillment for RI-002 for use by healthcare professionals and hospitals.

RI-002 achieved positive data in its clinical trials. RI-002 has been administered for a total of 793 infusions with zero serious adverse events to 59 patients in 9 treatment centers throughout the United States in a pivotal Phase III clinical trial. RI-002 is an injectable immune globulin derived from human plasma, enriched with standardized high levels of naturally occurring polyclonal antibodies (e.g., streptococcus pneumoniae, H. influenza type B, CMV, measles, tetanus, etc.) as well as high levels of antibodies targeted to Respiratory Syncytial Virus, or RSV. Our patented, microneutralization assay allows us to standardize RI-002's potency by effectively identifying and isolating hyperimmune donor plasma with high-titer RSV antibodies, thereby allowing us to differentiate our immune globulin and may potentially garner a premium price.

PIDD, a genetic disorder that causes a deficient or absent immune system, is caused by hereditary or genetic defects and can affect anyone regardless of age or gender. PIDD patients are more vulnerable to infections and more likely to suffer complications from these infections. Intravenous immune globulin, or IVIG, is a plasma derived product that is

used to prevent serious infections in patients with PIDD. It is comprised of polyclonal antibodies, which are proteins produced by B-cells that are used by the body's immune system to neutralize foreign objects such as bacteria and viruses. RI-002, a specialty IVIG with standardized levels of high-titer RSV antibodies, is intended to prevent infections in PIDD patients. The polyclonal antibodies which are present in RI-002 are expected to prevent infections in immune-compromised patients. It is estimated that there are about 250,000 diagnosed PIDD patients in the United States, approximately half of whom are treated with IVIG regularly. In the United States, sales of immune globulin products for all its uses were reported to be approximately \$4.8 billion in 2014. Since the introduction of IVIG therapy, the incidence of infections in IVIG-treated patients has dropped significantly.



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

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

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

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

We operate two FDA-licensed, German Health Authority, or GHA, and Korean Ministry of Food and Safety, or MFDS, certified source plasma collection facilities at our ADMA BioCenters located in Norcross, Georgia and Marietta, Georgia, which provide us with a portion of our blood plasma for the manufacture of RI-002. During the third quarter of 2014, we completed the expansion of our Norcross, Georgia ADMA BioCenters facility by securing additional rented space to increase our donor and collection screening areas to meet an increase in market demand for source plasma. In 2014, we entered into another lease for a second plasma collection center in Marietta, Georgia, and we completed construction of this new facility during the fourth quarter of 2014. In November 2014, we announced the opening of our second plasma collection center in Marietta, Georgia. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase, and market conditions at the time of sale. Plasma collected from ADMA BioCenters' two Georgia facilities that is not used for making RI-002 is sold to third party customers in the United States, and other locations where we are approved globally under supply agreements or in the open "spot" market. We have entered into long term manufacturing and licensing agreements with Biotest AG and their United States subsidiary, Biotest Pharmaceuticals, Inc., together

referred to as Biotest, that provide for the exclusive manufacture of RI-002. At the same time, we granted Biotest an exclusive, royalty-bearing license to market and sell RSV antibody-enriched IVIG in Europe and in other selected territories in North Africa and the Middle East.

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

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

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

#### 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. We have announced that the FDA accepted the BLA for RI-002 for review during the third quarter of 2015. We also have previously announced that RI-002 achieved positive Phase III results and successfully achieved meeting the primary endpoint for the treatment of PIDD in accordance with the FDA Guidance for Industry. We are seeking marketing approval of RI-002 from the FDA during 2016.
- 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 control of a portion 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 ADMA BioCenters' facilities. These programs would be initiated during the normal course of business and are expected to cost less than \$1 million to implement. We may also consider growth through the creation and licensing of additional ADMA BioCenters facilities in various regions of the United States. 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.

## 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 United States, or approximately 250,000 people. Of these 250,000 people diagnosed with PIDD in the United States, 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 United States, 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 400 plasma donation centers in the United States. As noted in a variety of plasma industry trade reports and related conferences, approximately 28 million liters of source plasma were collected in the United States in 2014. In the United States, 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 United States 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 United States, 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.

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 report, the worldwide market for plasma-derived therapeutic drug products was approximately \$15 billion and the United States market for all plasma-derived products was approximately \$7.8 billion. IVIG products accounted for approximately \$4.8 billion of sales in the United States 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.

## RI-002, Our Lead Product Candidate

### General

RI-002 is a plasma-derived, polyclonal IVIG, with standardized high levels of antibodies against RSV. RI-002 is initially being developed as a treatment for patients with PIDD. By using our patented proprietary assay, we are able to identify plasma donors with elevated amounts of RSV antibodies, measure these donors' plasma RSV levels and formulate RI-002 with standardized high levels of RSV antibodies. In addition, by using our assay within manufacturing, we are able to demonstrate consistent lot-to-lot RSV antibody titer potency. To our knowledge, there is no other IVIG product on the market that contains standardized high levels of RSV antibodies and that is produced with reported consistent lot-to-lot potency. RI-002 is an improved formulation of our prior product candidate RI-001. RI-002 is manufactured using the same FDA-approved contract manufacturing facility as its predecessor. To date, RI-002 has demonstrated improved production yields, an improved stability profile and comparable anti-RSV antibody titer potency levels relative to the prior formulation.

### Results of Phase III Clinical Trial

On December 3, 2014, we announced that RI-002 demonstrated positive Phase III results and successfully achieved its primary endpoint, that treatment with RI-002 resulted in no SBI observed in study subjects during the trial. The trial was conducted as a single arm study in which patients were treated approximately once per month for a period of 12 months plus 90 days thereafter for follow-up. Fifty-nine patients were enrolled in 9 treatment centers in the United States. The pivotal Phase III primary endpoint followed published FDA industry guidance, which provides for a reduction in the incidence of SBI to less than one per year in each subject receiving IVIG.

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

Data from our Phase III trial was presented as an abstract and presentation at the 2015 American Academy of Allergy Asthma & Immunology Annual Meeting on February 22, 2015. The poster presentation was titled: "Results of a Phase III trial in Patients with PIDD Using an IVIG Containing High Titer Neutralizing Antibody to Respiratory Syncytial Virus (RSV)."

### Results of Phase II Clinical and Compassionate Use Experience

We 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. In that trial, RI-001 treated patients demonstrated a statistically significant rise in anti-RSV titers compared to patients receiving placebo. This trial was conducted with 21 patients in the United States, 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 4-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. Serum samples were obtained from 13 patients. Samples showed that patients had a four-fold or greater rise in RSV antibody titers from baseline. Serum samples were not obtained from two patients that received Palivizumab. The drug was well-tolerated in these 15 patients and there were no reports of serious adverse events attributable to RI-001.

Data from our Phase II trial, compassionate use experience and testing of RI-002 in the cotton rat RSV animal model was presented as an abstract and oral presentation at the 2013 RSV Vaccines for the World Conference held on October 14, 2013. The abstract is titled: “Polyclonal human IVIG with standardized high-levels of RSV neutralizing antibodies: A summary of animal and human studies.”

### 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 Biotest.

In December 2012, we entered into our Manufacturing, Supply and License Agreement with Biotest. Under the agreement, we agreed to purchase exclusively from Biotest 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 Biotest’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.

Pursuant to the terms of a Plasma Purchase Agreement with Biotest, we have agreed to purchase from Biotest 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 Biotest, but may also collect high-titer RSV plasma from up to five wholly-owned ADMA BioCenters. During 2015, Biotest 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.

On June 22, 2012, we entered into a Plasma Supply Agreement with Biotest for the purchase of normal source plasma from our ADMA BioCenters, Norcross, Georgia facility to be used in Biotest'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, Biotest applied to the GHA for, and we have subsequently obtained, GHA certification.

On June 7, 2012, we entered into a Testing Services Agreement with Quest Diagnostics Clinical Laboratories, Inc., 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 United States 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 subsequent events and developments may cause our views to change. For a discussion of forward-looking statements, see, "Forward-Looking Statements" on page 4 of this annual report on Form 10-K, and "Item 1A – Risk Factors."

In our manufacturing, supply and license agreement, we granted Biotest 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 Biotest's plasma samples using our proprietary RSV assay, and to reference (but not access) our proprietary information for the purpose of Biotest seeking regulatory approval for the RSV antibody-enriched IVIG in the Territory. As consideration for the license, Biotest agreed to provide us with certain services at no charge and also compensate us with cash payments upon the completion of certain milestones. Biotest 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, Biotest has agreed to grant us an exclusive license for marketing and sales in the United States and Canada for Biotest's Varicella Zoster Immune Globulin, or VZIG, the terms of which we expect to finalize during 2016.



## 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 United States-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: Baxter HealthCare Corporation, CSL Behring, Grifols Biologicals, Octapharma and Biotest. 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 third quarter 2015, we announced that the U.S. Patent and Trademark Office or USPTO issued patent number 9,107,906. The patent titled, 'Compositions and Methods for the Treatment of Immunodeficiency' relates to the use of human plasma immune globulin compositions containing select antibody titers specific for a plurality of respiratory pathogens; methods of identifying human donors and donor samples for use in the compositions; methods of manufacturing the compositions; and methods of utilizing the compositions by prophylactic and or therapeutic treatments (e.g., passive immunization). The term of this patent extends to January 2035. 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 United States 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.

## United States Government Regulation

In the United States, the FDA regulates products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and related regulations. The process required by the FDA before our product candidates may be marketed in the United States 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 "Risk Factors."

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.

A BLA must contain data to assess the safety and effectiveness of the product candidate for the claimed indications in all relevant pediatric subpopulations. The FDA may grant deferrals for submission of data or full or partial waivers. 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 Complete Response Letter, or 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, 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 United States or foreign governmental action.

#### Other Regulatory Requirements

Any products manufactured or distributed by us pursuant to future FDA approvals are subject to continuing regulation by the FDA, including certain kinds of monitoring in the manufacturing of our products, recordkeeping requirements and reporting of adverse experiences associated with the product. Product manufacturers and their subcontractors are required to register with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. 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.

#### 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 United States, 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.

#### Research and Development

ADMA's expenditures on research and development were approximately \$7.0 million and \$9.5 million for fiscal years ended December 31, 2015 and 2014, respectively.

#### Employees

ADMA Biologics, Inc., together with its subsidiaries ADMA Plasma Biologics, Inc. and ADMA BioCenters, Inc., has a total of 74 employees, including 72 full-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 was founded on June 24, 2004 as a New Jersey corporation and re-incorporated in Delaware on July 16, 2007.

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



Edgar Filing: ADMA BIOLOGICS, INC. - Form 10-K

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 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, DC 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

Our only product candidate has completed Phase III clinical development and is pending FDA approval. If we are unable to successfully develop, receive approval, market and commercialize this product candidate, or experience significant delays in doing so, our business will be materially harmed.

Our success is substantially dependent upon achieving regulatory approval and successfully commercializing RI-002. The success of RI-002 and any of our other product candidates will depend on several factors. 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 drug candidate, which would materially harm our business.

We currently generate no revenue from the sale of any products other than blood plasma and we may never be able to develop a marketable product. We have invested substantially all of our efforts and financial resources in the development of our human blood plasma platform, the identification of potential product candidates using that platform and the development of our product candidates. Other than with respect to RI-002, our ability to generate revenue from any of our other product candidates, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of each such product candidate. The success of RI-002 and other product candidates will depend on several factors, including:

- successful completion of preclinical studies and clinical trials;
- receipt of marketing approvals with appropriate conditions from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- our contract manufacturers' ability to maintain their regulatory licenses, continue operations and meet our sales forecasts and manufacturing requirements;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- launching commercial sales of the products, if and when approved, building a sales team and commercial infrastructure, whether alone or in collaboration with others;
- acceptance and acceptable reimbursement levels of the products, if and when approved, by patients, the medical community, governmental and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- protecting our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the drugs following approval.

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.

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 would 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 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 a commercial sales force and commercial infrastructure and meet our obligations. If we are unable to successfully raise additional capital during the second half of 2016, 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.

We anticipate that with our current operations and expenditures, pursuing our commercialization strategy, anticipating FDA approval in the second half of 2016 and our current plasma collection and research and development efforts, our cash and cash equivalents and short term investments are expected to be sufficient to fund our operations into the second half of 2016. 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 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, 2015 and December 31, 2014, we had net losses of \$18.0 million and \$16.8 million, respectively, and from our inception in 2004 through December 31, 2015, we have incurred an accumulated net loss of \$87.4 million. Even if we succeed in developing and commercializing one or more 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 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; and
- expansion and build out of our plasma center network.

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.

Although our financial statements have been prepared on a going concern basis, we must raise additional capital during the second half of 2016 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, 2015, has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2015, 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 2016. 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 2016 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, how aggressively we execute on our commercial initiatives and when the FDA approves our BLA, if at all. If our assumptions underlying our estimated expenses prove to be wrong, we may have to raise additional capital sooner than the second half of 2016.

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 current 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. We estimate that the regulatory approval process for our product candidate, RI-002 will take between 6 to 12 months to complete and it could take up to several years for approval. 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 for RI-002 were performed outside of the United States, 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 filed and accepted 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 United States.

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 United States 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 United States 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 promotional activities may be protected under the First Amendment, the scope of any such protection is unclear. 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 substantially all of our revenues and, therefore, the loss of such customer could have a material adverse effect on our business, results of operations and financial condition.

Substantially all of our revenues are attributed to a single customer, Biotest. Our relationship with Biotest is an arm's length commercial relationship. The loss of Biotest as a customer or a material change in the revenue generated by Biotest 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 Biotest 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 do not intend to establish our own manufacturing facilities. We 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 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 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.

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 prove to be unrepresentative 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 are obligated to begin making payments of principle and interest on February 1, 2017, unless accelerated as a result of certain events of default or 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.

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 and the remaining \$5.0 million is available at our option upon RI-002's BLA being approved from the FDA on or before January 31, 2017. 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 (3) 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 nine 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: 3.0% if prepayment occurs through the second anniversary of funding, 1.0% if prepayment occurs after the second anniversary of the funding date and prior to maturity date of the principal amount of the term loans 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 United States 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 United States 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. Enforcement of claims in patent litigation can be very costly and no assurance can be given that we will prevail. 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. 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 United States 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 United States 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 United States, 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 United States 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 CEO, 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.

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 months, we expect to hire several new employees devoted to commercialization, sales, marketing, medical and scientific affairs, regulatory affairs, quality control, financial, general and operational management. We expect that the hiring of such additional personnel will increase our annual expenditures by approximately \$2.5 million or more. 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 United States 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 United States 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 United States, 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 United States), 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 United States, 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 United States 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 United States or the European Union, we could be adversely affected.

Also, under the United States Foreign Corrupt Practices Act, or FCPA, the United States has increasingly focused on regulating the conduct by United States businesses occurring outside of the United States, 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 United States 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 United States Sentencing Commission Guidelines Manual. Increasing numbers of United States-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 United States, 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 also introduced a biosimilar pathway that will permit companies to obtain FDA approval of generic versions of existing biologics based upon reduced documentation and data requirements deemed sufficient to demonstrate safety and efficacy than are required for the pioneer biologics. The new law provides that a biosimilar application may be submitted as soon as 4 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. With the likely introduction of biosimilars in the United States, we expect in the future to face greater competition from biosimilar products, including a possible increase in patent challenges. The FDA has reported meeting with sponsors who are interested in developing biosimilar products, and is developing regulations to implement the abbreviated regulatory review pathway.

The implementation of the healthcare reform law in the United States may adversely affect our business.

Through the March 2010 adoption of the healthcare reform law in the United States, substantial changes are being made to the current system for paying for healthcare in the United States, 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 United States 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 United States 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 United States 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 United States. 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 \$18.0 million and \$16.8 million for the years ended December 31, 2015 and 2014, respectively. We have an accumulated deficit of \$87.4 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, 2015 and 2014, we incurred research and development expenses of approximately \$7.0 million and \$9.5 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 will be sufficient to fund our operations, as currently conducted, into the second half of 2016. 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 our assumptions underlying our estimated expenses prove to be wrong, we may have to raise additional capital sooner than the second half of 2016. 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. Other than the LSA with Oxford, we currently have no agreements relating to any of these types of transactions and we cannot be certain that additional funding will be available on acceptable terms, or at all. 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, 2015, we had federal and state NOLs of \$72.5 million and \$46.0 million, respectively. The \$72.5 million and \$46.0 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 Capital Stock

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

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

- sales or potential sales of substantial amounts of our common stock;
- 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, nature of approval 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, 2015, almost all of our 10,713,087 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 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 60% 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 auditors 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.

#### 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 for the office, warehouse space and certain related services and have the ability to cancel this agreement upon 30 days’ notice. Areth, LLC is a company controlled by Dr. Jerrold B. Grossman, our Vice Chairman, and we pay 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 \$8,037 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 per month rent. The Norcross, Georgia lease 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 the high and low sales prices for our common stock for the periods indicated below following the quarter ended December 31, 2015, as reported by the NASDAQ Capital Market:

2015		
Quarter Ended	High	Low
March 31	\$ 10.00	\$ 7.57
June 30	\$ 9.58	\$ 8.26
September 30	\$ 9.96	\$ 8.00
December 31	\$ 9.65	\$ 7.74

The table below sets forth the high and low bid prices as quoted on the OTC Bulletin Board for our common stock for the periods specified below through the quarter ended December 31, 2014. Prices quoted on the OTC Bulletin Board reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not necessarily represent actual transactions.

2014		
Quarter Ended	High	Low
March 31	\$ 10.16	\$ 7.50
June 30	\$ 9.99	\$ 6.76
September 30	\$ 10.75	\$ 9.00
December 31	\$ 14.00	\$ 9.55

## Holders

As of March 17, 2016, there were 7 record holders of our common stock. We believe that we have in excess of 900 beneficial holders at such time.

## 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 in 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, 2015:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	1,464,203	\$ 8.02	331,939
Equity compensation plans not approved by security holders	-	\$ -	-
<b>Total</b>	<b>1,464,203</b>	<b>\$ 8.02</b>	<b>331,939</b>

## 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 the historical results of ADMA, 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

## Revenues

Revenue for the year ended December 31, 2015, of \$7,177,633 is primarily comprised of \$7,050,283 from the sale of normal source human plasma through our FDA-licensed, GHA and MFDA certified plasma collection centers segment and \$127,350 of license revenue 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, Biotest Pharmaceuticals Corporation, or Biotest, a subsidiary of Biotest AG, 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.

Our revenue is substantially attributable to a single customer. Depending on the agreement with the customer, 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 at the time of shipment. Revenue is recognized 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 2015, we recorded deferred revenue of \$1,500,000 for a milestone payment provided to us from Biotest upon filing the BLA for RI-002 with the FDA, in accordance with the terms of the license agreement. Deferred revenue of \$1,700,000 was recorded in 2013 as a result of certain research and development services provided in accordance with the same 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.

#### Research and Development Expense

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

The process of conducting pre-clinical 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 uncertainty 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. R&D expenses for the year ended December 31, 2015 decreased compared to the year ended December 31, 2014, due to the completion of our phase III clinical trial during 2014. R&D expenses for the year ended December 31, 2015 were primarily comprised of regulatory consulting fees and other costs incurred from the filing of our BLA for RI-002 with the FDA, testing and validation expenses and close out study costs from our Phase III clinical study along with wages and benefits for employees, including stock-based compensation.

#### General and Administrative Expense

General and administrative, or G&A expense, consists of wages, stock-based compensation and benefits for senior management and staff unrelated to R&D, consulting fees for commercialization planning and infrastructure costs, market research, legal fees, accounting and auditing fees, information technology, rent, maintenance and utilities, insurance, travel and other expenses related to the general operations of the business.

#### 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 and write-off of deferred financing costs, end of term fees, prepayment penalties for the repayment of debt to our prior debt lender and debt discounts amortization for each of the prior and current lender's, end of term fees, back end fees, value of warrants issued, facility and financing fees.

#### 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, 2015 Compared to Year Ended December 31, 2014

## Summary Table

The following table presents a summary of our results of operations for the year ended December 31, 2015 compared to the year ended December 31, 2014.

	Years Ended December 31,	
	2015	2014
Product revenue	\$ 7,050,283	\$ 5,839,989
License and other revenue	127,350	75,556
Total revenues	7,177,633	5,915,545
Cost of product revenue	4,311,461	3,742,367
Research and development	7,015,946	9,517,014
Plasma center	4,618,065	3,850,828
General and administrative	6,745,968	4,823,869
Total operating expenses	22,691,440	21,934,078
Loss from operations	(15,513,807 )	(16,018,533 )
Interest income	37,830	14,217
Interest expense	(1,842,716 )	(1,286,215 )
Change in fair value of stock warrants	67,860	(74,356 )
Loss on extinguishment of debt	(719,097 )	-
Loss before income taxes	(17,969,930 )	(17,364,887 )
State income tax benefit	-	551,724
Net loss	\$ (17,969,930 )	\$ (16,813,163 )
Loss before income taxes in plasma collection segment	\$ (1,879,243 )	\$ (1,752,944 )
Loss before income taxes in research and development	\$ (7,015,946 )	\$ (9,517,014 )

## Revenue

We recorded revenue of \$7,177,633 during the year ended December 31, 2015 compared to \$5,915,545 during the year ended December 31, 2014. Product revenue was \$7,050,283 for the year ended December 31, 2015, 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 Norcross and Marietta, Georgia-based plasma collection centers, compared to product revenue of \$5,839,989 for the year ended December 31, 2014. Product revenue for the year ended December 31, 2015 was primarily attributed to sales made pursuant to our plasma supply agreement with Biotest under which Biotest purchases normal source plasma from ADMA BioCenters to be used in their manufacturing. The increase in product revenue of \$1,210,294 was primarily attributable to revenue generated from the sale of normal source plasma collected at our Marietta, Georgia, plasma collection center, which received approval from the FDA during the third quarter 2015. We sold a majority of the normal source plasma collected from our plasma centers throughout the year. 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, 2015 and 2014, license and other revenue was \$127,350 and \$75,556, respectively, which primarily relates to services and a financial payment by Biotest in accordance with our license agreement and other third parties. We have not generated any revenue from our therapeutics, research and development business segment.

Cost of Product Revenue

Cost of product revenue was \$4,311,461 for the year ended December 31, 2015, and \$3,742,367 for the year ended December 31, 2014. The increased cost of product revenues of \$569,094 for the year ended December 31, 2015 was directly related to the increase in product revenues primarily related to our second plasma center, for the year ended December 31, 2015.

### Research and Development Expenses

R&D expenses, which are attributable to our R&D segment, were \$7,015,946 for the year ended December 31, 2015, a decrease of \$2,501,068 from \$9,517,014 for the year ended December 31, 2014. 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. The decrease in R&D expenses during 2015 compared to 2014 is primarily attributable to the Phase III study being completed during the fourth quarter of 2014 and substantially all drug product supply being manufactured during the year ended December 31, 2014. The decrease in R&D was offset by increased testing and validation studies of \$1,285,183 and regulatory consulting fees of \$606,705 related to our BLA filing for RI-002.

### Plasma Center Operating Expenses

Plasma center operating expenses were \$4,618,065 for the year ended December 31, 2015, an increase of \$767,237 from \$3,850,828 for the year ended December 31, 2014. 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 a result of ADMA BioCenters opening its second plasma collection facility during the fourth quarter of 2014, which resulted in higher costs in wages, rent, maintenance and plasma collection supplies for the year ended December 31, 2015, compared to the year ended December 31, 2014. Our second plasma collection facility received FDA approval to sell plasma in the U.S. during the third quarter ended September 30, 2015. We expect that as plasma collection increases, our operating expenses will also increase accordingly.

### General and Administrative Expenses

G&A expenses were \$6,745,968 for the year ended December 31, 2015, an increase of \$1,922,099 from \$4,823,869 for the year ended December 31, 2014. General and administrative expenses consist of 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 consulting services provided to us related to pre-launch, commercial planning activities, market research and analysis in preparation for anticipated product launch for RI-002 during the second half of 2016.

### Other Income (Expense); Interest Expense

Other expense, net was \$2,456,123 for the year ended December 31, 2015, compared to \$1,346,354 for the year ended December 31, 2014. The increase of \$1,109,769 is primarily related to a loss on extinguishment of debt of \$719,097, related to the June 2015 refinancing of an existing loan with a new venture debt lender, of which costs 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 debt lender. Increased interest expense also includes debt discounts amortization for our new debt lender's end of term fees, back end fees, value of warrants issued, facility and financing fees. The loss on extinguishment includes costs of writing off the previous unamortized debt discount, unamortized deferred financing costs and a prepayment premium. The increase also includes higher interest expense as we accessed an additional \$5,000,000 during the fourth quarter of 2014 upon the milestone achievement of announcing positive Phase III data in accordance with the

loan agreement with our previous venture debt lender.

#### Loss Before Income Taxes

Loss before income taxes was \$17,969,930 for the year ended December 31, 2015, an increase of \$605,043 from \$17,364,887 for the year ended December 31, 2014, for the reasons previously stated.

#### State Income Tax Benefit

In December 2014 we received \$551,724 from the sale of our State of New Jersey net operating losses. These losses were sold through the New Jersey Economic Development Authority Technology Business Tax Certificate Transfer Program. Under the terms of this program, if we do not use the proceeds from these sales for costs incurred with operating our biotechnology business in New Jersey, we are obligated to refund the face value of the proceeds. If we do not maintain our headquarters or a base of operations in New Jersey during the five years following receipt of these proceeds (other than due to liquidation), we are obligated to refund the face value of the proceeds less 20% for each year completed of the five year period. We did not qualify for this program in 2015 and cannot make assurances that we will qualify under this program in future years or that the program will exist in future years.

## Net Loss

Net loss increased to \$17,969,930 for the year ended December 31, 2015 from \$16,813,163 for the year ended December 31, 2014, for the reasons previously stated.

## Net Cash Used in Operating Activities

Net cash used in operating activities was \$15,418,403 for the year ended December 31, 2015. The net loss for this period was higher than net cash used in operating activities by \$2,551,527, 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 \$1,500,000 from a milestone payment received from Biotest 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 \$863,173.

Net cash used in operating activities was \$14,704,910 for the year ended December 31, 2014. The net loss for this period was higher than net cash used in operating activities by \$2,108,253, which was primarily attributable to stock-based compensation of \$1,248,454, associated Hercules note charges related to amortization of debt discount, deferred financing costs, warrant liability and payment-in-kind interest charges of \$509,575, increases in accrued expenses of \$1,351,937 partly offset by an increase in accounts receivable of \$383,961 and a decrease of accounts payable of \$937,779.

## Net Cash Used in Investing Activities

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

Net cash used in investing activities was \$4,040,743 for the year ended December 31, 2014, which pertained to purchases of property and equipment primarily related to the expansion and construction of our existing and new plasma centers of \$2,323,251, and short term investments of \$1,717,492.

## Net Cash Provided by Financing Activities

Net cash provided by financing activities totaled \$10,401,907 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 \$10,306,606 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 \$172,363 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.

Net cash provided by financing activities totaled \$9,795,206 for the year ended December 31, 2014, which primarily consisted of proceeds from our debt financings with Hercules offset by debt issuance costs.

## Liquidity and Capital Resources

### Overview

As of December 31, 2015, we had working capital of \$17.0 million, consisting primarily of \$10.4 million of cash and cash equivalents, \$6.4 million of short term investments, \$3.4 million of inventories, \$0.9 million of accounts receivable and \$0.1 million of prepaid expenses, offset by \$4.2 million of current liabilities, which are mainly comprised of accounts payable and accrued expenses.

We have had limited revenue from operations and we have incurred cumulative losses of \$87.4 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. We received net cash proceeds of approximately \$10.2 million from the sales of our common stock in March 2015, \$26.6 million in October 2013 from our Initial Public Offering, or IPO, a total of \$16.0 million from venture debt lenders in various financings since 2012; and \$15.3 million in the 2012 financing. Our funds are being used and have been used to conduct clinical trials, manufacture drug product, collect and procure plasma, test plasma donors for RSV titers, file our BLA for RI-002, pre-launch activities, commercialization and marketing activities, the buildout and expansion of our first plasma center and the buildout of our second plasma center and the remainder for payment of existing accounts payable, general and administrative, research and development expenses as well as other business activities and general corporate purposes.

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 will be sufficient to fund our operations, as currently conducted, into the second half of 2016. 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 2016 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, how aggressively we execute on our commercial initiatives and when the FDA approves our BLA. 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 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, as such these conditions raise 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, 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.

During December 2014, we received \$0.6 million from the sale of our State of New Jersey net operating losses through the New Jersey Economic Development Authority program. We cannot make assurances that funding will be available for us in the future under this program.



## Loan and Security Agreement

In June 2015, we entered into an LSA with Oxford, as collateral agent and lender, pursuant to which we accessed 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 its 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”). We may elect to access an additional term loan under the LSA in the aggregate principal amount of \$5.0 million if we receive approval of our BLA for RI-002 from the FDA on or before January 31, 2017. Also, at our discretion, if we receive BLA approval for RI-002 from the FDA within the initial 18-month interest only period, we may elect to extend our interest only period for an additional six months. 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 (3) 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: 3.0% if prepayment occurs through the second anniversary of funding, 1.0% if prepayment occurs after the second anniversary of the funding date and prior to maturity date of the principal amount of the term loans 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: 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, an expected dividend yield of 0.0%, a risk-free interest rate of 1.99% and a term of 7 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.

45

---

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 will be sufficient to fund our operations into the second half of 2016. 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 2016 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, 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 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 recognize that if the financial markets are not receptive, or if we are otherwise not able to raise additional capital, or if we incur delays in receiving FDA approval for RI-002, we can delay commercialization efforts, postpone research and development activities and otherwise reduce expenditures to maintain operations into the first quarter of 2017.

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. Because of numerous risks and uncertainties associated with the research, development and 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. We have reported losses since inception in June 2004 through December 31, 2015, and we have as of December 31, 2015, an accumulated deficit of \$87.4 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, forcing 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. In addition, the incurrence of indebtedness would result in increased fixed obligations and could result in covenants that would restrict our operations or other financing alternatives.

Financial markets in the United States, 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. The continued 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 United States and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flow or cash position.

#### Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board or FASB issued Accounting Standards Update or 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 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.

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 defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the Company's 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 United States of America, 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 evaluating the impact of this update on our condensed consolidated financial statements.

#### 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 United States of America, 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, 2015, we used the Black-Scholes option pricing model. We granted options to purchase an aggregate of 432,500 shares of common stock during the year ended December 31, 2015. 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 expenses include all R&D costs as incurred, of which such expenses include costs associated with planning and conducting clinical trials, drug product manufacturing including the cost of plasma, plasma storage and transportation costs quality, testing, validation, regulatory consulting and filing fees and 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. Revenue is recognized at the time of delivery if we retain the risk of loss during shipment. Our revenues are substantially attributable to one customer. 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 AG have been completed. During the third quarter 2015, we recorded deferred revenue of \$1,500,000 in accordance with a license agreement payment we received related to the filing of our BLA with the FDA. Deferred revenue of \$1,700,000 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.

49

---

## Accounting for Loan and Security Agreement

On June 19, 2015, we entered into the LSA with Oxford for up to \$21.0 million and refinanced our existing loan with Hercules. The first tranche of \$16.0 million from the Oxford loan was primarily used to repay our existing facility with Hercules and the remaining \$5.0 million is available at our option upon RI-002's BLA being approved from the FDA on or before January 31, 2017. 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 (3) 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 nine 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: 3.0% if prepayment occurs through the second anniversary of funding, 1.0% if prepayment occurs after the second anniversary of the funding date and prior to maturity date of the principal amount of the term loans 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).

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, 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, an expected dividend yield of 0.0%, a risk-free interest rate of 1.99% and 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 debt issuance costs, debt discount related to the warrants issued to Hercules along with a prepayment penalty.

In connection with our Prior Loan Agreement and Prior Loan Amendment, 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 Agreement and Prior Loan Amendment 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.

#### Off-Balance Sheet Arrangements

We have entered into leases for our ADMA BioCenters' facilities in Norcross, Georgia and Marietta, Georgia. The Norcross, Georgia lease expires on September 30, 2023, and the Marietta, Georgia lease expires on January 31, 2024. There is a total minimum rent due under these leases of \$2.9 million through the end of the 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 report 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 recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and 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 the end of the period covered by this report. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective to provide such reasonable assurance.

In designing and evaluating the disclosure controls and procedures, management recognized that such controls and procedures, as any controls and procedures, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

##### 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, 2015. 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, 2015, 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 our most recent fiscal quarter 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 the Company have been detected. We do not expect that our disclosure controls and procedures or our internal control over financial reporting are able to prevent with certainty all errors and all fraud.

#### Item 9B. Other Information

None.

### Part III

#### Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated by reference to our definitive proxy statement or an amendment to our annual report on Form 10-K to be filed within 120 days of our fiscal year end.

#### Item 11. Executive Compensation

The information required by this Item is incorporated by reference to our definitive proxy statement or an amendment to our annual report on Form 10-K to be filed within 120 days of our fiscal year end.

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

The information required by this Item is incorporated by reference to our definitive proxy statement or an amendment to our annual report on Form 10-K to be filed within 120 days of our fiscal year end.

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

The information required by this Item is incorporated by reference to our definitive proxy statement or an amendment to our annual report on Form 10-K to be filed within 120 days of our fiscal year end.

#### Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated by reference to our definitive proxy statement or an amendment to our annual report on Form 10-K to be filed within 120 days of our fiscal year end.

### Part IV

#### Item 15. Exhibits, Financial Statement Schedules

Financial Statement Schedules

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

(1) Consolidated Financial Statements.

	Page
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2015 and 2014	F-3
Consolidated Statements of Operations for the years ended December 31, 2015 and 2014	F-4
Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2015 and 2014	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2015 and 2014	F-6
Notes to Consolidated Financial Statements	F-7

(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.



SIGNATURES

Pursuant to the requirements of sections 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, in the City of Ramsey, State of New Jersey on March 23, 2016.

ADMA Biologics, Inc.

By: /s/ Adam S. Grossman  
 Name: Adam S. Grossman  
 Title President and Chief Executive Officer

POWER OF ATTORNEY

The undersigned directors and officers of ADMA Biologics, Inc. do hereby constitute and appoint Adam S. Grossman and Brian Lenz with full power of substitution and resubstitution, as their true and lawful attorneys and agents, to do any and all acts and things in their name and behalf in their capacities as directors and officers and to execute any and all instruments for them and in their names in the capacities indicated below, which said attorneys and agents, may deem necessary or advisable to enable said corporation to comply with the Securities Exchange Act of 1934, as amended, and any rules, regulations and requirements of the Securities and Exchange Commission, in connection with this annual report on Form 10-K, including specifically but without limitation, power and authority to sign for them or any of them in their names in the capacities indicated below, any and all amendments hereto, and they do hereby ratify and confirm all that said attorneys and agents, or either of them, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Adam S. Grossman Adam S. Grossman	President and Chief Executive Officer (Principal Executive Officer)	March 23, 2016
/s/ Brian Lenz Brian Lenz	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 23, 2016
/s/ Steven A. Elms Steven A. Elms	Chairman of the Board of Directors	March 23, 2016
/s/ Dr. Jerrold B. Grossman Dr. Jerrold B. Grossman	Vice Chairman of the Board of Directors and Director	March 23, 2016
/s/ Bryant E. Fong Bryant E. Fong	Director	March 23, 2016

/s/ Dov A. Goldstein Dov A. Goldstein, M.D.	Director	March 23, 2016
/s/ Lawrence P. Guiheen Lawrence P. Guiheen	Director	March 23, 2016
/s/ Eric I. Richman Eric I. Richman	Director	March 23, 2016

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

TABLE OF CONTENTS

	Page
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2015 and 2014	F-3
Consolidated Statements of Operations for the years ended December 31, 2015 and 2014	F-4
Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2015 and 2014	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2015 and 2014	F-6
Notes to Consolidated Financial Statements	F-7

F-1

---

Report of Independent Registered Public Accounting Firm

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, 2015 and 2014, and the related consolidated statements of operations, changes in stockholders' 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, 2015 and 2014, and their results of operations and 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  
March 23, 2016

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
December 31, 2015 and 2014

	December 31, 2015	December 31, 2014
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$ 10,440,959	\$ 17,199,030
Short-Term Investments	6,368,177	4,652,675
Accounts Receivable	924,468	383,961
Inventories	3,445,773	1,708,763
Prepaid Expenses	111,027	143,586
Total Current Assets	21,290,404	24,088,015
Property and Equipment at Cost, Net	2,396,950	2,840,698
Other Assets:		
Deferred Financing Costs	-	67,640
Deposits	27,163	27,163
Total Other Assets	27,163	94,803
<b>TOTAL ASSETS</b>	<b>\$ 23,714,517</b>	<b>\$ 27,023,516</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$ 2,087,855	\$ 1,779,197
Accrued Expenses	1,968,384	2,223,639
Accrued Interest	-	105,664
Current Portion of Deferred Revenue	145,154	75,556
Current Portion of Leasehold Improvement Loan	15,139	13,841
Total Current Liabilities	4,216,532	4,197,897
Notes Payable, Net of Debt Discount	14,247,212	14,568,285
Warrant Liability	-	476,760
End of Term Liability, Notes Payable	1,432,000	132,500
Deferred Revenue	2,832,867	1,504,815
Deferred Rent Liability	128,676	83,214
Leasehold Improvement Loan	36,256	51,395
<b>TOTAL LIABILITIES</b>	<b>22,893,543</b>	<b>21,014,866</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY</b>		
Common Stock \$0.0001 par value 75,000,000 shares authorized, and 10,713,087 and 9,291,823 shares issued and outstanding as of December 31, 2015 and December 31, 2014, respectively	1,072	929
Additional Paid-In Capital	88,239,569	75,457,458
Accumulated Deficit	(87,419,667 )	(69,449,737 )
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>820,974</b>	<b>6,008,650</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 23,714,517</b>	<b>\$ 27,023,516</b>

See notes to consolidated financial statements



ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS  
Years Ended December 31, 2015 and 2014

	2015	2014
<b>REVENUES:</b>		
Product revenue	\$ 7,050,283	\$ 5,839,989
License and other revenue	127,350	75,556
<b>Total Revenues</b>	<b>7,177,633</b>	<b>5,915,545</b>
<b>OPERATING EXPENSES:</b>		
Cost of product revenue	4,311,461	3,742,367
Research and development	7,015,946	9,517,014
Plasma centers	4,618,065	3,850,828
General and administrative	6,745,968	4,823,869
<b>TOTAL OPERATING EXPENSES</b>	<b>22,691,440</b>	<b>21,934,078</b>
<b>LOSS FROM OPERATIONS</b>	<b>(15,513,807 )</b>	<b>(16,018,533 )</b>
<b>OTHER INCOME (EXPENSE):</b>		
Interest income	37,830	14,217
Interest expense	(1,842,716 )	(1,286,215 )
Change in fair value of stock warrants	67,860	(74,356 )
Loss on extinguishment of debt	(719,097 )	-
<b>OTHER EXPENSE, NET</b>	<b>(2,456,123 )</b>	<b>(1,346,354 )</b>
<b>LOSS BEFORE INCOME TAXES</b>	<b>(17,969,930 )</b>	<b>(17,364,887 )</b>
State income tax benefit	-	551,724
<b>NET LOSS</b>	<b>\$ (17,969,930 )</b>	<b>\$ (16,813,163 )</b>
<b>NET LOSS PER COMMON SHARE, Basic and Diluted</b>	<b>\$ (1.73 )</b>	<b>\$ (1.81 )</b>
<b>WEIGHTED AVERAGE SHARES OUTSTANDING, Basic and Diluted</b>	<b>10,412,305</b>	<b>9,291,823</b>

See notes to consolidated financial statements

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
Years Ended December 31, 2015 and 2014

	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-in Capital	Deficit	
Balance – December 31, 2013	9,291,823	\$929	\$74,209,004	\$(52,636,574)	\$21,573,359
Stock-based compensation	-	-	1,248,454	-	1,248,454
Net loss	-	-	-	(16,813,163)	(16,813,163)
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)
Balance – December 31, 2015	10,713,087	\$1,072	\$88,239,569	\$(87,419,667)	\$820,974

See notes to consolidated financial statements



ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
Years Ended December 31, 2015 and 2014

	2015	2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (17,969,930 )	\$ (16,813,163 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	469,821	247,852
Stock-based compensation	1,711,047	1,248,454
Warrant liability	(67,860 )	74,356
Amortization of debt discount	353,635	133,197
Amortization of deferred financing costs	39,717	125,777
Payment-in-kind interest	124,536	176,245
Amortization of license and other revenue	(127,350 )	(75,556 )
Loss on extinguishment of debt	719,097	-
Changes in operating assets and liabilities:		
Accounts receivable	(540,507 )	(383,961 )
Inventories	(1,737,010 )	(39,704 )
Prepaid expenses	32,559	155,144
Other assets	-	(14,586 )
Accounts payable	308,658	(937,779 )
Accrued expenses	(199,615 )	1,351,937
Accrued interest	(105,664 )	69,067
Deferred revenue	1,525,000	-
Deferred rent liability	45,462	(22,190 )
Net cash used in operating activities	(15,418,404 )	(14,704,910 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of short-term investments	(1,715,502 )	(1,717,492 )
Purchase of property and equipment	(26,073 )	(2,323,251 )
Net cash used in investing activities	(1,741,575 )	(4,040,743 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from Oxford note payable	16,000,000	-
Proceeds from issuance of common stock	10,257,380	-
Proceeds from stock options exercised	49,227	-
Proceeds from Hercules note payable, net of fees	-	9,850,000
Repayment of Hercules note payable	(15,300,781 )	-
Prepayment penalty of early extinguishment of note payable	(229,512 )	-
Payment of debt issuance costs	(228,065 )	(30,140 )
Payment of Hercules end of term fee	(132,500 )	-
Equity issuance costs	-	(12,000 )
Payments of leasehold improvement loan	(13,841 )	(12,654 )
Net cash provided by financing activities	10,401,908	9,795,206
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(6,758,071 )</b>	<b>(8,950,447 )</b>
<b>CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR</b>	<b>17,199,030</b>	<b>26,149,477</b>
<b>CASH AND CASH EQUIVALENTS - END OF YEAR</b>	<b>\$ 10,440,959</b>	<b>\$ 17,199,030</b>
<b>SUPPLEMENTAL INFORMATION:</b>		
Cash paid for interest	\$ 1,326,788	\$ 785,527

## Supplemental Disclosure of Noncash Financing Activities:

Reclassification of equity issuance costs to additional paid-in capital	\$ 12,000	\$ -
Warrants issued in connection with note payable	\$ 367,700	\$ 402,404
Accrued equity issuance costs	\$ -	\$ 55,640
End of term liability in connection with note payable	\$ 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, 2015 AND 2014

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 treatment 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 its wholly-owned subsidiary, ADMA BioCenters 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. Both the Norcross and Marietta centers have achieved German Health Authority (“GHA”) and the Korean Ministry of Food and Drug Safety (“MFDS”) certifications. ADMA BioCenters provides ADMA with a portion of its raw material plasma for the manufacture of RI-002, ADMA’s lead product candidate, which is intended for the treatment of Primary Immune Deficiency Disease, (“PIDD”). A Biologics License Application (“BLA”) for RI-002 was submitted to the FDA on July 31, 2015 and accepted for review on September 18, 2015. The Company’s Marietta, Georgia center received FDA approval to sell human source plasma within the U.S. on September 17, 2015.

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 October 2013, the Company completed an Initial Public Offering (“IPO”) to raise gross proceeds of \$29.1 million, and in February 2012, the Company completed a private placement to raise gross proceeds of \$17.3 million, and during December 2012, 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 Finance LLC (“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 a Loan and Security Agreement (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 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 its 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”). ADMA may elect to access an additional term loan under the LSA in the aggregate principal amount of \$5.0 million if it receives approval of its BLA for RI-002 from the FDA on or before January 31, 2017. Also, at ADMA’s discretion, if it receives BLA approval for RI-002 from the FDA within the initial 18-month interest only period, it may elect to extend its interest only period for an additional six months.

As of December 31, 2015, the Company had working capital of \$17.0 million, consisting primarily of \$10.4 million of cash and cash equivalents, \$6.4 million of short-term investments, \$0.9 million of accounts receivable, \$3.4 million of inventories, and \$0.1 million of prepaid expenses, offset primarily by \$2.1 million of accounts payable, \$1.9 million of accrued expenses and \$0.1 million of deferred revenue. Based upon the Company’s projected revenue and expenditures for 2016, including the ongoing implementation of the Company’s commercialization and expansion activities, management currently believes that its cash, cash equivalents, short-term investments and accounts receivable as of December 31, 2015 are sufficient to fund ADMA’s operations, as currently conducted, into the second half of 2016. In order to have sufficient cash to fund the Company’s operations, the Company will need to raise additional equity or debt capital by the end of the second half of 2016 in order to continue as a going concern and we cannot provide any assurance that the Company will be successful in doing so. Because the Company does not anticipate receiving FDA approval for RI-002 earlier than the second half of 2016, if at all, the Company would not expect to generate revenue from the commercialization of RI-002 earlier than such time, if at all. This time frame may

change based upon the timing of the Company's commercial manufacturing scale up activities, how aggressively the Company executes on its commercial initiatives and when the FDA approves the Company's BLA for RI-002, if at all. Furthermore, if the Company's assumptions underlying its estimated expenses and revenues are incorrect, it may have to raise additional capital sooner than 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, 2015 of \$87.4 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 BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

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.

### 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 deposits 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.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

#### 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) are carried at the lower of cost or market value determined on 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, 2015 and December 31, 2014 consists of high titer plasma and normal source plasma.

#### Debt

In April 2015, the Financial Accounting Standards Board issued Accounting Standards Update (“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. Early adoption is permitted for financial statements that have not been previously issued. The Company has early adopted ASU 2015-03 in its second quarter 2015 condensed consolidated financial statements and recast the prior period balances to conform to the current period presentation.

#### Revenue recognition

Depending on the agreement with the customer, 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. Revenue is recognized at the time of delivery if the Company retains the risk of loss during shipment. The Company's revenues are substantially attributable to one customer. 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, 2015 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 AG and Biotest Pharmaceuticals Corporation, or Biotest, a subsidiary of Biotest AG, has provided the Company with certain financial payment and services in accordance with the related license agreement and is obligated to pay the Company certain amounts in the future if certain milestones are achieved. During the third quarter 2015, the Company recorded deferred revenue of \$1.5 million for a milestone payment provided to the Company upon its filing of the BLA for RI-002 with the FDA, in accordance with the terms of the license agreement. Deferred revenue of \$1.7 million was recorded in 2013 as a result of certain research and development services provided in accordance with the same 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.

#### Concentration of significant customers and accounts receivable

As of and for the years ended December 31, 2015 and 2014, the Company's trade receivable balance and revenues were substantially attributable to one customer.

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.

F-9

---

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

#### 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, 2015 and 2014. The Company's U.S. Federal and state income tax returns prior to fiscal year 2012 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 1.7 million and 1.3 million as of December 31, 2015 and 2014, respectively.

F-10

---

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

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, 2015 and 2014, stock options to purchase 432,500 and 221,932 shares of common stock, respectively, were issued to employees and non-employee directors. 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, 2015 and 2014, the Company recorded stock-based compensation expense to employees of \$1,711,047 and \$1,248,454, 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:

Year Ended      Year Ended

Edgar Filing: ADMA BIOLOGICS, INC. - Form 10-K

	December 31, 2015	December 31, 2014
Expected term	6.3 years	6.3 years
Volatility	51-58%	60%
Dividend yield	0.0	0.0
Risk-free interest rate	1.49-2.14%	2.19%

F-11

---

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

#### 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.

### 3. PROPERTY AND EQUIPMENT

Property and equipment consist of the following at December 31,	2015	2014
Lab and office equipment	\$ 1,272,042	\$ 1,236,553
Computer software	188,277	188,277
Leasehold improvements	2,690,320	2,699,736
	4,150,639	4,124,566
Less: Accumulated depreciation and amortization	(1,753,689 )	(1,283,868 )
	\$ 2,396,950	\$ 2,840,698

The Company recorded depreciation and amortization expense of \$469,821 and \$247,852 for the years ended December 31, 2015 and 2014, 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:

2016	\$15,139
2017	16,559
2018	18,113
2019	1,584
	\$51,395

### 5. DEBT

#### Loan and Security Agreement

On June 19, 2015, the Company entered into the LSA with Oxford for up to \$21.0 million and refinanced its existing loan with Hercules. The first tranche of \$16.0 million from the Oxford loan was primarily used to repay its existing facility with Hercules and the remaining \$5.0 million is available at ADMA's option upon RI-002's BLA being approved from the FDA on or before January 31, 2017. 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 (3) 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 is 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 the Company's option, if it receives 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 the Company elects to prepay the loan, the Company is obligated to pay a prepayment charge corresponding to a percentage of the principal amount of the loan, with such percentage being: 3.0% if prepayment occurs through the second anniversary of funding, 1.0% if prepayment occurs after the second anniversary of the funding date and prior to maturity date of the principal amount of the term loans prepaid. The loan matures no later than January 1, 2020. The loan is 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. 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 the Company 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 the Company 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 taking immediate possession of, and selling, any collateral securing the loan.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

In connection with 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: volatility of 57% 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 1.99% and a term of 7 years. 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.

A summary of the Oxford loan balance as of December 31, 2015 is as follows:

Gross proceeds	\$ 16,000,000
Less: debt discount, net	
End of term fee	(1,250,194 )
Warrants	(310,196 )
Financing fees	(192,398 )
Note payable	\$ 14,247,212

In connection with the Prior Loan Agreement with Hercules, the Company borrowed a total of \$15.0 million, which was repaid and terminated in June 2015 through a new loan with Oxford. The Company 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. The Company issued to Hercules a warrant to purchase 31,750 shares of common stock with an exercise price of \$7.56 in December 2012, and in connection with the Prior Loan Amendment, the Company issued to Hercules a warrant to purchase an additional 58,000 shares of its 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 amended 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 Amendment warrant was 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 the Company's common stock ("the next round of equity financing"). The Company 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 the Company's 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, the Company 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, the Company recorded an expense of \$74,356 from the change in the fair value of warrant liability. During the first quarter ended March 31, 2015, the Company 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, the Company 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 the Company's 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.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

A summary of the recast Hercules loan balance as of December 31, 2014 is as follows:

Gross proceeds	\$ 15,000,000
Plus:	
payment in kind interest	176,245
	15,176,245
Less: debt discount, net	
Warrants Financing fees	(403,979 )
	(161,951 )
End of term fee	(42,030 )
Note payable	\$ 14,568,285

## 6. STOCKHOLDERS' EQUITY

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 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).





ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

## 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. Rent expense amounted to \$96,448 for each of the years ended December 31, 2015 and 2014, respectively. The Company also reimburses its landlord for office related expenses, equipment and certain other operational expenses, which have been insignificant to the consolidated financial statements for the years ended December 31, 2015 and 2014. The Company maintains deposits and other accounts at a bank which is less than 5%-owned by related parties and where a stockholder is a member of the Board of Directors of the bank.

## 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 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 2015 and 2014 was approximately \$420,000 and \$414,000, respectively.

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

2016	\$354,383
2017	359,059
2018	362,774
2019	375,198
2020	376,812
Thereafter	1,113,408
	\$2,941,634

### Vendor and Licensor Commitments

On December 31, 2012, the Company entered into a Manufacturing, Supply and License Agreement with Biotest, which replaces a prior agreement that expired on December 31, 2012. Under the agreement, the Company agreed to purchase exclusively from Biotest 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 Biotest'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.



ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

In a separate license agreement effective December 31, 2012, the Company granted Biotest 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 Biotest’s plasma samples using the Company’s proprietary RSV assay, and to reference (but not access) the Company’s proprietary information for the purpose of Biotest seeking regulatory approval for the RSV antibody-enriched IVIG in the Territory. As consideration for the license, Biotest 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. Biotest 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, Biotest has agreed to grant the Company an exclusive license for marketing and sales in the United States and Canada for Biotest’s Varicella Zoster Immune Globulin (“VZIG”), the terms of which the Company expects to finalize during 2016. As such, the Company expects to account for the value of this license as a charge to operations once the terms of the in-license agreement are finalized.

Pursuant to the terms of a Plasma Purchase Agreement with Biotest, the Company has agreed to purchase from Biotest 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 Biotest but may also collect high-titer RSV plasma from up to five wholly-owned ADMA BioCenters. During 2015, Biotest and ADMA amended its Plasma Purchase Agreement with Biotest, 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.

#### 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, 2015. The Company does not anticipate recognizing any significant losses relating to these arrangements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

## 9. STOCK OPTIONS

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 on February 21, 2014. On July 16, 2007 (the “Effective Date”), the Company’s Board and stockholders adopted the Plan. On July 17, 2012, the Company’s Board and stockholders amended the Plan to increase the aggregate number of options available for grant to 903,224. 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 Prospective Plan. The aggregate options approved in the Plan and 2014 Plan as of December 31, 2015 is 1,788,628 with 1,464,203 outstanding and expected to vest and 324,425 available for future issuance as of December 31, 2015. During the year ended December 31, 2015, 7,514 options were exercised; such options were included in the Plan.

The Plan 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 Plan 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, 2015 and 2014:

	Year Ended December 31, 2015		Year Ended December 31, 2014	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	1,048,927	\$7.24	826,995	\$6.90
Forfeited	(9,710 )	\$9.16	-	-
Exercised	(7,514 )	\$6.55	-	-
Granted	432,500	\$9.92	221,932	\$8.50
Outstanding at end of year and expected to vest	1,464,203	\$8.02	1,048,927	\$7.24
Options exercisable	880,457	\$7.19	635,763	\$6.81
Weighted average fair value of options granted during the year		\$5.25		\$5.06

The weighted average remaining contractual term of stock options outstanding and expected to vest at December 31, 2015 is 7.2 years. The weighted average remaining contractual term of stock options exercisable at December 31,

2015 is 6.1 years.

F-17

---

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

Stock-based compensation expense for the years ended December 31, 2015 and 2014 was:

	2015	2014
Research and development	\$ 724,776	\$ 541,140
Plasma centers	48,386	56,900
General and administrative	937,885	650,414
Total stock-based compensation expense	\$ 1,711,047	\$ 1,248,454

As of December 31, 2015, the total unrecognized compensation expense related to unvested options totaled \$2,657,226. The weighted-average vesting period over which the total compensation expense will be recorded related to unvested options at December 31, 2015 was approximately 2.7 years.

The aggregate intrinsic value is calculated as the difference between (i) the closing price of the common stock at December 31, 2015 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 \$952,773 and \$880,457 as of December 31, 2015, respectively.

## 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,	
	2015	2014
Benefit at US federal statutory rate	\$ (6,109,776 )	\$ (5,904,062 )
State taxes - deferred	(124,874 )	879,793
Increase in valuation allowance, inclusive of true-ups	6,021,614	5,147,244
Research and development credits	(389,355 )	(551,863 )
Sale of state net operating loss	-	(551,724 )
Other	602,391	428,888
Benefit for income taxes	\$ -	\$ (551,724 )

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

	December 31,	
	2015	2014
Federal and state net operating loss carryforwards	\$ 25,834,860	\$ 21,004,587
Federal and state research credits	4,353,534	3,649,268
Accrued expenses and other	1,371,547	884,472
Total gross deferred tax assets	31,559,941	25,538,327
Less: valuation allowance for deferred tax assets	(31,559,941 )	(25,538,327 )
Net deferred tax assets	\$ -	\$ -

As of December 31, 2015, the Company had Federal and state net operating loss carryforwards of approximately \$72.5 million and \$46.0 million, respectively. The Company also had Federal and state research and development tax



credit carryforwards of approximately \$3.7 million and \$0.6 million, respectively. The net operating loss carryforwards and tax credits will expire at various dates beginning in 2027 if not utilized.

F-18

---

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

The Company received \$551,724 in December 2014 from the sale of net operating loss and research and development credit carryforwards under the New Jersey Economic Development Authority Technology Business Tax Certificate Transfer Program. These amounts are recorded on the consolidated financial statements as income tax benefits in the year they are received. The Company did not qualify for this program in 2015, as such, the Company cannot make assurances that it will qualify for this program or that the program will exist in future years.

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.

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2015 AND 2014

Year Ended December 31, 2015	Plasma Collection Centers	Research and Development	Corporate	Consolidated
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
Year Ended December 31, 2014	Plasma Collection Centers	Research and Development	Corporate	Consolidated
Revenues	\$ 5,839,989	\$-	\$75,556	\$5,915,545
Cost of product revenue	3,742,367	-	-	3,742,367
Gross profit	2,097,622	-	75,556	2,173,178
Loss from operations	(1,753,206 )	(9,517,014 )	(4,748,313 )	(16,018,533 )
Other income (expense)	262	-	(1,346,616 )	(1,346,354 )
Loss before income taxes	(1,752,944 )	(9,517,014 )	(6,094,929 )	(17,364,887 )
Total assets	3,073,179	-	23,950,337	27,023,516
Depreciation and amortization expense	198,244	2,729	46,879	247,852

The “Corporate” column includes general and administrative overhead expenses. Property and equipment, net, 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 \$0.1 million of related compensation expense for the years ended December 31, 2015 and 2014.

F-20

---

EXHIBIT INDEX

Exhibit No.	Description
3.1 (1)	Certificate of Incorporation, as amended
3.2 (2)	Certificate of Amendment of Certificate of Incorporation
3.3 (3)	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*	Form of Warrant Agreement with Oxford Finance LLC
4.5 (6)	Form of Secured Promissory Note issued to Oxford Finance LLC (included as Exhibit D to Loan and Security Agreement, dated as of June 19, 2015, among Oxford Finance LLC, the Lenders listed therein, and ADMA Biologics, Inc.)
10.1† (7)	2007 Employee Stock Option Plan, as amended
10.2†*	Amended and Restated Employment Agreement, dated January 28, 2016, by and between ADMA Biologics, Inc. and Adam Grossman
10.3+ (8)	Plasma Purchase Agreement, dated as of November 17, 2011, between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc., as amended as of December 1, 2011
10.3.1#*	Amendment No. 2 to Plasma Purchase Agreement, as amended, dated December 18, 2015, between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc.
10.4 (4)	Agreement for Services, dated July 23, 2007, between ADMA Biologics, LLC and Areth Inc.
10.5 (1)	Agreement of Lease between ADMA BioCenters Georgia, Inc. and ADMA Biologics, Inc. and CIVF I-GA1W15-W23, LLC (DCT Holdings), effective June 1, 2008 and confirmed on November 13, 2008, for the premises located in Norcross, Georgia, as amended
10.6+ (11)	Agreement of Lease, dated as of January 20, 2014, between ADMA BioCenters Georgia, Inc. and U.S. Bank National Association, as trustee, effective February 1, 2014, for the premises located in Marietta, Georgia
10.7 (1)	Form of Indemnification Agreement
10.8†*	Amended and Restated Employment Agreement, dated January 28, 2016, by and between ADMA Biologics, Inc. and Brian Lenz
10.9+ (9)	Testing Services Agreement, dated June 7, 2012, between ADMA Biologics, Inc. and Quest Diagnostics Clinical Laboratories, Inc.
10.10#*	Amended and Restated Plasma Supply Agreement, dated March 23, 2016, between ADMA Biologics, Inc. and Biotest Pharmaceuticals Corporation
10.11†*	Amended and Restated Employment Agreement, dated January 28, 2016, by and between ADMA Biologics, Inc. and James Mond
10.12 (5)	Loan and Security Agreement, dated as of December 21, 2012, by and among ADMA Biologics, Inc., ADMA Plasma Biologics, Inc., ADMA BioCenters Georgia, Inc. and Hercules Technology Growth Capital, Inc.
10.12.1 (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 BioCenters Georgia, Inc. and Hercules Technology Growth Capital, Inc.
10.13 (5)	Equity Rights Letter, dated December 21, 2012, from ADMA Biologics, Inc. to Hercules Technology Growth Capital, Inc.

Edgar Filing: ADMA BIOLOGICS, INC. - Form 10-K

- 10.14+ (5) Manufacturing, Supply and License Agreement, dated as of December 31, 2012, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc.
  - 10.15+ (5) License Agreement, dated December 31, 2012, by and between ADMA Biologics, Inc. and Biotest Aktiengesellschaft
-

- 10.16† (10) 2014 Omnibus Incentive Compensation Plan
- 10.17 (6) Loan and Security Agreement, dated as of June 19, 2015, among Oxford Finance LLC, the Lenders listed therein, and ADMA Biologics, 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 Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2\* Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1\*\* Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2\*\* Certification of Principal Financial Officer 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, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets at December 31, 2015 and December 31, 2014, (ii) Statements of Operations for the years ended December 31, 2015 and 2014 (iii) Statements of Changes in Stockholders' Equity for the years ended December 31, 2015 and 2014, (iv) Statements of Cash Flows for the years ended December 31, 2015 and 2014 and (v) Notes to the 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 Commission on February 13, 2012.
- (2) Incorporated herein by reference to the Company's Current Report on Form 8-K, filed with the Commission on August 26, 2013.
- (3) Incorporated herein by reference to the Company's Registration Statement on Form 10-SB, filed with the Commission on July 10, 2006.
- (4) Incorporated herein by reference to Amendment No. 1 to the Company's Current Report on Form 8-K/A (000-52120), filed with the Commission on March 29, 2012.
- (5) Incorporated herein by reference to the Company's Registration Statement on Form S-1, filed with the Commission on February 11, 2013.

Edgar Filing: ADMA BIOLOGICS, INC. - Form 10-K

- (6) Incorporated herein by reference to the Company's Quarterly Report on Form 10-Q, Filed with the Commission on August 11, 2015.
- (7) Incorporated herein by reference to Exhibit A to the Information Statement on Schedule 14C, filed with the Commission on October 29, 2012.
- (8) Incorporated herein by reference to Amendment No. 3 to the Company's Current Report on Form 8-K/A, filed with the Commission on June 22, 2012.
- (9) Incorporated herein by reference to Amendment No. 4 to the Company's Registration Statement on Form S-1, filed with the Commission on August 10, 2012.
- (10) Incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement filed with the Commission on April 29, 2014.
- (11) Incorporated herein by reference to the Company's Annual Report on Form 10-K, filed with the Commission on March 28, 2014.