

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, 2012

Transition Report under Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from to

Commission File Number: 000-52120

**ADMA BIOLOGICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or Other Jurisdiction of Incorporation or Organization)

**56-2590442**

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

**65 Commerce Way,  
Hackensack, New Jersey**

(Address of principal executive offices)

**07601**

(Zip Code)

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

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

Title of Each Class:

Name of Each Exchange on Which Registered:

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

Title of Class: **Common stock, par value \$0.0001 per share**

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

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

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

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

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

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

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

Smaller Reporting Company

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

The aggregate market value of voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: Not applicable because there is no public market for the common equity.

The number of shares of the registrant's Common Stock, par value \$0.0001 per share, outstanding as of March 5, 2013 was 4,622,831.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2013 Annual Meeting of Stockholders or Annual Report on Form 10-K/A, to be filed on or before April 30, 2013, are incorporated by reference into Part III of this Report.

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## ADMA BIOLOGICS, INC.

### PART I

|          |   |    |
|----------|---|----|
| Item 1.  | <a href="#">Business</a>                  | 4  |
| Item 1A. | <a href="#">Risk Factors</a>              | 17 |
| Item 1B. | <a href="#">Unresolved Staff Comments</a> | 33 |
| Item 2.  | <a href="#">Properties</a>                | 34 |
| Item 3.  | <a href="#">Legal Proceedings</a>         | 34 |
| Item 4.  | <a href="#">Mine Safety Disclosures</a>   | 34 |

### PART II

|          |  |    |
|----------|--|----|
| Item 5.  | <a href="#">Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</a> | 34 |
| Item 6.  | <a href="#">Selected Financial Data</a>  | 36 |
| Item 7.  | <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>                            | 36 |
| Item 7A. | <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>   | 45 |
| Item 8.  | <a href="#">Financial Statements and Supplementary Data</a>  | 45 |
| Item 9.  | <a href="#">Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</a>                             | 45 |
| Item 9A. | <a href="#">Controls and Procedures</a>  | 45 |
| Item 9B. | <a href="#">Other Information</a>  | 46 |

### PART III

|          |  |    |
|----------|--|----|
| Item 10. | <a href="#">Directors and Executive Officers and Corporate Governance</a>                                      | 46 |
| Item 11. | <a href="#">Executive Compensation</a>   | 46 |
| Item 12. | <a href="#">Security Ownership Of Certain Beneficial Owners and Management and Related Stockholder Matters</a> | 46 |
| Item 13. | <a href="#">Certain Relationships and Related Transactions, and Director Independence</a>                      | 46 |
| Item 14. | <a href="#">Principal Accountant Fees and Services</a>   | 46 |

### PART IV

|          |  |    |
|----------|--|----|
| Item 15. | <a href="#">Exhibits and Financial Statement Schedules</a> | 47 |
|----------|--|----|

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### **Special Note Regarding Forward-Looking Statements**

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

- our plans to develop RI-002, including ongoing and planned clinical trials of RI-002, particularly the timing for initiation, enrollment and outcome;
- the expected timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the potential indications for our product candidates;
- our intellectual property position;
- our manufacturing capabilities and strategy;
- our plans relating to manufacturing, supply and other collaborative agreements; and
- our estimates regarding expenses, capital requirements and needs for additional financing.

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,” “should,” or “will” or the negative of these terms, although some forward-looking statements are expressed differently. You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to the factors referenced above.

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, taken as a whole, and also refer to the operations of ADMA Plasma Biologics, Inc. prior to the merger on February 13, 2012, as discussed below, which resulted in ADMA Plasma Biologics, Inc. becoming our wholly-owned subsidiary. In each case, references to ADMA Plasma Biologics, Inc. also include its subsidiary ADMA BioCenters Georgia, Inc., or ADMA BioCenters, a Delaware corporation.*

#### Business of ADMA

##### Overview

ADMA Biologics is a specialty immune globulin company that develops, manufactures and intends to market 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 disease or who may be immune-suppressed for medical reasons. Our lead product candidate, RI-002, for which we have commenced a pivotal Phase III clinical trial, is intended for the treatment of primary immune deficiency disease, or PIDD. RI-002 is an injectable immune globulin derived from human plasma enriched with high levels of naturally occurring polyclonal antibodies including those targeted to respiratory syncytial virus, or RSV. RSV is a common virus that ordinarily leads to mild, cold-like symptoms in healthy adults and children. In high-risk groups, such as the immune-compromised, RSV can lead to a more serious infection and may even cause death. Our proprietary microneutralization assay allows us to effectively identify and isolate donor plasma with high-titer RSV antibodies, to standardize RI-002's potency and thereby 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 IGIV, 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 IGIV 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 IGIV regularly. In the United States, sales of immune globulin products for all its uses were reported to be approximately \$3.5 billion in 2011. Since the introduction of IGIV therapy, the incidence of infections in IGIV-treated patients has dropped significantly.

We commenced our pivotal Phase III clinical trial of RI-002 for the treatment of patients with PIDD in 2013. The trial is a single arm, open label study in which patients will be treated approximately once per month for a period of 12 months of treatment plus up to 90 days for safety monitoring and follow up. We intend to treat an aggregate of between 60 and 70 patients in approximately 12 treatment centers in the United States. The pivotal Phase III primary endpoint follows the published FDA industry guidance, which provides for a reduction in the incidence of serious infections to less than one per year in those receiving IGIV. The secondary endpoint is safety and includes other data collection points including antibody titers for certain agents, including RSV antibody levels at various time points after infusion. Following the FDA's guidance for our protocol should provide that a successful single Phase III trial and Biological License Application, or BLA, submission should lead to FDA approval. 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, which successfully completed a Phase II trial. RI-002 is manufactured using the same FDA-approved contract manufacturing facility as its predecessor. RI-002 has demonstrated improved production yields, an improved stability profile and comparable anti-RSV antibody titer potency relative to the prior formulation.

We have established, qualified and validated a proprietary microneutralization assay for plasma collection and donor screening as well as for determining the appropriate anti-RSV antibody potency for the manufacture of RI-002. Our assay provides for measurement of RSV antibody titer levels of RI-002 that are consistent and reproducible, which we believe is a competitive advantage and a barrier to the entry of competitive products. Our microneutralization assay could serve as a platform for identifying next generation virus-specific plasma-based therapeutics.

We have an FDA-licensed source plasma collection facility, ADMA BioCenters, which provides us with a portion of our blood plasma for the manufacture of RI-002. A typical plasma collection center, such as ADMA BioCenters, can collect 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 that is not used for making RI-002 is sold to customers under an existing supply agreement 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 IGIV in Europe and in other selected territories in North Africa and the Middle East.

The founders of ADMA have a combined 60 years of experience marketing and distributing blood plasma products and devices. With the appointment of the executive team and the board of directors, we added over 150 years of deep medical, technical and development 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:

- Complete our pivotal Phase III trial and 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 for RI-002.
- Develop additional plasma-derived products for the treatment of infectious diseases in immune-compromised patient populations.
- 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 commenced our pivotal Phase III clinical trial for RI-002 for the treatment of PIDD in accordance with the FDA Guidance for Industry. If the pivotal Phase III trial produces the anticipated safety and efficacy results, we would expect to file a BLA in the second half of 2014 and anticipate potential FDA approval within approximately a year of filing.

- **Commercialize RI-002 as a treatment for PIDD.** We plan to hire 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.

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. Previously marketed RSV IGIV product and RI-001 have historically been used in immune-compromised patient populations, including patients with cystic fibrosis, prematurely born infants, stem cell and solid organ transplant patients, oncology patients and other patients at risk for or requiring treatment for RSV. Currently, there are no approved treatments specifically for RSV infections in PIDD.
- **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 proprietary assays and other technologies, we have identified potential new product candidates that we may advance into preclinical activities.
- **Develop and expand ADMA BioCenters.** In order to generate revenues in advance of RI-002's commercialization and to control a portion of our raw material plasma supply for RI-002, we formed ADMA BioCenters, a subsidiary that operates a plasma collection facility in Norcross, Georgia. The facility received its FDA license in August 2011. Under FDA license, ADMA BioCenters can 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 manufacturing of RI-002. We may initiate other hyperimmune plasma collection programs at the Norcross facility. These programs will 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 disorder 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 IGIV 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 IGIV and it is estimated that over 300,000 patients worldwide receive monthly IGIV 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 immunocompetence 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 IGIV therapy for survival. Benefits of adequate IGIV 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 IGIV product contains polyclonal antibodies against various infectious agents, including 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 that 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.

#### *The Plasma Industry*

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. In 2011, approximately 20 million plasma donations were made in the United States in which over 19 million liters of source plasma were collected. In the United States, a donor may donate plasma a maximum of two times in every 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. In June 2008, the FDA published “Guidance for Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency,” which we refer to as the FDA Guidance for Industry outlining the regulatory pathway for the approval of intravenous immune globulins, or IGIV, for the treatment of PIDD.

Immune globulins can be administered in three ways: intramuscularly, intravenously or subcutaneously. IGIV principally contains antibodies and, as such, provides passive immunization for individuals who are immune-deficient or who have been exposed to various infectious agents. IGIV 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 IGIV in a clinical study for the treatment of Alzheimer’s disease. Additionally, IGIV 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 IGIV products, there are only 14 labeled indications approved by the FDA. However, medical literature identifies at least 150 evidence based uses for IGIV, 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.

In 2011, 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 \$5 billion. IGIV products accounted for approximately \$3.5 billion of sales in the United States in 2011. IGIV products are used to treat primary immune deficiencies, certain autoimmune diseases, 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 IGIV utilization.

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

### *General*

RI-002 is a plasma-derived, polyclonal IGIV, with standardized high levels of antibodies against RSV. RI-002 is initially being developed as a treatment for patients with PIDD. By using our 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 IGIV product on the market that contains standardized high levels of RSV antibodies and that is produced with reported consistent lot-to-lot potency. We believe these characteristics will differentiate RI-002 from currently marketed IGIV products.

### *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. 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. The drug was well-tolerated in these patients and there were no reports of serious adverse events attributable to RI-001.

### *Phase III Clinical Trial*

We commenced our pivotal Phase III clinical trial of RI-002 as a treatment for PIDD in accordance with FDA Guidance for Industry. Our pivotal Phase III clinical study is a single arm, open label study in which patients will be treated approximately once per month for 12 months of treatment plus up to 90 days for safety monitoring and follow up. We intend to treat an aggregate of between 60 and 70 patients in approximately 12 treatment centers in the United States. Dosage will vary by patient and may range from 300mg/kg to 800mg/kg, based on the patient's current IGIV dose, every 21 to 28 days. The pivotal Phase III study's primary endpoint is the occurrence of less than a single serious infection per person over 12 months and the secondary endpoint will be safety. We will also include other data collection points, including anti-RSV antibody levels and antibody levels for other agents as well.

## 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, an FDA-licensed source plasma collection facility, is our wholly-owned subsidiary and provides us with a portion of our plasma requirements. By using our 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 AG and their United States subsidiary, Biotest Pharmaceuticals, Inc., together referred to as Biotest.

On December 31, 2012, we entered into a new Manufacturing, Supply and License Agreement with Biotest, which replaces a prior agreement that expired on December 31, 2012. 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. 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. 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 facility to be used in Biotest's manufacturing. The agreement expires on December 31, 2014, unless terminated earlier as provided in the agreement. 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, once Biotest applies to the German Health Authority, we must use our best effort to take necessary steps as soon as possible to become compliant with such authority's regulations and receive its 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 agrees and acknowledges that the Company paid for the development and validation of the testing assay and as such, the assay is the sole property of ADMA and shall only be utilized for our benefit.

## **Marketing and Sales**

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 and 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.

In a license agreement effective December 31, 2012, we granted Biotest an exclusive license to market and sell RSV antibody-enriched IGIV 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 IGIV 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 IGIV 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 by the end of the second quarter of 2013.

## **Competition**

Although blood plasma and its derivative proteins are not subject to patent protection, the FDA recognizes each immunoglobulin product as unique and generally requires a separate 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**

We rely on a combination of trade secrets and nondisclosure and non-competition agreements to protect our proprietary intellectual property and will continue to do so. We do not own any issued patents. 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 any threats to our intellectual property, there can be no assurance 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 two pending provisional patent applications filed with the United States 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 Investigational New Drug, or 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. Further, 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. ADMA BioCenters has completed these requirements and received its FDA license in August 2011. 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 ADMA BioCenters is currently in compliance with state and industry standards. Delays in obtaining, or failures to obtain, regulatory approvals for any facility 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 \$3.5 million and \$0.6 million for the fiscal years ended December 31, 2012 and 2011, respectively.

## **Employees**

ADMA Biologics, Inc. and ADMA Plasma Biologics have nine employees (who are all full-time employees), as well as additional full-and part-time consultants and temporary staff. ADMA BioCenters, which has its own dedicated staff trained and certified to operate the plasma collection center, has 18 employees (who are all full-time employees), as well as specialized consultants and select temporary staff. Over the course of the next year, we anticipate hiring additional full-time employees devoted to research and development and general and administrative activities as well as hiring additional staff to the plasma collection center as appropriate. We intend to use clinical research organizations, or CROs, third parties and consultants to perform our clinical studies and manufacturing and other regulatory affairs and quality control services.

## **Corporate Information**

ADMA Biologics, Inc. ("Former ADMA") was incorporated in New Jersey on June 24, 2004 and re-incorporated in Delaware on July 16, 2007. On February 13, 2012, Former ADMA merged (the "Merger") into a subsidiary of R&R Acquisition VI, Inc., a Delaware "blank check" company, which had been incorporated in 2006 and which changed its name to ADMA Biologics, Inc. upon completion of the Merger. In connection with, and immediately prior to the closing of the Merger, Former ADMA completed a private placement (the "2012 Financing") of 1,828,128 shares of its common stock at a price per share of \$9.60 to accredited investors. In lieu of repayment of senior secured promissory notes in the aggregate principal amount of \$250,000 (plus \$12,740 in accrued interest), the aggregate amount of unpaid principal and interest on the notes was invested by the holders of such notes in the 2012 Financing in exchange for shares of Former ADMA's common stock.

Rodman & Renshaw, LLC (the "Placement Agent") acted as the exclusive placement agent in connection with the 2012 Financing. Former ADMA paid the Placement Agent a cash fee for its services equal to 7% of the aggregate offering price paid by each investor in the 2012 Financing, other than with respect to certain investors. As additional compensation, Former ADMA issued the Placement Agent warrants (the "Placement Agent Warrants") to purchase 87,865 shares of common stock of Former ADMA. The Placement Agent Warrants, which were exchanged for warrants of R&R Acquisition VI, Inc. in the Merger, are exercisable at \$9.60 per share of our common stock at any time beginning on August 11, 2012 and ending on February 12, 2017.

In connection with the Merger and pursuant to the terms of the related merger agreement, all of the then issued and outstanding shares of Former ADMA's common stock, including the common stock issued in the 2012 Financing and including the shares of Former ADMA's Series A preferred stock, which were converted into common stock immediately prior to and as part of the Merger, were automatically exchanged into 4,601,270 shares of common stock of R&R Acquisition VI, Inc., par value \$0.0001 per share, which we refer to as our "common stock," at a 1:1 exchange ratio; all warrants, options and other rights to purchase or acquire shares of Former ADMA's common stock outstanding immediately prior to the Merger, including the Placement Agent Warrants and including the additional options granted to Adam S. Grossman, CEO, under his new employment agreement, were converted into warrants, options or other rights, as the case may be, to purchase an aggregate of 383,380 shares of our common stock at the same exercise prices; and 2,446,967 of the 2,500,000 shares of our common stock held by the stockholders of R&R Acquisition VI, Inc. immediately prior to the Merger were canceled such that these stockholders held 53,033 shares of our common stock post-Merger, not including the 87,865 shares issuable upon exercise of the Placement Agent Warrants, held by an affiliate of one of such stockholders.

Immediately prior to the Merger and the transactions described above, (i) 3,386,454 shares of Series A preferred stock of Former ADMA were converted into 11,243,748 shares of Former ADMA's common stock after giving effect to cumulative anti-dilution adjustments and accrued dividends, and 4,835,224 shares of Former ADMA's Series A preferred stock issued in December 2011 upon the conversion of convertible notes were converted into an equal number of shares of Former ADMA's common stock and (ii) the shares of Former ADMA's common stock were reverse split at a ratio of 1-for-6.8 (the "Reverse Split"). The consolidated financial statements were adjusted to give retroactive effect to the Reverse Split.

For accounting purposes, the Merger was accounted for as a reverse acquisition, with Former ADMA as the accounting acquiror (legal acquiree) and R&R Acquisition VI, Inc. (now ADMA Biologics, Inc.) as the accounting acquiree (legal acquiror), effectively a recapitalization of Former ADMA.

Our executive offices are located at 65 Commerce Way, Hackensack, New Jersey. Our telephone number is (201) 478-5552.

The Company maintains a website at [www.admabiologics.com](http://www.admabiologics.com); however, the information on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. This Annual Report on Form 10-K and all of the Company's filings under the Exchange Act, including copies of annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, are available free of charge through our website on the date we file those materials with, or furnish them to, the Securities and Exchange Commission (the "SEC"). Such filings are also available to the public on the internet at the SEC's website at [www.sec.gov](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.

### **Legal Proceedings**

We are not involved in any pending legal proceedings and are not aware of any threatened legal proceedings against us.

### **Item 1A. Risk Factors**

#### **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 operation may be materially adversely affected. In such case, the trading price of our common stock could decline and investors in our common stock could lose all or part of their investment.*

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

*To date, we have generated limited product revenues 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 limited revenues. All of our revenues to date have been derived from the sale of plasma collected by ADMA BioCenters, 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 will be unable to sell and generate revenues from that product. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from the revenues that may be generated by the sale of plasma collected by ADMA Biocenters, as well as cash on hand and potential future capital raises. While ADMA BioCenters is committed to maintain compliance with all applicable regulations, we cannot assure you that we will be able to retain the FDA license for our plasma collection center, which we need in order to sell plasma collected by ADMA BioCenters.

Our ability to continue as a going concern 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. 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, forcing us to curtail our activities and, ultimately, 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.

We anticipate that, based upon our projected revenue and expenditures for 2013, our current cash and cash equivalents, along with (i) our option to borrow an additional \$2 million in two equal tranches of \$1 million upon the satisfaction of certain milestones under our Loan Agreement with Hercules, and (ii) an aggregate \$4 million backstop financing agreement with the Lead Investors from the 2012 Financing (including Burrill Capital Fund IV, LP, Aisling Capital II, LP and Dr. Jerrold B. Grossman and Adam S. Grossman), will be sufficient to fund our operations into the second quarter of 2014. The relevant milestones under our Loan Agreement with Hercules consist of (a) enrolling at least one patient in a pivotal (Phase III) clinical study of our lead product candidate RI-002 and (b) the closing of an equity financing or subordinated unsecured convertible debt financing with aggregate unrestricted net proceeds of at least \$10 million on or before June 30, 2013. If our assumptions underlying our estimated expenses prove to be wrong, we may have to raise additional capital sooner than anticipated, and 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 could delay, discontinue or prevent product development and clinical trial 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.

*Our shares have never traded and if we are quoted on the OTC Bulletin Board, the trading volume in our shares could be limited.*

We have been a public reporting company since February 13, 2012. However, we have fewer than ten stockholders and there is not currently, nor has there ever been, any public market for our common stock. To the extent that we will not be eligible for listing on the NASDAQ or any other national securities exchange, our trading volume and the liquidity of our shares could be limited.

*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, 2012 and December 31, 2011, we had net losses of \$7.3 million and \$5.9 million, respectively, and from our inception in 2004 through December 31, 2012, we have incurred a net loss of \$37.1 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:

- continue to undertake development and clinical trials for RI-002;
- seek regulatory approval(s);
- implement additional internal systems, controls and infrastructure; and
- hire additional personnel.

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.

*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 additional clinical testing. Clinical trials are 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 submit a Biological License Application, or BLA, for regulatory approval for RI-002 or whether any such BLA will be accepted or approved. We estimate that clinical trials of our product candidate will take at least 18 months to several years to complete. Furthermore, failure can occur at any stage of the trials, 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, we or the FDA or an Institutional Review Board, or 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 Investigational New Drug Application, or IND, submissions or the conduct of these trials. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. We completed clinical trials in 2008 and 2009, during which we enrolled 21 patients. The focus of our planned Phase III clinical trial has been designed in accordance with the FDA Guidance for Industry and we believe that the revised design will increase the probability of successful trial enrollment. No assurance can be given that we will be able to enroll sufficient patients to complete a successful Phase III clinical trial.

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 if our clinical trials are 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 the filing of a BLA with the FDA and, ultimately, 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 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, or any other product candidate, 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 attain required FDA approval of any other product candidate generally requires significant research and testing, referred to as preclinical studies, as well as human tests, referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in products that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the product approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidate;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject our BLA. 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.

*We depend on third-party researchers and developers 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, 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.

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

We have limited experience in manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources to manufacture RI-002. Although we have agreements pertaining to the manufacture, supply, storage and distribution of product supplies of RI-002 for clinical development purposes, we do not have any agreements for the commercial scale manufacture of RI-002, and upon commercialization, it is possible that our manufacturing requirements may exceed the available supply allotments under our existing agreements. We will rely on one or more third-party contractors to manufacture our products. 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 supply our clinical trials or to successfully produce, store and distribute our products.
- Product manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- 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 our clinical trials, 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.

*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.

*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 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 Hercules is subject to acceleration in specified circumstances, which may result in Hercules taking possession and disposing of any collateral.*

On December 21, 2012, we entered into a Loan and Security Agreement, or the Loan Agreement, with Hercules Technology Growth Capital, Inc., or Hercules. Under the Loan Agreement, we may borrow up to a maximum of \$6 million. We borrowed \$4 million on the closing date and have the option to borrow an additional \$2 million in two equal tranches of \$1 million upon the satisfaction of certain milestones. Our obligations under the Loan Agreement are secured by a security interest in all of our assets, except for our intellectual property (which is subject to a negative pledge). The Loan Agreement contains customary representations, warranties and covenants, including limitations on acquisitions, dispositions, incurrence of indebtedness and the granting of security interests. Upon the occurrence and during the continuance of any event of default, including upon the occurrence of any event deemed to result in a material adverse event, Hercules may, and at the written request of the requisite lenders shall, terminate the commitments under the facilities and declare any or all of the obligations to be immediately due and payable, without demand or notice to us. However, any event of default relating to timely payment of debts, insolvency, liquidation, bankruptcy or similar events will result in automatic acceleration. Among the remedies available to Hercules in case of an event of default are the taking possession and disposition of any collateral under the Loan Agreement.

*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.

*We do not own any issued patents and we do not have any patent applications currently pending relating to our primary product candidate. If we are unable to protect our trade secrets or other proprietary rights, our competitiveness and business prospects may be materially damaged.*

We do not own any issued patents and we do not have any patent applications currently pending relating to our primary product candidate. Rather, we rely exclusively on a combination of trade secrets and nondisclosure and non-competition agreements to protect our proprietary intellectual property, and we will continue to do so. While we intend to defend against any threats to our intellectual property, there can be no assurance 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. 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.

*Third parties could obtain patents that may require us to negotiate licenses to conduct our business, and there can be no assurance that the required licenses would be available on reasonable terms or at all.*

We may not be able to operate our business without infringing third-party patents. Numerous U.S. and foreign patents and pending patent applications owned by third parties exist in fields that relate to the development and commercialization of immune globulins. In addition, many companies have employed intellectual property litigation as a way to gain a competitive advantage. It is possible that infringement claims may occur as the number of products and competitors in our market increases. In addition, to the extent that we gain greater visibility and market exposure as a public company, we face a greater risk of being the subject of intellectual property infringement claims. We cannot be certain that the conduct of our business does not and will not infringe intellectual property or other proprietary rights of others in the 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 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 would be harmed.

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

Our performance is substantially dependent on the continued service and performance of our management team, who have extensive experience and specialized expertise in our business. In particular, the loss of Adam S. Grossman, our president and chief executive officer, could adversely affect our business and operating results. We do not have “key person” life insurance policies for any members of our management team. We have employment agreements with each of our executive officers, however, the existence of an employment agreement does not guarantee retention of members of our management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms.

*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 finance and accounting, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. In particular, over the next 12 months, we expect to hire up to 10 new employees devoted to medical and scientific affairs, regulatory affairs, quality control, financial services, and general and operational management. We expect that the hiring of such additional personnel will increase our annual expenditures by approximately \$1.5 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 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 False Claims Act and the Anti-Kickback Law and the Public Health Service Act, and any regulations promulgated under their authority, 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, even 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, can result in substantial legal penalties, including, among others, exclusion from the Medicare and Medicaid programs, and arrangements with referral sources must be structured with care to comply with applicable requirements. Also, certain business practices, such as 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 Healthcare 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, Medicare and Medicaid Anti-Kickback provisions, 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. 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 882.1 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.

*Our manufacturing processes 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. Although we and our contract manufacturers attempt to maintain high standards for product testing, manufacturing, process controls and quality assurance, our products can become non-releasable or otherwise fail to meet our stringent specifications through a failure of one or more of these processes. Extensive testing is performed throughout the process to ensure the safety and effectiveness of our products. We may, however, 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 current Good Manufacturing Practices, or cGMP, or other regulations. Such an event of noncompliance would likely result in our determination that the implicated products should not be released 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.

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 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 involve 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. Bayer and 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.*

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 collections at our existing and possible future plasma collection centers. This strategy is dependent upon our ability to successfully integrate develop new centers, to obtain FDA approval for any unlicensed plasma centers, to maintain a cGMP compliant environment in all plasma centers and to expand production and attract donors to our 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 government and health administration authorities, private health maintenance organizations and health insurers and other healthcare payers.*

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. 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, 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 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.

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.

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.

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 economy may adversely impact our business.*

The difficult economic environment may adversely affect demand for our products. RI-002, our current product candidate, is expected to be sold to hospitals, specialty pharmacies and clinicians in the U.S. As a result of loss of jobs, patients may lose medical insurance and be unable to purchase supply or may be unable to pay their share of deductibles or co-payments. Hospitals adversely affected by the economy may steer patients to less costly therapies, resulting in a reduction in demand, or demand may shift to public health hospitals, which may purchase at a lower government price. While to date we cannot directly trace any material reduction in demand to the recession, if economic conditions do not improve, the impact may become material.

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

*We are a clinical 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 clinical 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 \$7.3 million and \$5.9 million for the years ended December 31, 2012 and 2011, respectively. At December 31, 2012, we had an accumulated deficit of approximately \$37.1 million. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development 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 will need substantial 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, 2012 and 2011, we incurred research and development expenses of approximately \$3.5 million and \$0.6 million, respectively. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. We anticipate that, based upon our projected revenue and expenditures for 2013, our current cash and cash equivalents, along with (i) our option to borrow an additional \$2 million in two equal tranches of \$1 million upon the satisfaction of certain milestones under our Loan Agreement with Hercules, and (ii) an aggregate \$4 million backstop financing agreement with the Lead Investors from the 2012 Financing (including Burrill Capital Fund IV, LP, Aisling Capital II, LP and Dr. Jerrold B. Grossman and Adam S. Grossman), will be sufficient to fund our operations into the second quarter of 2014. The relevant milestones under our Loan Agreement with Hercules consist of (a) enrolling at least one patient in a pivotal (Phase III) clinical study of our lead product candidate RI-002 and (b) the closing of an equity financing or subordinated unsecured convertible debt financing with aggregate unrestricted net proceeds of at least \$10 million on or before June 30, 2013. 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 Loan and Security Agreement with Hercules, 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. We have filed with the Securities and Exchange Commission a registration statement relating to a proposed public offering of common stock. No assurances can be given that we will complete such offering or that we can do so on terms that are acceptable to our investors or to us. If we are unable to raise additional capital, we will have to delay, curtail or eliminate one or more of our research and development programs.

*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, it may be necessary to relinquish potentially valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

*If we fail to maintain proper and effective internal controls 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, for the year ended December 31, 2012, 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 may need to further upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

*We have only recently remediated previously reported material weaknesses in our internal control over financial reporting.*

Since the year ended December 31, 2011, we have remediated the following previously disclosed material weaknesses in our internal control over financial reporting: (i) the financial statement closing process did not identify all journal entries that needed to be recorded (ii) we had an inadequate level of accounting expertise among management to properly ensure that accounting transactions were properly recorded, such as the preparation of financial statements and (iii) we had inadequate segregation of duties by management in the financial reporting area. We have remediated these material weaknesses through, among other things, the recent hiring of a Chief Financial Officer with requisite accounting expertise in providing for the accuracy and proper recording of accounting transactions and the timely preparation and closing of financial statements, along with the engagement of a consultant to assist in the review of various aspects of our financial reporting.

### **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;
- 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 biotechnological 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.*

Almost all of our 4.6 million outstanding shares of common stock, as well as a substantial number of shares of our common stock underlying outstanding options and warrants, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act or an effective registration statement. 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. 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.

*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. 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.

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.

*If our common stock becomes subject to the penny stock rules, our shares may be more difficult to sell.*

The Securities and Exchange Commission has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than \$5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTC Bulletin Board does not meet such requirements and if the price of our common stock is less than \$5.00, our securities will be deemed penny stocks. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore security holders may have difficulty selling their shares.

*We are an "emerging growth company," and may 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 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 for up to five years after 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.

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**

None.

## **Item 2. Properties**

Our executive offices are located in approximately 5,000 square feet of space at 65 Commerce Way, Hackensack, 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. Although we may relocate our offices in the future, we anticipate that we will continue to maintain a services relationship with Areth LLC. We do not anticipate the amount of space and cost of rent to change materially from current levels.

ADMA BioCenters' facility is located at 6290 Jimmy Carter Boulevard, Suite 208, Norcross, Georgia. In June 2008, we entered into a lease for approximately 15,000 square feet of space which has been designed to meet the needs of a plasma collection center. The current rent is \$15,475 per month. Annual rent increases of no more than 2.5% per year are provided for in the lease agreement. The lease agreement expires on September 30, 2018.

## **Item 3. Legal Proceedings.**

We are not party to any material legal proceedings.

## **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**

We have been a public reporting company since February 13, 2012. However, there is not currently, and there has never been, any public market for our common stock. Our common stock is not currently eligible for trading on any national securities exchange or any over-the-counter markets, including the OTC Bulletin Board. Under the 2012 merger agreement, we are obligated to qualify the shares of our common stock for quotation on the OTC Bulletin Board and we are applying to have our common stock so quoted. We cannot assure you that our common stock will qualify for quotation, or, if it does, that it will continue to be quoted on the OTC Bulletin Board or that an active trading market will ever develop.

### **Holders**

As of March 5, 2013, there were 9 record holders of our common stock.

### **Registration Rights**

In connection with the 2012 Financing and the Merger, we agreed, pursuant to a registration rights agreement (the "Registration Rights Agreement"), to register on a registration statement (the "Investor Registration Statement") the resale of the shares of common stock issued in the Merger in exchange for the shares of common stock issued in the 2012 Financing and the shares of common stock owned by our pre-Merger stockholders, as well as the resale of the shares of common stock issuable upon exercise of the warrants issued to the placement agent and its designees in the Merger in exchange for the Placement Agent Warrants. Such registration statement was declared effective on August 13, 2012.

We refer to the securities the resale of which is required to be registered on the Investor Registration Statement as the “Registrable Securities.” If, among other events, the Investor Registration ceases to remain effective for more than 10 consecutive trading days or any 15 trading days during any 12-month period, we are required to pay in cash to the investors in the 2012 Financing an amount per month equal to one percent of the investors’ subscription amount for Registrable Securities still held by the investors, until the Investor Registration Statement is filed, declared effective or continues to be effective (as the case may be). This payment is subject to a maximum of (i) one percent of the investors’ subscription amount for Registrable Securities still held by the investors if we are diligently using our best efforts to have the Investor Registration Statement declared effective and the delays associated with the effectiveness of the Investor Registration Statement are the result of either continuing comments from or delays in reviewing by the SEC and (ii) ten percent of the investors’ subscription amount for Registrable Securities still held by the investors in all other cases.

We agreed to make such filings as are necessary to keep the Investor Registration Statement effective until the date on which all of the Registrable Securities have been sold or are saleable pursuant to Rule 144 (“Rule 144”) or its other subsections (or any successor thereto) under the Securities Act. We are obligated to bear registration expenses (exclusive of transfer taxes, underwriters’ discounts and commission) of all such registrations required.

The stockholders of Former ADMA also have registration rights with respect to the shares of common stock issued in the Merger in exchange for shares of Former ADMA’s common stock and shares of common stock issuable upon exercise of options they hold, pursuant to the Investors’ Rights Agreement. They have agreed to waive their piggy back registration rights with respect to the Investor Registration Statement; however, they will be entitled to require the filing of a resale registration statement pursuant to the Investors’ Rights Agreement.

Under the terms of the securities purchase agreement entered into in connection with the 2012 Financing, we are obligated to cause securities to be delivered to non-affiliates without any restrictive legends if the resale of such securities has been registered, such securities have been sold pursuant to Rule 144 or, in certain circumstances, if such securities are eligible for sale under Rule 144. If we fail to do so, we are obligated to pay to the investor, for each \$1,000 of shares, \$1 per trading day, increasing to \$2 per trading day five trading days after such damages have begun to accrue, until unrestricted certificates are delivered. In addition, if the Company fails to satisfy the current public information requirement under Rule 144(c), then the Company is obligated to pay to an investor, for any delay in or reduction of its ability to sell the securities, an amount equal to 1% of the aggregate subscription amount of such investor’s securities on the date of such current public information failure and on every 30th day thereafter (prorated for shorter periods) until the failure is cured or public information is no longer required for a Rule 144 sale.

#### **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 existing and future debt agreements may preclude us from paying dividends. 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, 2012:

| <b>Plan Category</b>                                       | <b>Number of securities to be issued upon exercise of outstanding options, warrants and rights</b> | <b>Weighted-average exercise price of outstanding options, warrants and rights</b> | <b>Number of securities remaining available for future issuance under equity compensation plans</b> |
|--|--|--|---|
| Equity compensation plans approved by security holders     | 589,937  | \$ 8.71  | 121,263   |
| Equity compensation plans not approved by security holders | -  | \$ -   | -   |
| <b>Total</b>   | <b>589,937</b>   | <b>\$ 8.71</b>   | <b>121,263</b>  |

## Recent Sales of Unregistered Securities

On December 21, 2012, ADMA and its subsidiaries entered into the Loan Agreement with Hercules. Under the Loan Agreement, ADMA may borrow on a revolving basis up to a maximum of \$6.0 million. In connection with the Loan Agreement, ADMA issued to Hercules a warrant to purchase 25,000 shares of common stock with an exercise price set at the lower of (i) \$9.60 or (ii) the price per share of the next institutional round of financing, subject to customary anti-dilution adjustments. The warrant expires after 10 years and has piggyback registration rights.

The issuance of the warrant was not registered under the Securities Act. No general solicitation or advertising was used in connection with the issuance. In making the issuance to an accredited investor without registration under the Securities Act, the Company relied upon the exemption from registration contained in Section 4(2) of the Securities Act and/or Regulation D thereunder.

## Purchases of Equity Securities by the Issuer and Affiliated Purchasers

| Period              | Total number of shares (or units) purchased | Average price paid per share (or unit) | Total number of shares (or units) purchased as part of publicly announced plans or programs | Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs |
|---------------------|---|--|---|---|
| October 1-31, 2012  | 31,472(1)                                   | \$ 4.77                                | -   | -   |
| November 1-30, 2012 | -   | -                                      | -   | -   |
| December 1-31, 2012 | -   | -                                      | -   | -   |
| Total               | 31,472                                      | \$ 4.77                                | -   | -   |

(1) These shares were purchased other than through a publicly announced plan or program and involved a private transaction between the Company and one of its shareholders.

## 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 and its predecessor business, 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**

### ***Revenue***

As of December 31, 2012, we have generated \$1,879,160 of revenue since inception from the sale of normal source human plasma collected at our plasma collection center and plasma-derived medicinal products. Revenue is recognized at the time of transfer of title and risk of loss to the customer, which usually occurs at the time of shipment; however, revenue is recognized at the time of delivery if we retain the risk of loss during shipment.

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

Research and development expenses 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; as well as wages and benefits for employees directly related to the research and development of RI-002. All research and development is expensed as incurred.

The process of conducting preclinical studies and clinical trials 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, 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. We expect that our research and development expenses will increase during 2013 as a result of our pivotal Phase III clinical program, the hiring of a Chief Scientific and Medical Officer in the second half of 2012 and additional clinical operations staff, consultants and vendor requirements attributed to the development of RI-002.

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

General and administrative expenses consist of professional fees for our attorneys, accountants and auditors, wages and stock-based compensation for our senior management and staff unrelated to research and development, maintenance and utilities, insurance, information technology, travel and other expenses related to the general operations of the business. We expect that our general administrative expenses will increase during 2013, as a result of our hiring a Chief Financial Officer in the first half of 2012 and additional staff after becoming a public company in February 2012.

### ***Interest Income and Interest Expense***

Interest income consists of interest earned on our cash and cash equivalents. Interest expense consists of interest incurred on our notes payable and previous convertible notes up to their automatic conversion into our common stock upon the completion of our private placement in February 2012, as well as the amortization and write-off of deferred financing costs and debt discounts and a charge for the beneficial conversion feature relating to our notes payable and previous convertible notes.

## **Results of Operations**

### **Year Ended December 31, 2012 Compared to Year Ended December 31, 2011**

#### ***Summary Table***

The following table presents a summary of our results of operations for the year ended December 31, 2012 compared to the year ended December 31, 2011.

|   | Year ended<br>December 31,<br>2012 | Year ended<br>December 31,<br>2011 |
|---|------------------------------------|------------------------------------|
| Revenues  | \$ 1,118,118                       | \$ 761,042                         |
| Cost of sales   | 669,056                            | 207,570                            |
| Gross profit  | 449,062                            | 553,472                            |
| Research and development expenses                     | 3,469,078                          | 646,756                            |
| Loss on sale of inventory                             | -                                  | 1,934,630                          |
| Plasma center operating expenses                      | 1,746,864                          | 1,163,148                          |
| General and administrative expenses                   | 3,142,289                          | 1,431,894                          |
| Total operating expenses                              | 8,358,231                          | 5,176,428                          |
| Interest income                                       | 20,924                             | 1,689                              |
| Interest expense                                      | (30,683)                           | (1,602,958)                        |
| Loss before income taxes                              | (7,918,928)                        | (6,224,225)                        |
| Income tax benefit                                    | 617,615                            | 320,765                            |
| Net loss  | (7,301,313)                        | (5,903,460)                        |
| Loss before income taxes in plasma collection segment | (1,297,802)                        | (609,676)                          |
| Loss before income taxes in research and development  | (3,469,078)                        | (2,581,386)                        |

### **Revenue**

We recorded revenue of \$1,118,118 during the year ended December 31, 2012 compared to \$761,042 during the year ended December 31, 2011. We received FDA approval for ADMA BioCenters in August 2011 and began collecting blood plasma in February 2009. Our revenue is primarily derived from sales under a plasma supply agreement entered into with Biotest Pharmaceuticals Corporation, or Biotest, during June 2012, under which Biotest purchases normal source plasma from our Georgia facility to be used in their product manufacturing. We have not generated any revenue from our therapeutics/research and development segment.

### **Cost of Sales**

Cost of sales was \$669,056 for the year ended December 31, 2012, an increase of \$461,486 from \$207,570 for the year ended December 31, 2011. The increase of cost of sales was related to increased costs associated to increased normal source plasma revenues attributed to the plasma supply agreement entered into with Biotest in June 2012.

### **Research and Development Expenses**

Research and development expenses were \$3,469,078 for the year ended December 31, 2012, an increase of \$2,822,322 from \$646,756 for the year ended December 31, 2011. Research and development expenses consist of 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.

Research and development expenses increased primarily as a result of higher manufacturing, testing, and regulatory costs in preparation for our Phase III clinical study as well as the recent appointment of our Chief Scientific Officer/Chief Medical Officer and related wages and stock-based compensation expense during the year ended December 31, 2012. Our regulatory and clinical trial expenses in 2011 were extremely limited.

During the year ended December 31, 2012, there was no loss on the sale of research and development inventory as compared to a loss of \$1,934,630 during the year ended December 31, 2011, as a result of disposal of certain of our inventory that we previously acquired to conduct research and development for a different product. The total amount of inventory sold at book value was \$2,439,487, of which we received \$504,857 in total net proceeds from the inventory sales, thus resulting in a loss on the sale of research and development inventory of \$1,934,630 for the year ended December 31, 2011. This plasma, which was sold on a non-recurring basis, had not been collected at our plasma collection facility, but had been purchased from third parties.

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

Plasma center operating expenses were \$1,746,864 for the year ended December 31, 2012, an increase of \$583,716 from \$1,163,148 for the year ended December 31, 2011. Plasma center operating expenses consist of general and administrative overhead including rent, maintenance and utilities, wages and benefits for center staff, plasma transportation and storage (off-site) and computer software fees directly related to donor collections. Plasma center expenses increased following FDA approval of our plasma center in August 2011 as a result of increased donor collections, increased expenses related to donor collections such as additional facility expenses, supplies, and increased headcount during 2012. We expect that as plasma collection increases, our plasma center operating expenses will also increase accordingly.

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

General and administrative expenses were \$3,142,289 for the year ended December 31, 2012, an increase of \$1,710,395 from \$1,431,894 for the year ended December 31, 2011. 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 our attorneys, accountants and auditors, maintenance and utilities, insurance, information technology, travel and other expenses related to the general operations of the business. General and administrative expenses increased as a result of increases in stock-based compensation costs of \$525,181 for the year ended December 31, 2012 compared to \$22,056 for the year ended December 31, 2011, resulting from 2012 option grants to our President and Chief Executive Officer, members of our Board of Directors, our Chief Financial Officer who was appointed in May 2012, and new hires during 2012 in addition to higher professional services fees and SEC filing fees as a result of becoming a public reporting company in February 2012.

#### ***Total Operating Expenses***

Total operating expenses were \$8,358,231 for the year ended December 31, 2012, an increase of \$3,181,803 from \$5,176,428 during the year ended December 31, 2011, for the reasons stated above.

#### ***Interest Income/Expense***

We had interest income of \$20,924 and \$1,689 during the years ended December 31, 2012 and 2011, respectively, and interest expense of \$30,683 and \$1,602,958 during the years ended December 31, 2012 and 2011, respectively. The increase in interest income of \$19,235 for the year ended December 31, 2012 was attributed to higher cash balances during the year ended December 31, 2012 compared to the year ended December 31, 2011 as a result of the private placement of 1,800,000 shares of our common stock with gross proceeds in cash of \$17,287,288 in February 2012. The decrease of interest expense of \$1,572,275 for the year ended December 31, 2012 compared to the prior year was attributed to the conversion of our outstanding notes in December 2011 and February 2012. All but \$450,000 in principal amount of those loans was converted or repaid prior to December 31, 2011, with the remaining \$250,000 (plus \$12,740 in accrued interest) invested in the private placement of securities completed in 2012 and \$200,000 repaid in 2012.

#### ***Loss Before Income Taxes***

Loss before income taxes was \$7,918,928 for the year ended December 31, 2012, an increase of \$1,694,703 from \$6,224,225 during the year ended December 31, 2011, for reasons stated above.



### **State Income Tax Benefit**

In January 2012 and 2011, we received \$617,615 and \$320,765, respectively, 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 have 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 have to refund the face value of the proceeds less 20% for each year completed of the five year period. We cannot make assurances that we will qualify under this program in future years or even that the program will exist in future years.

### **Net Loss**

Net loss increased to \$7,301,313 for the year ended December 31, 2012 from \$5,903,460 for the year ended December 31, 2011, for reasons stated above.

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

Net cash used in operating activities was \$6,903,795 for the year ended December 31, 2012. The net loss for the year ended December 31, 2012 is higher than cash used in operating activities by \$397,518, as a result of increases in restricted cash related to our letter of credit for our Georgia facility, inventories of finished goods normal source plasma available for sale and accrued expenses primarily relating to accrued compensation, offset by a decrease in accounts payable and non-cash expenses of stock-based compensation of \$626,787 and depreciation and amortization of \$182,089.

Net cash used in operating activities was \$1,431,188 for the year ended December 31, 2011. The net loss for this period is higher than net cash used in operating activities by \$4,472,272, which was primarily due to the loss on sale of inventory, an increase in non-cash interest expense and a decrease in inventories, offset by depreciation and amortization of \$219,552 and amortization of debt discount and beneficial conversion charges of \$740,603 related to the notes payable during 2011 and 2012, of which all notes converted during February 2012.

### **Net Cash Used in Investing Activities**

Net cash used in investing activities for the year ended December 31, 2012 was \$118,853 related to equipment purchases.

Minimal cash was used in investing activities for the year ended December 31, 2011.

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

Net cash provided by financing activities of \$19,470,549 for the year ended December 31, 2012, was attributable to the proceeds of \$17,287,288 received from the private placement of our common stock on February 13, 2012, net of equity issuance costs of \$1,338,009 consisting of professional services fees related to the February 2012 private placement of common stock and the proposed upcoming financing, proceeds from a note payable of \$3,906,000 and related debt issuance costs of \$25,000 along with a repurchase of our common stock for \$150,000 and the repayment of our notes payable of \$200,000.

Net cash provided by financing activities for the year ended December 31, 2011 was \$1,290,258, principally attributable to proceeds from the issuance of convertible notes of \$1,500,000, net of repayment of notes payable of \$200,000.

## Liquidity and Capital Resources

### Overview

We have had limited revenue from operations and we have incurred cumulative losses of \$37.1 million since inception. We have funded our operations to date primarily from equity investments and loans from our primary stockholders. We received net cash proceeds of approximately \$15.3 million in our 2012 Financing, after the payment of all related expenses, including legal, printing, and travel expenses, the placement agent's commissions and expense reimbursements, which amount does not include the secured promissory notes that were satisfied in exchange for common stock in the 2012 Financing. We have also received funds through our Loan Agreement with Hercules, as described under "Hercules Loan and Security Agreement" below. We anticipate that based upon our projected revenue and expenditures for 2013, our current cash and cash equivalents, along with (i) our option to borrow an additional \$2 million in two equal tranches of \$1 million upon the satisfaction of certain milestones under our Loan Agreement with Hercules, and (ii) an aggregate \$4 million backstop financing agreement with the Lead Investors from the 2012 Financing, (including Burrill Capital Fund IV, LP, Aisling Capital II, LP and Dr. Jerrold B. Grossman and Adam S. Grossman), will be sufficient to fund our operations into the second quarter of 2014. The relevant milestones under our Loan Agreement with Hercules consist of (a) enrolling at least one patient in a pivotal (Phase III) clinical study of our lead product candidate RI-002 and (b) the closing of an equity financing or subordinated unsecured convertible debt financing with aggregate unrestricted net proceeds of at least \$10 million on or before June 30, 2013.

As we do not anticipate receiving FDA approval for RI-002, until at the earliest, the second half of 2015, if at all, and would therefore not be able to generate revenues from the commercialization of RI-002 until after that date, we will have to raise additional capital prior to the second quarter of 2014 to continue product development and operations. We are unable to predict with reasonable certainty when, if ever, we will generate revenues from the commercialization of RI-002 and, therefore, how much additional capital we will need to raise prior to the second quarter of 2014. Furthermore, if our assumptions underlying our estimated revenues and expenses prove to be wrong, we may have to raise additional capital sooner than anticipated. 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 clinical trials and development activities. Our current estimates may be subject to change as circumstances regarding 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.

Additional equity or debt financing, grants, or corporate collaboration and potential licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned clinical trials and delay or abandon potential commercialization efforts of our lead product candidate. See also "Future Financing Needs" below.

As of December 31, 2012, we had working capital of \$12.1 million, consisting primarily of \$12.5 million of cash and cash equivalents and \$1.3 million of inventories and \$0.1 million of prepaid expenses, offset by \$1.8 million in accounts payable and accrued expenses.

During January 2012, we received \$617,615 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.

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

On December 21, 2012, we and our subsidiaries entered into a Loan and Security Agreement, or the Loan Agreement, with Hercules Technology Growth Capital, Inc., or Hercules. Under the Loan Agreement, we may borrow up to a maximum of \$6 million. We borrowed \$4 million on the closing date and we have the option to borrow an additional \$2 million in two equal tranches of \$1 million each upon the satisfaction of (a) enrolling at least one patient in a pivotal (Phase III) clinical study of our lead product candidate RI-002 and (b) the closing of an equity financing or subordinated unsecured convertible debt financing with aggregate unrestricted net proceeds of at least \$10 million on or before June 30, 2013. The loan bears interest at a rate per annum equal to the greater of (i) 8.5% and (ii) the sum of (a) 8.5% plus (b) the Prime Rate (as reported in *The Wall Street Journal*) minus 5.75%. The loan is secured by our assets, except for our intellectual property (which is subject to a negative pledge). The principal will be repaid over 27 months beginning no later than May 1, 2014, unless accelerated as a result of certain events of default. Interest is due and payable on the first of every month and at the termination date, unless accelerated as a result of an event of default. In addition, a backend fee equal to 2.65% of the amount funded under the facility is due on the maturity or prepayment date or the date that the secured obligations become due and payable and a 1% facility fee in the amount of \$60,000 and a commitment fee in the amount of \$25,000 were both due at closing. The loan matures no later than August 2016.

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 in the first year, 2% if prepayment occurs in the second year and 0.5% if prepayment occurs after the second year but prior to the last day of the term.

The Loan Agreement 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 Loan Agreement 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 Loan Agreement.

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 Loan Agreement or other loan documents on a timely basis; (iii) failure to observe any covenant or secured obligation under the Loan Agreement 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 in excess of \$50,000 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 Loan Agreement and taking immediate possession of, and selling, any collateral securing the loan.

In connection with the Loan Agreement, we issued to Hercules a warrant to purchase 25,000 shares of common stock with an exercise price set at the lower of (i) \$9.60 or (ii) the price per share of the next round of financing, 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. In addition, we have also granted Hercules the option to invest (until the loan maturity date) up to \$1 million in future equity financings at the same terms as the other investors.

The Loan Agreement contains certain provisions that require the warrants issued to Hercules to be accounted for as a liability and “marked-to-market” each reporting period. Changes in the valuation of this liability at the end of each reporting period will be included in our reported operating results, and may create volatility in our reported operating results.

#### ***Future Financing Needs***

The net proceeds from our 2012 Financing and the first \$4 million borrowed under the Hercules Loan Agreement have been used to test plasma donors for RSV titers, collect and procure plasma, manufacture drug product, conduct clinical trials, and the remainder for payment of existing accounts payable, general and administrative expenses as well as other business activities and general corporate purposes, including for the payment of accrued expenses and premiums for directors’ and officers’ insurance. We anticipate that, based upon our projected revenue and expenditures for 2013, our current cash and cash equivalents, along with (i) our option to borrow an additional \$2 million in two equal tranches of \$1 million upon the satisfaction of certain milestones under our Loan Agreement with Hercules, and (ii) an aggregate \$4 million backstop financing agreement with the Lead Investors from the 2012 Financing (including Burrill Capital Fund IV, LP, Aisling Capital II, LP and Dr. Jerrold B. Grossman and Adam S. Grossman), will be sufficient to fund our operations into the second quarter of 2014.

Our ability to continue as a going concern will be dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. 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, forcing us to delay, discontinue or prevent product development and clinical trial activities or the approval of any of our potential products or curtail our activities and, ultimately, 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 of stockholders' interests 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.

We have filed with the Securities and Exchange Commission a registration statement relating to a proposed public offering of common stock. No assurances can be given that we will complete such offering or that we can do so on terms that are acceptable to our investors or to us.

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**

The Financial Accounting Standards Board has issued certain accounting pronouncements as of December 31, 2012 that will become effective in subsequent periods; however, we do not believe that any of those pronouncements would have significantly affected our financial accounting measurements or disclosures had they been in effect during the year ended December 31, 2012 or that they will have a significant impact at the time they become effective.

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

On April 5, 2012, the JOBS Act was signed into law. 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 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.

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 model. The non-cash 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 the purpose of valuing options and warrants granted to our employees, non-employees and directors and officers during the year ended December 31, 2012, we used the Black-Scholes option pricing model. We granted options to purchase an aggregate of 506,559 shares of common stock during the year ended December 31, 2012. Of the 506,559 options granted, 212,134 options were granted to our President and Chief Executive Officer, 106,067 options were granted to our Chief Scientific and Medical Officer, 66,292 options were granted to our Chief Financial Officer, 106,066 options in the aggregate were granted to our Board of Directors and 16,000 options in the aggregate were granted to non-executive employees. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of 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 Bulletin 107 which is based the average between vesting term and contractual term. 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 historical volatilities for similar publicly traded industry peers, since we do not have any trading history for our common stock. We will continue to analyze the expected stock price volatility and expected term assumptions as historical data for our common stock becomes available. We have not experienced 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 expenses include all research and development costs as incurred including on the disposition plasma and equipment for which there is no alternative future use. Such expenses include costs associated with planning and conducting clinical trials.

Our agreement with Biotest includes the in-license of certain rights to incomplete, in-process technology, which we expect to finalize by the end of the second quarter of 2013. As such, we expect to account for the value of this license as a charge to operations once the terms of the in-license agreement are finalized.

### ***Revenue Recognition***

Revenue from the sale of human plasma collected by ADMA BioCenters and plasma-derived medicinal products 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 attributed to one customer.

The plasma inventory sold in 2011 had been purchased from third parties specifically for use in research and development activities. It had not been collected by ADMA BioCenters and sold in the ordinary course of business. Therefore, the sale was not recorded as revenue with related cost of sales, but was instead recorded as a loss on sale.

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

We do not have any off-balance sheet arrangements except that we are currently obligated under a ten-year lease agreement for our ADMA BioCenters plasma collection facility. There is a total minimum rent due under the lease of \$952,064 through the end of the lease term in September 2018.

#### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

Not applicable.

#### **Item 8. Financial Statements and Supplementary Data.**

See the financial statements included at the end 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) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (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, 2012. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organization of the Treadway Commission ("COSO") in "Internal Control-Integrated Framework." Based on this assessment, management concluded that as of December 31, 2012, 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**

During management's assessment of the effectiveness of the Company's internal control over financial reporting, management identified the following change that occurred during the quarter ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting: During the fourth quarter ended December 31, 2012, we engaged a third party consultant to assist in the review of various aspects of the Company's financial reporting to remediate our previously reported material weakness in our financial reporting process with respect to inadequate segregation of duties by management in the financial reporting area.

#### **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 Accountant 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 and Financial Statement Schedules.**

**Financial Statement Schedules**

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

**EXHIBIT INDEX**

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 2.1 (1)            | Agreement and Plan of Merger, dated February 13, 2012, among R&R Acquisition VI, Inc., ADMA Biologics, Inc. and ADMA Acquisition Sub, Inc.   |
| 2.2 (1)            | Certificate of Merger, dated February 13, 2012, merging ADMA Acquisition Sub, Inc. with and into ADMA Biologics, Inc.  |
| 3.1 (1)            | Certificate of Incorporation of R&R Acquisition VI, Inc., as amended   |
| 3.2 (8)            | Bylaws of R&R Acquisition VI, Inc.   |
| 4.1 (2)            | Specimen Common Stock Certificate  |
| 4.2 (1)            | Form of Placement Agent Warrant  |
| 4.3 (9)            | Form of Warrant Agreement with Hercules Technology Growth Capital, Inc. ("Hercules")   |
| 4.4 (9)            | Form of Secured Term Loan Promissory Note issued to Hercules   |
| 10.1** (6)         | 2007 Employee Stock Option Plan (as amended)   |
| 10.2 (1)           | Form of Securities Purchase Agreement, dated as of February 13, 2012, between ADMA Biologics, Inc. and each purchaser identified on the signature pages thereto  |
| 10.3 (1)           | Form of Registration Rights Agreement, dated as of February 13, 2012, between R&R Acquisition VI, Inc. and each of the several purchasers signatory thereto  |
| 10.4 (1)           | Amended and Restated Placement Agency Agreement, dated February 12, 2012, between ADMA Biologics, Inc. and Rodman & Renshaw, LLC   |
| 10.5 (2)           | Form of Lockup Agreement (February 13, 2012)   |
| 10.6** (1)         | Employment Agreement, dated February 13, 2012, by and between ADMA Biologics, Inc. and Adam Grossman   |
| 10.7 (1)           | Investors' Rights Agreement, dated July 17, 2007, by and among the Company and each of the investors listed on Schedule A thereto  |
| 10.8+ (5)          | Manufacturing Agreement, dated as of October 23, 2006, by and between Biotest Pharmaceuticals Corporation ("Biotest") and ADMA Biologics, Inc., as amended as of October 23, 2011 and as of December 2, 2011                                       |
| 10.9+ (5)          | Plasma Purchase Agreement, dated as of November 17, 2011, between Biotest and ADMA Biologics, Inc., as amended as of December 1, 2011  |
| 10.10 (2)          | Agreement for Services between the Company and Areth Inc., dated July 23, 2007   |
| 10.11 (1)          | Agreement of Lease between the Company and C1VF I-GA1W15-W23, LLC (DCT Holdings), effective June 1, 2008 and confirmed on November 13, 2008, for the premises located at 6290 Jimmy Carter Boulevard, Suite 206-208, Norcross, Georgia, as amended |
| 10.12 (1)          | Form of Indemnification Agreement  |
| 10.13 ** (3)       | Employment Agreement, dated as of April 30, 2012, by and between ADMA Biologics, Inc. and Brian Lenz   |
| 10.14 (4)          | Modification and Release Agreement dated June 15, 2012, between ADMA Biologics, Inc. and Rodman & Renshaw, LLC   |
| 10.15+(7)          | Testing Services Agreement, dated June 7, 2012, between ADMA and Quest Diagnostics Clinical Laboratories, Inc.   |
| 10.16+(7)          | Plasma Supply Agreement, dated June 22, 2012, between ADMA and Biotest   |



|             |   |
|-------------|---|
| 10.17** (7) | Employment Agreement, dated July 18, 2012, by and among the Company and James Mond.   |
| 10.18 (9)   | Loan and Security Agreement, dated as of December 21, 2012 by and among ADMA, ADMA Plasma Biologics, Inc., ADMA Bio Centers Georgia Inc. and Hercules   |
| 10.19 (9)   | Equity Rights Letter, dated December 21, 2012, from ADMA to Hercules  |
| 10.20+ (9)  | Manufacturing, Supply and License Agreement, dated as of December 31, 2012, by and between Biotest and ADMA   |
| 10.21+ (9)  | License Agreement, dated December 31, 2012, by and between ADMA and Biotest Aktiengesellschaft  |
| 16.1 (1)    | Letter from Sherb & Co, LLP regarding change in certifying accountants  |
| 21.1 (2)    | Subsidiaries of Registrant  |
| 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, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets at December 31, 2012 and December 31, 2011, (ii) Statements of Operations for the years ended December 31, 2012 and 2011 (iii) Statements of Changes in Stockholders' Equity (Deficiency) for the years ended December 31, 2012 and 2011, (iv) Statements of Cash Flows for the years ended December 31, 2012 and 2011 and (v) Notes to the Financial Statements.*** |

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

\*\* Management compensatory plan, contract or arrangement.

\*\*\* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

- (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/A filed with the Commission on March 29, 2012.
- (3) Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the Commission on May 3, 2012.
- (4) Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the Commission on June 21, 2012.
- (5) Incorporated herein by reference to Amendment No. 3 to the Company's current report on Form 8-K filed with the Commission on June 22, 2012.
- (6) Incorporated herein by reference to Exhibit A to the Information Statement on Schedule 14C filed with the Commission on October 29, 2012.
- (7) Incorporated herein by reference to Amendment No. 4 to the Company's registration statement on Form S-1 (333-180449) filed with the Commission on August 10, 2012.
- (8) Incorporated herein by reference to Exhibit 3.2 to R&R Acquisition VI, Inc.'s registration statement on Form 10-SB, as filed with the Securities and Exchange Commission on July 10, 2006.
- (9) Incorporated herein by reference to the Company's registration statement on Form S-1 (333-186579) filed with the Securities and Exchange Commission on February 2, 2013.

**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 Hackensack, State of New Jersey on March 6, 2013.

**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:

| <b>Signature</b>  | <b>Title</b>  | <b>Date</b>   |
|---|---|---------------|
| <u>/s/ Adam S. Grossman</u><br>Adam S. Grossman               | President and Chief Executive<br>Officer (Principal Executive Officer)                    | March 6, 2013 |
| <u>/s/ Brian Lenz</u><br>Brian Lenz                           | Chief Financial Officer (Principal Financial<br>Officer and Principal Accounting Officer) | March 6, 2013 |
| <u>/s/ Steven A. Elms</u><br>Steven A. Elms                   | Chairman of the Board of Directors  | March 6, 2013 |
| <u>/s/ Dr. Jerrold B. Grossman</u><br>Dr. Jerrold B. Grossman | Vice Chairman of the Board of Directors<br>and Director                                   | March 6, 2013 |

|   |          |               |
|---|----------|---------------|
| <u>/s/ Bryant E. Fong</u><br>Bryant E. Fong                 | Director | March 6, 2013 |
| <u>/s/ Dov A. Goldstein, M.D.</u><br>Dov A. Goldstein, M.D. | Director | March 6, 2013 |
| <u>/s/ Lawrence P. Guiheen</u><br>Lawrence P. Guiheen       | Director | March 6, 2013 |
| <u>/s/ Eric I. Richman</u><br>Eric I. Richman               | Director | March 6, 2013 |

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**

**CONSOLIDATED FINANCIAL STATEMENTS**

**TABLE OF CONTENTS**

|  | <u>Page</u> |
|--|-------------|
| Report of Independent Registered Public Accounting Firm  | F-2         |
| Consolidated Balance Sheets as of December 31, 2012 and 2011   | F-3         |
| Consolidated Statements of Operations for the years ended December 31, 2012 and 2011                                   | F-4         |
| Consolidated Statements of Changes in Stockholders' Equity (Deficiency) for the years ended December 31, 2012 and 2011 | F-5         |
| Consolidated Statements of Cash Flows for the years ended December 31, 2012 and 2011                                   | F-6         |
| Notes to Consolidated Financial Statements   | F-7         |

## **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, 2012 and 2011, and the related consolidated statements of operations, changes in stockholders' equity (deficiency) 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 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 audits 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall 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, 2012 and 2011, 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.

/s/ CohnReznick LLP  
Roseland, New Jersey  
March 6, 2013

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**December 31, 2012 and 2011**

|  | 2012                 | 2011                |
|--|----------------------|---------------------|
| <b>ASSETS</b>  |                      |                     |
| Current Assets:  |                      |                     |
| Cash and Cash Equivalents  | \$ 12,535,672        | \$ 87,771           |
| Accounts Receivable  | 39,112               | -                   |
| Inventories  | 1,265,593            | 1,147,345           |
| Prepaid Expenses   | 107,761              | 59,244              |
| Total Current Assets   | 13,948,138           | 1,294,360           |
| Property and Equipment, at Cost, Net   | 779,297              | 860,932             |
| Other Assets:  |                      |                     |
| Deferred Financing Costs   | 363,403              | 421,077             |
| Restricted Cash  | 452,004              | 336,963             |
| Deposits   | 12,577               | 12,577              |
| Total Other Assets   | 827,984              | 770,617             |
| <b>TOTAL ASSETS</b>  | <b>\$ 15,555,419</b> | <b>\$ 2,925,909</b> |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                      |                     |
| Current Liabilities:   |                      |                     |
| Accounts Payable   | \$ 1,058,671         | \$ 1,303,414        |
| Accrued Expenses   | 747,079              | 537,705             |
| Current Portion of Leasehold Improvement Loan  | 11,569               | 10,576              |
| Notes Payable - Related Parties  | -                    | 450,000             |
| Total Current Liabilities  | 1,817,319            | 2,301,695           |
| Note Payable, Net of Debt Discount   | 3,773,524            | -                   |
| Warrant Liability  | 229,345              | -                   |
| End of Term Liability, Note Payable  | 106,000              | -                   |
| Deferred Rent Liability  | 127,595              | 149,785             |
| Leasehold Improvement Loan   | 77,890               | 88,613              |
| <b>TOTAL LIABILITIES</b>   | <b>6,131,673</b>     | <b>2,540,093</b>    |
| <b>COMMITMENTS AND CONTINGENCIES</b>   |                      |                     |
| <b>STOCKHOLDERS' EQUITY</b>  |                      |                     |
| Preferred Stock - \$0.001 par value, 10,000,000 and 8,221,678 shares authorized, 0 and 8,221,678 shares issued and outstanding with a liquidation preference of \$0 and \$31,959,545 at December 31, 2012 and 2011, respectively       | -                    | 8,222               |
| Common Stock - \$0.0001 and \$0.001 par value at December 31, 2012 and 2011, respectively; 75,000,000 and 6,500,000 shares authorized, 4,622,831 and 408,589 shares issued and outstanding at December 31, 2012 and 2011, respectively | 462                  | 409                 |
| Additional Paid-In Capital   | 46,532,612           | 30,185,200          |
| Accumulated Deficit  | (37,109,328)         | (29,808,015)        |
| <b>TOTAL STOCKHOLDERS' EQUITY</b>  | 9,423,746            | 385,816             |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>  | <b>\$ 15,555,419</b> | <b>\$ 2,925,909</b> |

See notes to consolidated financial statements

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**Years Ended December 31, 2012 and 2011**

|   | Years Ended December 31, |                       |
|---|--------------------------|-----------------------|
|   | 2012                     | 2011                  |
| <b>REVENUES</b>   | \$ 1,118,118             | \$ 761,042            |
| Cost of revenues  | 669,056                  | 207,570               |
| Gross profit  | <u>449,062</u>           | <u>553,472</u>        |
| <b>OPERATING EXPENSES</b>   |                          |                       |
| Research and development expenses   | 3,469,078                | 646,756               |
| Loss on sale of inventory   | -                        | 1,934,630             |
| Plasma center operating expenses  | 1,746,864                | 1,163,148             |
| General and administrative expenses   | <u>3,142,289</u>         | <u>1,431,894</u>      |
| <b>TOTAL OPERATING EXPENSES</b>   | <u>8,358,231</u>         | <u>5,176,428</u>      |
| <b>LOSS FROM OPERATIONS</b>   | (7,909,169)              | (4,622,956)           |
| Interest income   | 20,924                   | 1,689                 |
| Interest expense  | <u>(30,683)</u>          | <u>(1,602,958)</u>    |
| <b>LOSS BEFORE INCOME TAXES</b>   | (7,918,928)              | (6,224,225)           |
| State income tax benefit  | <u>617,615</u>           | <u>320,765</u>        |
| <b>NET LOSS</b>   | <u>\$ (7,301,313)</u>    | <u>\$ (5,903,460)</u> |
| <b>NET LOSS PER SHARE – BASIC AND DILUTED</b>                                       | <u>\$ (1.76)</u>         | <u>\$ (16.72)</u>     |
| <b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING<br/>– BASIC AND DILUTED</b> | <u>4,146,276</u>         | <u>353,098</u>        |

See notes to consolidated financial statements

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY)**  
**Years Ended December 31, 2012 and 2011**

|   | <u>Preferred Stock</u> |               | <u>Common Stock</u> |               | <u>Additional<br/>Paid-in Capital</u> | <u>Accumulated<br/>Deficit</u> | <u>Total</u>   |
|---|------------------------|---------------|---------------------|---------------|---------------------------------------|--------------------------------|----------------|
|   | <u>Shares</u>          | <u>Amount</u> | <u>Shares</u>       | <u>Amount</u> |                                       |                                |                |
| Balance – January 1, 2011   | 3,386,454              | \$ 3,386      | 351,535             | \$ 352        | \$ 19,974,125                         | \$ (23,904,555)                | \$ (3,926,692) |
| Stock based compensation  | -                      | -             | -                   | -             | 22,947                                | -                              | 22,947         |
| Beneficial conversion charge  | -                      | -             | -                   | -             | 556,418                               | -                              | 556,418        |
| Cashless exercise of warrants   | -                      | -             | 57,054              | 57            | (57)                                  | -                              | -              |
| Conversion of notes payable and accrued interest - December 22, 2011                      | 4,835,224              | 4,836         | -                   | -             | 9,631,767                             | -                              | 9,636,603      |
| Net loss  | -                      | -             | -                   | -             | -                                     | (5,903,460)                    | (5,903,460)    |
| Balance – December 31, 2011   | 8,221,678              | 8,222         | 408,589             | 409           | 30,185,200                            | (29,808,015)                   | 385,816        |
| Conversion of preferred shares and accumulated dividends                                  | (8,221,678)            | (8,222)       | 2,364,553           | 2,364         | 5,858                                 | -                              | -              |
| Conversion of notes payable and accrued interest into common stock in private placement   | -                      | -             | 27,369              | 27            | 262,713                               | -                              | 262,740        |
| Common stock sold in private placement, net of expenses                                   | -                      | -             | 1,800,759           | 1,801         | 15,597,915                            | -                              | 15,599,716     |
| Common stock retained by stockholders of shell company as part of reverse merger          | -                      | -             | 53,033              | 53            | (53)                                  | -                              | -              |
| Effects of change in par value from \$0.001 to \$0.0001 as a result of the reverse merger | -                      | -             | -                   | (4,189)       | 4,189                                 | -                              | -              |
| Repurchase of common stock from placement agent   | -                      | -             | (31,472)            | (3)           | (149,997)                             | -                              | (150,000)      |
| Stock-based compensation  | -                      | -             | -                   | -             | 626,787                               | -                              | 626,787        |
| Net loss  | -                      | -             | -                   | -             | -                                     | (7,301,313)                    | (7,301,313)    |
| Balance – December 31, 2012   | -                      | \$ -          | 4,622,831           | \$ 462        | \$ 46,532,612                         | \$ (37,109,328)                | \$ 9,423,746   |

See notes to consolidated financial statements



**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**Years Ended December 31, 2012 and 2011**

|   | Years Ended<br>December 31, |                |
|---|-----------------------------|----------------|
|   | 2012                        | 2011           |
| <b>Cash Flows from Operating Activities:</b>                                |                             |                |
| Net Loss  | \$ (7,301,313)              | \$ (5,903,460) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                             |                |
| Depreciation and Amortization   | 182,089                     | 219,552        |
| Stock-Based Compensation  | 626,787                     | 22,947         |
| Amortization of Debt Discount and Beneficial Conversion Charge              | 2,869                       | 740,603        |
| Amortization of Deferred Financing Costs                                    | 2,644                       | -              |
| Noncash Interest Expense Related to Notes Payable                           | 1,959                       | 847,082        |
| Loss on Sale of Inventory   | -                           | 1,934,630      |
| Loss on Disposal of Equipment   | 18,399                      | 945            |
| Changes in Operating Assets and Liabilities:                                |                             |                |
| Accounts Receivable   | (39,112)                    | -              |
| Inventories   | (118,248)                   | 308,480        |
| Prepaid Expenses  | (48,517)                    | 5,537          |
| Restricted Cash   | (115,041)                   | 90,000         |
| Accounts Payable  | (244,743)                   | 40,160         |
| Accrued Expenses  | 150,622                     | 284,526        |
| Deferred Rent Liability   | (22,190)                    | (22,190)       |
| Net Cash Used in Operating Activities                                       | (6,903,795)                 | (1,431,188)    |
| <b>Cash Flows from Investing Activities</b>                                 |                             |                |
| Purchase of Equipment   | (118,853)                   | (270)          |
| Net Cash Used in Investing Activities                                       | (118,853)                   | (270)          |
| <b>Cash Flows from Financing Activities</b>                                 |                             |                |
| Proceeds from the issuance of common stock, net of note payable conversion  | 17,287,288                  | -              |
| Payment of Equity Issuance Costs  | (1,338,009)                 | -              |
| Proceeds from Note Payable, Net of Fees                                     | 3,906,000                   | -              |
| Debt Issuance Costs   | (25,000)                    | -              |
| Repurchase of Common Stock  | (150,000)                   | -              |
| Proceeds from Convertible Notes Payable                                     | -                           | 1,500,000      |
| Repayments of Notes Payable   | (200,000)                   | (200,000)      |
| Payments of Leasehold Improvement Loan                                      | (9,730)                     | (9,742)        |
| Net Cash Provided by Financing Activities                                   | 19,470,549                  | 1,290,258      |
| <b>Net Increase (Decrease) in Cash and Cash Equivalents</b>                 | 12,447,901                  | (141,200)      |
| <b>Cash and Cash Equivalents, Beginning of Year</b>                         | 87,771                      | 228,971        |
| <b>Cash and Cash Equivalents, End of Year</b>                               | \$ 12,535,672               | \$ 87,771      |
| <b>SUPPLEMENTAL INFORMATION:</b>  |                             |                |
| Interest paid   | \$ 1,085                    | \$ 15,273      |
| <b>SUPPLEMENTAL DISCLOSURES:</b>  |                             |                |
| <b>NONCASH FINANCING ACTIVITIES:</b>  |                             |                |
| Preferred stock issued upon note payable and interest conversion            | \$ -                        | \$ 9,636,603   |
| Equity issuance costs, accrued and not paid                                 | \$ 69,533                   | \$ 421,077     |
| Issuance of common stock through the cashless exercise of warrants          | \$ -                        | \$ 57          |
| Stock retained by stockholders of shell company                             | \$ 53                       | -              |
| Conversion of notes payable and interest in private placement               | \$ 262,740                  | -              |
| End of term liability for note payable                                      | \$ 106,000                  | -              |
| Warrants issued in connection with note payable                             | \$ 229,345                  | \$ -           |

See notes to consolidated financial statements

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2012 AND 2011**

**1. ORGANIZATION AND BUSINESS**

ADMA Biologics, Inc. (“ADMA” or the “Company”) is a specialty immune globulin Company that develops and manufactures and intends to market plasma-based biologics for the treatment and prevention of certain infectious diseases. ADMA focuses on developing and commercializing plasma-derived human immune globulins through its wholly-owned subsidiary, ADMA Plasma Biologics, Inc. founded in 2004. ADMA is based in Hackensack, New Jersey. In addition, ADMA operates ADMA Bio Centers of Georgia. This wholly-owned subsidiary is a Delaware corporation that was formed on April 3, 2008. ADMA Bio Centers of Georgia is an FDA-licensed source plasma collection facility located in Norcross, Georgia.

The Company has experienced net losses and negative cash flows from operations since inception and expects these conditions to continue for the foreseeable future. The Company has needed to raise capital from the sales of its securities to sustain operations. In February 2012, the Company completed a private placement to raise gross proceeds of \$17.3 million (see Note 7).

Based upon the Company’s projected revenue and expenditures for 2013, management currently believes the Company’s existing cash along with the option to borrow an additional \$2 million in two equal tranches of \$1 million each upon the satisfaction of (i) enrolling at least 1 patient in a pivotal clinical study, Phase III of our lead product candidate RI-002 and (ii) the closing of an equity financing or subordinated unsecured convertible debt financing, both or individually on or before June 30, 2013, from its existing Loan and Security Agreement with Hercules Technology Growth Capital, Inc., or Hercules, in addition to an aggregate \$4 million backstop financing agreement with the Lead Investors from the February 2012 private placement, including Burrill Capital Fund IV, LP, Aisling Capital II, LP and Dr. Jerrold B. Grossman and Adam S. Grossman, will be sufficient to enable it to fund its operating expenses, research and development expenses and capital expenditures into the second quarter of 2014. Because the Company does not anticipate receiving FDA approval for RI-002 until, at the earliest, the second half of 2015, if at all, and would therefore not be able to generate revenues from the commercialization of RI-002 until after that date, it will have to raise additional capital prior to the second quarter of 2014 to continue product development and operations. The Company is unable to predict with reasonable certainty when, if ever, it will generate revenues from the commercialization of RI-002 and, therefore, how much additional capital it will need to raise prior to the second quarter of 2014. Furthermore, if the Company’s assumptions underlying its estimated revenues and expenses prove to be wrong, it may have to raise additional capital sooner than anticipated. There can be no assurance that such funds, if available at all, can be obtained on terms acceptable to the Company. Because of numerous risks and uncertainties associated with the research, development and future commercialization of the Company’s product candidate, it is unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with its anticipated clinical trials and development activities. Its current estimates may be subject to change as circumstances regarding requirements further develop.

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.

Prior to the last quarter of 2011, ADMA was a development stage company. ADMA’s primary focus since 2004 has been conducting research and development of human plasma-derived products for the treatment of specific disease states. The plasma collection center in Georgia was established in 2008 as a complementary business operation. The Georgia facility received its Food and Drug Administration or FDA license in August 2011. Under FDA license, ADMA BioCenters can collect normal source plasma and high-titer RSV plasma. The Company sells a portion of the collected normal source plasma to buyers in the open “spot” market. The Company also plans to use the high-titer Respiratory Syncytial Virus or RSV plasma collected by ADMA BioCenters in the manufacturing of RI-002. ADMA transitioned to an operating company from the development stage during the fourth quarter of 2011 when it began to generate revenues from this business segment.

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2012 AND 2011**

**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.

Inventories

Plasma inventories (both plasma intended for resale and plasma intended for internal use in our research and development activities) are carried at the lower of cost or market value determined on the first-in, first-out method. Once the research and development plasma is processed to a finished good for ongoing trials it is then expensed to research and development. Inventory at December 31, 2012 and 2011 consists of raw materials. Inventory also includes plasma collected at the Company's FDA licensed plasma collection center. Approximately 9,000 liters of plasma inventory was sold in 2011, and the Company recorded a loss of \$1,934,630. The total amount of inventory sold at book value was \$2,439,487 and the Company received \$504,857 in proceeds from the sales.

Revenue recognition

Revenue from the sale of human plasma collected at the Company's FDA licensed plasma collection center and plasma-derived medicinal products 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 the Company retains the risk of loss during shipment. The Company's revenues are substantially attributed to one customer.

This plasma inventory sold in 2011 was sold on a non-recurring basis and had not been collected at our plasma collection facility, but had been purchased from third parties to conduct research and development for a different product. The Company abandoned the research program and sold the inventory to generate additional funds for operations. Therefore, the sale was not recorded as revenue with related cost of sales, but was instead recorded as a loss on sale of inventory.

Research and development costs

The Company expenses all research and development costs as incurred including plasma and equipment for which there is no alternative future use. Such expenses include licensing fees and costs associated with planning and conducting clinical trials.

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 of stock-based compensation, and the allowance for the valuation of future tax benefits.

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2012 AND 2011**

Concentration of credit risk

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

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

From June 24, 2004 to July 16, 2007, the Company elected to be taxed as an S corporation for both Federal and state income tax reporting purposes. Accordingly, the taxable income or loss related to that period was includable in the personal income tax returns of the stockholders.

Effective July 16, 2007, the Company was merged into a C corporation and adopted guidance issued by the Financial Accounting Standards Board, "Accounting for Income Taxes" which requires that the Company recognize deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the 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, 2012 and 2011. The Company's U.S. Federal and state income tax returns prior to fiscal year 2009 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

Net loss per share is determined in accordance with the two-class method. This method is used for computing basic net loss per share when companies have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the Company. Under the two-class method, net loss is allocated between common shares and other participating securities based on their participation rights in both distributed and undistributed earnings. The Company's Series A convertible preferred stock are participating securities, since the stockholders are entitled to share in dividends declared by the board of directors with the common stock based on their equivalent common shares.

Basic net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Because the holders of the Series A convertible Preferred Stock are not contractually required to share in the Company's losses in applying the two-class method to compute basic net loss per common share, no allocation to preferred stock was made for the years ended December 31, 2012 and 2011.

Diluted net loss per share is calculated by dividing net loss applicable 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 shares include the shares of common stock issuable upon the exercise of outstanding stock options and a warrant (using the treasury stock method) and the conversion of the shares of Series A convertible preferred stock (using the more dilutive of the (a) as converted method or (b) the two-class method). Potential common shares in the diluted net loss per share computation are excluded to the extent that they 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. Potentially dilutive securities that would be issued upon conversion of convertible notes, conversion of Series A convertible preferred stock, and the exercise of outstanding warrants and stock options were 0.7 million at December 31, 2012 and 1.7 million at December 31, 2011.

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2012 AND 2011**

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 options granted under the Company's 2007 Employee Stock Option Plan (the "Plan") are recognized as compensation expense over the option-vesting period.

During the years ended December 31, 2012 and 2011, the Company recorded stock-based compensation expense to employees and a consultant of \$626,787 and \$22,947, respectively. There were 506,559 and 0 options granted to employees and members of the Board of Directors for the years ended December 31, 2012 and 2011, 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. Because there is no public market for the Company's stock and very little historical experience with the Company's stock options, a small similar publicly traded company was used for comparison and expectations as to assumptions required for fair value computation using the Black-Scholes methodology. Guidance for stock-based compensation requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company currently estimates there will be no forfeitures of options.

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 December 31,<br>2012 |
|-----------------------------------|---------------------------------|
| Risk-free interest rate           | 0.97-1.62%                      |
| Expected volatility               | 82-85%                          |
| Expected term of options in years | 6.25                            |
| Expected dividend yield           | 0.0%                            |

Fair value of financial instruments

The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts payable, and notes payable are shown at cost which approximates fair value due to the short-term nature of these instruments. The carrying value of the long-term note payable approximates its fair value as of December 31, 2012, due to the timing of its closing which occurred on December 21, 2012.

### 3. PROPERTY AND EQUIPMENT

| Property and equipment consist of the following at December 31: | 2012              | 2011              |
|---|-------------------|-------------------|
| Lab and office equipment  | \$ 523,300        | \$ 465,778        |
| Computer software   | 141,277           | 141,277           |
| Leasehold improvements  | 940,103           | 940,103           |
|   | 1,604,680         | 1,547,158         |
| Less: accumulated depreciation and amortization                 | (825,383)         | (686,226)         |
|   | <u>\$ 779,297</u> | <u>\$ 860,932</u> |

The Company recorded depreciation and amortization expense of \$182,089 and \$219,552 for the years ended December 31, 2012 and 2011, respectively. The Company recorded a loss on disposal of equipment of \$18,399 for the year ended December 31, 2012 and \$945 for the year ended December 31, 2011.

### 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 December 31, 2018. Principal maturities under the loan are as follows:

|            |                  |
|------------|------------------|
| 2013       | \$ 11,569        |
| 2014       | 12,654           |
| 2015       | 13,841           |
| 2016       | 15,139           |
| 2017       | 16,559           |
| Thereafter | 19,697           |
| Total      | <u>\$ 89,459</u> |

### 5. NOTES PAYABLE TO SIGNIFICANT STOCKHOLDERS

As of February 13, 2012, all Notes and accrued interest and Preferred Stock have been converted into common stock or repaid in full.

Prior to February 13, 2012, the Company has issued senior secured convertible promissory notes (the "Notes") to significant stockholders pursuant to the terms of Note Purchase Agreements. The outstanding principal and interest under the notes are due and payable upon the earliest to occur of: (i) March 31, 2012 (as amended); (ii) the date on which the Company consummates a preferred stock financing in which the gross proceeds to the Company total at least \$10,000,000 ("Qualified Financing" as defined in the Notes); and (iii) the occurrence of an Event of Default (as defined in the Notes), the first of these three events to occur referred to as the "Maturity Date". Interest accrues on the outstanding principal at the stated rate and is payable on the Maturity Date.

If all or any of the principal and accrued interest thereon remains outstanding prior to the date of a Qualified Financing, those amounts shall automatically convert into shares of the Company's preferred stock at the lower of (a) the price per share paid by investors in the Qualified Financing or (b) the stated Conversion Price.

Any principal and accrued interest thereon that remains outstanding will convert into preferred shares at the stated conversion price if immediately prior to the Maturity Date, a Qualified Financing has not occurred and the Company does not have sufficient cash on hand to repay the outstanding balance in full. The Series A-1 and A-2 Preferred Stock shall have the same rights and privileges as the Company's Series A Preferred Stock and shall be senior to the Series A Preferred Stock in liquidation preference.

If the principal amounts due under these notes are repaid on the Maturity Date, the payees have the option to convert all of the accrued interest into shares of Series A Preferred Stock determined by dividing the interest by the Conversion Price.

In the Event of a Default, the interest rate stated on the notes shall be increased by three percent (3%) per annum. The Notes are collateralized by all of the assets of the Company.

The Company issued promissory notes, which are not convertible, to significant stockholders pursuant to the terms of Note Purchase Agreements. The outstanding principal and interest under the notes are due and payable upon the earliest to occur of: (i) March 31, 2012 (as amended); (ii) the occurrence of a prepayment event (as defined in the Notes) or (iii) the occurrence of an Event of Default (as defined in the Notes), the first of these three events to occur referred to as the "Maturity Date".

In December 2011, \$8,150,000 of the convertible notes payable and \$1,486,603 of accrued interest thereon were converted into 4,835,224 shares of the Company's Series A-1 preferred stock at a conversion price of \$1.9930 per share.

Notes payable consist of the following as of and for the year ended December 31, 2011:

| Issue Date | Principal December 31, 2010 | Principal Issued in 2011 | Principal Converted in 2011 | Principal Repaid in 2011 | Principal December 31, 2011 | Interest Rate | Conversion Price |
|------------|-----------------------------|--------------------------|-----------------------------|--------------------------|-----------------------------|---------------|------------------|
| Aug-09     | \$ 2,500,000                | \$ ---                   | \$ (2,500,000) *            | \$ ---                   | \$ ---                      | 9%            | \$ 1.9930        |
| Dec-09     | 2,500,000                   | ---                      | (2,500,000) *               | ---                      | ---                         | 9%            | \$ 1.9930        |
| Jun-10     | 1,800,000                   | ---                      | (1,800,000) *               | ---                      | ---                         | 12%           | \$ 1.9930        |
| Dec-10     | 500,000                     | ---                      | (500,000) *                 | ---                      | ---                         | 10%           | \$ 1.9930        |
| Feb-11     | ---                         | 300,000                  | (300,000) *                 | ---                      | ---                         | 10%           | \$ 1.9930        |
| May-11     | ---                         | 250,000                  | (250,000) *                 | ---                      | ---                         | 10%           | \$ 1.9930        |
| Jun-11     | ---                         | 300,000                  | (300,000) *                 | ---                      | ---                         | 10%           | \$ 1.9930        |
| Aug-11     | ---                         | 250,000                  | ---                         | ---                      | 250,000                     | 10%           | \$ 1.9930        |
| Sep-11     | ---                         | 100,000**                | ---                         | (100,000)                | ---                         | 18%           | ---              |
| Oct-11     | ---                         | 100,000**                | ---                         | (100,000)                | ---                         | 18%           | ---              |
| Dec-11     | ---                         | 200,000                  | ---                         | ---                      | 200,000                     | 18%           | ---              |
|            | <u>\$ 7,300,000</u>         | <u>\$ 1,500,000</u>      | <u>\$ (8,150,000)</u>       | <u>\$ (200,000)</u>      | <u>\$ 450,000</u>           |               |                  |

\*Notes convertible into Series A-1 and A-2 Preferred Stock. The conversion price was amended to \$1.9930 on December 22, 2011, resulting in a charge to interest expense of \$556,418. Additional charges to interest of \$184,185 and \$132,662 were recorded in 2011 and 2010, respectively, for the beneficial conversion feature on the notes issued in June and December 2010.

\*\*Notes paid in full during the year ended December 31, 2011 including interest of \$1,972.

Total interest expense incurred on the notes payable for the years ended December 31, 2012 and 2011 was \$1,959 and \$1,587,685, respectively.

#### Stock purchase warrants

In connection with the issuance of the June 2010, August 2011 and September 2011 Notes, the Company issued common stock purchase warrants expiring ten years from date of issue to existing common and preferred stockholders at an exercise price of \$0.07 per share. Such warrants vested immediately and can be exercised at any time up to the expiration date. As of January 1, 2011, there were 52,730 warrants outstanding. For the year ended December 31, 2011, there were 5,198 warrants issued, 586 were cancelled, and 57,342 were exercised, resulting in no warrants outstanding as of December 31, 2011.

## 6. DEBT

### *Hercules Debt Agreement*

In December 2012, the Company entered into a Loan and Security (the "Loan Agreement") with Hercules Technology Growth Capital, Inc. ("Hercules"). Under the Loan Agreement, the Company may borrow on a revolving basis up to a maximum of \$6.0 million which is comprised of the initial \$4 million note obligation committed to in December 2012, along with an additional \$2 million consisting of \$1 million each of the satisfaction of (i) enrolling at least 1 patient in a pivotal clinical study, Phase III of our lead product candidate RI-002 and (ii) the closing of an equity financing or subordinated unsecured convertible debt financing, both or individually on or before June 30, 2013. Pursuant to the Loan Agreement, the Company issued a \$4 million note and received net proceeds of \$3.9 million. The loan bears interest daily at the greater of (i) 8.5% and (ii) the sum of (a) 8.5% plus (b) the Prime Rate (as reported in *The Wall Street Journal*) minus 5.75%. The line of credit is collateralized by all of the Company's assets, except for our intellectual property (which is subject to a negative pledge). The principal will be repaid over 27 months beginning no later than May 1, 2014, unless accelerated as a result of certain events of default. If the Company generates any proceeds from the collateral securing the line of credit, such proceeds must be paid to the lender up to the amount of any outstanding balance. Interest is due and payable on the first of every month and at the termination date, unless accelerated as a result of an event of default.

A backend fee of \$106,000, equal to 2.65% of the amount funded under the facility, is due on the maturity or prepayment date or the date that the secured obligations become due and payable and a 1% facility fee in the amount of \$60,000 and \$34,000 of reimbursable legal fees incurred by Hercules were deducted from the \$4 million note. The Company also made a \$25,000 payment to Hercules as a commitment fee as part of the due diligence process prior to receiving funding. The Loan Agreement expires no later than August 2016, but can be terminated early in the following circumstances: (a) automatically upon the commencement of insolvency proceedings by or against the Company, (b) at the option of the lender without notice upon any other event of default, and (c) at the option of the Company upon seven business days' prior written notice. In the event of early termination, whether effected by the Company (which may prepay the loan in full), the lender or automatically, the Company is obligated to pay an amount corresponding to a percentage of the principal amount of the loan, with such percentage being: 3% if termination occurs in the first year, 2% if termination occurs in the second year and 0.5% if termination occurs after the second year but prior to the last day of the term.

The Loan Agreement contains customary representations, warranties and covenants, including limitations on incurring indebtedness, engaging in mergers or acquisitions and making investments, distributions or transfers.

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 Loan Agreement or other loan documents on a timely basis; (iii) failure to observe any covenant or secured obligation under the Loan Agreement, 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 in excess of \$50,000 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 any portion of the Company's assets are attached or seized. Remedies for events of default include acceleration of amounts owing under the Loan Agreement and taking immediate possession of, and selling, any collateral securing the loan.

In connection with the Loan Agreement, the Company issued to Hercules a warrant to purchase 25,000 shares of common stock with an exercise price set at the lower of (i) \$9.60 or (ii) the price per share of the next institutional round of financing, subject to customary anti-dilution adjustments. The warrant expires after 10 years and has piggyback registration rights. In addition, the Company has also granted Hercules the option to invest (so long as the credit facility remains) up to \$1 million in any future equity financings at the same terms as the other investors.



The fair value of the 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 (“downround protection”) in the next issuance of the Company’s common stock (the next round of equity financing). The key assumptions used to value the warrants included the expected date of the next round of equity financing, volatility of 84% on the Company’s common stock based upon similar public companies’ volatilities for comparison, an expected dividend yield of 0.0%, and a term of 10 years. The Company recorded the fair value of the warrant of \$229,345 as warrant liability and as a debt discount to the carrying value of the loan. This warrant liability will be adjusted 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. Also, upon full repayment or maturity of the loan, Hercules is due a payment of 2.65% of the loan, or \$106,000, which is recorded as deferred financing costs and as a long-term liability. Additionally, as noted above, the Company incurred fees related to the loan agreement and reimbursed Hercules for costs incurred by them related to the loan aggregating \$119,000. The Company will amortize these loan costs totaling \$225,000 to interest expense over the term of the loan. For the year ended December 31, 2012, interest expense related to the Hercules loan was \$9,386.

## **7. STOCKHOLDERS’ EQUITY**

The Company was originally organized as an S corporation and issued 100 shares of stock at a par value of \$0.01 each. On July 16, 2007, the Company merged into a C corporation and, concurrent with this election, each of the shares of stock of the terminating S corporation converted into 23,904.38 shares of common stock of the C corporation, resulting in a total of 351,535 shares outstanding. Since the shareholders of the S corporation became the majority shareholders of the C corporation, this was accounted for as a reverse merger. Accordingly, the pre-merger financial statements of the S corporation have become the historical financial statements of the C corporation.

Upon conversion of the Company from an S corporation to a C corporation, the Company increased its authorized common stock to 6,500,000 shares with a par value of \$.001 per share and authorized 3,400,000 shares of Series A preferred (Series A shares), with a par value of \$.001 per share. On July 17, 2007, the Company completed a private placement and raised gross proceeds of \$17,000,000 from the sale of 3,386,454 Series A convertible preferred shares at a sale price of \$5.02 per share.

In December 2011, 57,054 shares of Common Stock were issued in connection with the cashless exercise of 57,342 Stock Purchase Warrants and 4,835,224 shares of Series A-1 Preferred Stock were issued in connection with the conversion of notes payable and accrued interest thereon.

In December 2011, the corporate charter was amended to increase the authorized capital from 6,500,000 to 16,800,000 common shares and from 3,400,000 to 8,221,678 preferred shares.

On December 22, 2011, \$8,150,000 of notes payable to significant shareholders plus accrued interest were converted to Series A Preferred Stock at a conversion rate of \$1.993 per share resulting in the issuance of 4,835,224 additional shares of Series A Preferred Stock. The note holders also exercised 57,342 warrants in a cashless transaction for 57,054 shares of common stock and cancelled warrants for an additional 586 shares of common stock. The due date on all remaining notes payable to significant shareholders was extended from December 31, 2011 to March 31, 2012.

The Series A Preferred Shares had the following rights and preferences:

### Dividends

From and after the date of their issuance, dividends at the rate per annum of \$0.3514 per share accrued on Series A Preferred shares. The Company was under no obligation to pay such accrued dividends. However, dividends on the Preferred Shares were cumulative from the date of issuance and were to be paid before any dividends on shares of any other class of stock of the Company. No such dividends were declared prior to December 31, 2010. As of December 31, 2012 and 2011, \$0 and \$5,326,207, respectively, in dividends had accumulated on the Series A shares.

### Conversion

The holders of the Series A Preferred Shares had the right to convert their shares to common stock at any time at an initial conversion price of \$5.02 per share. In certain situations, the Preferred Shares were protected from dilution by future issuances of common stock at less than the Series A Preferred Share conversion price. At December 31, 2011, the conversion price was \$13.5524 per share under these anti-dilution provisions.

The Company was required, at all times, to reserve a sufficient number of shares of common stock to effect the conversion of all outstanding shares of preferred stock.

### Liquidation preference

Upon liquidation or dissolution of the Company, the holders of the Series A shares were entitled to be paid an amount per share equal to the Series A Original Issue Price (\$5.02 per share) plus the cumulative unpaid dividends and any other dividends declared but unpaid.

### Voting

The stockholders of the Series A Preferred Shares vote together with all other classes of stock as a single class on matters presented to the stockholders of the Company. Each holder of Series A Preferred Shares was entitled to a number of votes (one vote) equal to the number of whole shares of common stock into which the Series A Preferred Shares of such holder were convertible as of the record date for determining stockholders to vote on such matters, except with respect to certain corporate actions, which require a fifty percent (50%) approval of the then outstanding Series A Preferred Shares. The holders of record of the Series A shares, as a separate class, were entitled to elect two directors of the five-member Board of the Company. One of the two "Series A Directors" served as Chairman of the Board. The holders of record of the common stock were also entitled to elect two directors.

As of February 13, 2012, there were no Preferred Shares outstanding.

### 2012 Merger and Financing

On February 13, 2012, in connection with, and immediately prior to the closing of the Merger (as defined below), the Company completed a private placement (the "2012 Financing") of 1,828,128 shares of the Company's common stock at a price per share of \$9.60 to accredited investors, for gross proceeds to the Company of \$17,550,029 pursuant to a securities purchase agreement (the "Securities Purchase Agreement"). In lieu of repayment of senior secured promissory notes in the aggregate principal amount of \$250,000 (plus \$12,740 in accrued interest), the aggregate amount of unpaid principal and interest on the notes was invested by the holders of such notes in the 2012 Financing in exchange for shares of the Company's common stock. The net cash proceeds from the 2012 Financing, after the payment of all expenses related to the 2012 Financing and the Merger, approximated \$15.3 million.

Rodman & Renshaw, LLC (the "Placement Agent") acted as the exclusive placement agent in connection with the 2012 Financing. The Company paid the Placement Agent a cash fee for its services equal to 7% of the aggregate offering price paid by each investor in the 2012 Financing, other than with respect to certain investors. As additional compensation, the Company issued the Placement Agent warrants (the "Placement Agent Warrants") to purchase 87,865 shares of common stock of the Company. The Placement Agent Warrants, which were exchanged for warrants of ParentCo (as defined below) in the Merger, are exercisable at \$9.60 per share of Common Stock at any time beginning on August 11, 2012 and ending on February 12, 2017. The Company also agreed to reimburse the Placement Agent for up to \$100,000 of expenses it incurred in connection with the 2012 Financing and to indemnify it against certain liabilities in connection with the 2012 Financing.

On February 13, 2012, R & R Acquisition VI, Inc. ("ParentCo") entered into a merger agreement (the "Merger Agreement") with the Company and ADMA Acquisition Sub, Inc., a Delaware corporation ("Acquisition Sub") ("Merger"). Upon closing of the Merger, Acquisition Sub was merged with and into the Company, and the Company, as the surviving corporation in the Merger, became a wholly-owned subsidiary of ParentCo. ParentCo's corporate name was changed to ADMA Biologics, Inc.

In connection with the Merger and pursuant to the terms of the Merger Agreement, all of the then issued and outstanding shares of the Company's common stock, including the common stock issued in the 2012 Financing and including the shares of the Company's Series A preferred stock, which were converted into common stock immediately prior to and as part of the Merger, were automatically exchanged into 4,601,270 shares of common stock of ParentCo, par value \$0.0001 per share (the "Common Stock") at a 1:1 exchange ratio; all warrants, options and other rights to purchase or acquire shares of the Company's common stock outstanding immediately prior to the Merger, including the Placement Agent Warrants and including the additional options granted to Adam S. Grossman, CEO, under his new employment agreement, were converted into warrants, options or other rights, as the case may be, to purchase an aggregate of 383,380 shares of Common Stock at the same exercise prices; and 2,446,967 of the 2,500,000 shares of Common Stock held by the stockholders of ParentCo immediately prior to the Merger were canceled such that these stockholders held 53,033 shares of Common Stock, not including the 87,865 shares issuable upon exercise of the Placement Agent Warrants, held by an affiliate of one of such stockholders.

Immediately prior to the Merger and the transactions described above, (i) 3,386,454 shares of Series A Preferred Stock of the Company were converted into 11,243,748 shares of the Company's common stock after giving effect to cumulative anti-dilution adjustments and accrued dividends, and 4,835,224 shares of the Company's Series A Preferred Stock issued in December 2011 upon the conversion of convertible notes were converted into an equal number of shares of the Company's common stock and (ii) the shares of common stock of the Company were reverse split at a ratio of 1-for-6.8 (the "Reverse Split"). The consolidated financial statements were adjusted to give retroactive effect to the Reverse Split.

As part of the Merger, ParentCo assumed certain of the Company's obligations under an investors' rights agreement, dated July 17, 2007, by and among the Company and its stockholders (the "Investors' Rights Agreement"), assumed the Company's obligations under the Securities Purchase Agreement, and assumed the Company's Plan. After an increase in authorized shares under the Plan in connection with the Merger, the Company currently has options to purchase 295,515 shares of Common Stock issued and outstanding under the Plan and has reserved for future issuance under the Plan an additional 265,685 shares of Common Stock.

For accounting purposes, the Merger was accounted for as a reverse acquisition, with the Company as the accounting acquiror (legal acquiree) and ParentCo as the accounting acquiree (legal acquiror), effectively a recapitalization of the Company.

Following the Merger, the Company is authorized by its certificate of incorporation to issue an aggregate of 85,000,000 shares of capital stock, of which 75,000,000 are shares of common stock and 10,000,000 are shares of preferred stock, each with a par value of \$0.0001 per share.

On February 13, 2012, the Company entered into a new employment agreement with its President and Chief Executive Officer, Adam S. Grossman, which has an initial term of three (3) years, with automatic three (3) year renewal periods unless notice is provided 90 days in advance. The employment agreement provides that Mr. Grossman (i) will initially be paid \$350,000 annually beginning on the date on which the Merger closed (the "Effective Date"); (ii) is eligible for an annual cash bonus, the target of which is \$100,000, based upon the attainment of certain performance objectives mutually agreed to by the Board of Directors and Mr. Grossman; (iii) was to be granted on the Effective Date options to purchase shares of Common Stock representing 4% of the Company's equity on a fully diluted basis (options to purchase 212,134 shares of Common Stock at an exercise price of \$9.60 were granted pursuant to this provision) and (iv) is eligible to participate in the Company's standard benefits package. All options granted to Mr. Grossman were issued under the Company's stock option plan and vest over a four year period, with 25% of the options vesting on the Effective Date, and the remaining 75% vesting in equal monthly installments over the following 48 months of continued employment (full vesting on the fourth anniversary of the Effective Date), subject to accelerated vesting under certain circumstances. Mr. Grossman also received a bonus in connection with his 2011 performance, including in connection with the 2012 Financing and Merger, of \$50,000 on the date on which the Merger closed.

On October 1, 2012, the Company and Rodman & Renshaw, LLC, entered into a Securities Purchase Agreement (“SPA”) whereby the Company purchased 31,472 shares of common stock, par value \$0.0001 per share, for \$150,000 from Rodman & Renshaw, LLC. The shares of common stock purchased by the Company had originally been issued to R&R Investments IV, Inc., an affiliate of Rodman & Renshaw, LLC. See Note 1 - Organization and Business for additional information regarding the Merger and the 2012 Financing. These shares of common stock were retired, thus reducing the total shares of common stock outstanding from 4,654,303 to 4,622,831.

**8. 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, 2012 and 2011, respectively. 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.

The Company owed \$0 and \$450,000 to existing common and preferred stockholders under senior secured convertible promissory notes and nonconvertible promissory notes at December 31, 2012 and 2011, respectively. During 2011, there were additional borrowings of \$1,500,000 from the Company’s existing common and preferred stockholders and repayments of \$200,000 plus interest of \$1,972.

**9. COMMITMENTS AND CONTINGENCIES**

Lease commitments

Effective June 1, 2008, the Company entered into a 10-year lease for commercial space in a Georgia office building, commencing October 1, 2008. The lease provides for annual rent increases and renewal options at market rent. Rent expense under this lease was approximately \$140,000 in both 2012 and 2011.

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

|            |           |                |
|------------|-----------|----------------|
| 2013       | \$        | 156,058        |
| 2014       |           | 159,995        |
| 2015       |           | 164,026        |
| 2016       |           | 168,089        |
| 2017       |           | 172,278        |
| Thereafter |           | 131,618        |
|            | <u>\$</u> | <u>952,064</u> |

Irrevocable letter of credit

On May 27, 2008, the Company established a \$426,963 Standby Letter of Credit or LOC in favor of a landlord to guarantee payment under the Georgia office building lease. The landlord granted a temporary reduction of \$90,000 in the amount of the required letter of credit to \$336,963. This reduction was valid until the Company received FDA license for its plasma collection center in Georgia and begins to receive proceeds from the sale of plasma collected from the center. This license was granted by the FDA in August 2011 and the Company has reestablished the LOC to \$452,004 in accordance with the lease and required bank minimum standards for such LOC. The entire amount under this letter of credit is maintained in a restricted cash account as of December 31, 2012 and 2011. The letter of credit expires on September 30, 2018. Provided the Company is in good standing with the landlord, the Company has the ability to extinguish the LOC in accordance with the lease agreement as of September 30, 2013.

## Other commitments

On December 31, 2012, the Company entered into a new 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 Respiratory Syncytial Virus (“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 Food and Drug Administration (“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.

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 (“IGIV”) 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 IGIV 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. Biotest is also obligated to pay the Company an adjustable royalty based on a percentage of revenues from the sale of RSV antibody-enriched IGIV 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 by the end of the second quarter of 2013. 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 our receipt of a Biologics License Application (“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. 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 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, 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.

## **10. STOCK OPTIONS**

On July 16, 2007 (the “Effective Date”), the Company’s Board and stockholders adopted the 2007 Employee Stock Options Plan (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 711,200. The Plan has been adopted as a means of attracting, motivating, and retaining the best available personnel for positions of substantial responsibility within the Company.

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 non-qualified options (“NQOs”) unless specified by the Committee to be incentive stock options (“ISOs”), as defined by the Internal Revenue Code. 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, 2012 and 2011:

|  | Year Ended December 31, 2012 |  | Year Ended December 31, 2011 |  |
|--|------------------------------|--|------------------------------|--|
|  | Shares                       | Weighted<br>Average<br>Exercise<br>Price | Shares                       | Weighted<br>Average<br>Exercise<br>Price |
| Outstanding at beginning of period                               | 83,378                       | \$ 3.33                                  | 83,378                       | \$ 3.33                                  |
| Forfeited  | -                            | \$ -                                     | -                            | -  |
| Granted  | 506,559                      | \$ 9.60                                  | -                            | -  |
| Outstanding at end of period and expected to vest                | 589,937                      | \$ 8.71                                  | 83,378                       | \$ 3.33                                  |
| Options exercisable  | 175,022                      | \$ 6.67                                  | 80,282                       | \$ 3.38                                  |
| Weighted-average fair value of options granted during the period |                              | \$ 6.82                                  |                              | \$ -                                     |

The weighted average remaining contractual term of stock options outstanding and expected to vest at December 31, 2012 is 8.6 years. The weighted average remaining contractual term of stock options exercisable at December 31, 2012 is 7.1 years.

Stock-based compensation expense for the years ended December 31, 2012 and 2011 was:

|  | 2012       | 2011      |
|--|------------|-----------|
| Research and development               | \$ 101,606 | \$ 891    |
| General and administrative             | 525,181    | 22,056    |
| Total stock-based compensation expense | \$ 626,787 | \$ 22,947 |

As of December 31, 2012, the total compensation expense related to unvested options not yet recognized totaled \$2,832,702. The weighted-average vesting period over which the total compensation expense will be recorded related to unvested options not yet recognized at December 31, 2012 was approximately 3.3 years. As of December 31, 2012, the Company had 121,263 options available for future grant under the Plan and exercisable options of 175,022.

## 11. INCOME TAXES

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

|  | Year ended December 31, |                     |
|--|-------------------------|---------------------|
|  | 2012                    | 2011                |
| Benefit at US federal statutory rate                   | \$ (2,692,436)          | \$ (2,116,237)      |
| State taxes - deferred                                 | (395,946)               | (373,454)           |
| Beneficial conversion feature                          | -                       | 189,182             |
| Increase in valuation allowance, inclusive of true-ups | 3,088,382               | 2,397,522           |
| Research and development credits                       | -                       | (97,013)            |
| Sale of state net operating loss                       | (617,615)               | (320,765)           |
| Benefit for income taxes                               | <u>\$ (617,615)</u>     | <u>\$ (320,765)</u> |

A summary of our deferred tax assets is as follows:

Deferred tax assets:

|  |               |               |
|--|---------------|---------------|
| Federal and state net operating loss carryforwards | \$ 11,602,301 | \$ 10,267,000 |
| Federal and state research credits                 | 1,938,664     | 1,890,966     |
| Total gross deferred tax assets                    | 13,540,965    | 12,157,966    |
| Less: valuation allowance for deferred tax assets  | (13,540,965)  | (12,157,966)  |
| Net deferred tax assets                            | <u>\$ -</u>   | <u>\$ -</u>   |

As of December 31, 2012, the Company had Federal and state net operating loss carryforwards of approximately \$31.6 million and \$19.6 million, respectively. The Company also had Federal and state research and development tax credit carryforwards of approximately \$1.3 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.

The Company received \$617,615 and \$320,765 in January 2012 and January 2011, respectively, 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 financial statements as income tax benefits in the year they are received.

## 12. SEGMENTS

The Company is engaged in the development and commercialization of human plasma and plasma-derived therapeutics. The Company also operates an FDA-licensed source plasma collection facility located in Norcross, 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 plasma collection center segment includes the Company's operation 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:

| Year ended December 31, 2012          | Plasma<br>Collection<br>Center | Research<br>and<br>Development | Corporate   | Consolidated |
|---------------------------------------|--------------------------------|--------------------------------|-------------|--------------|
| Revenues                              | \$ 1,118,118                   | \$ ---                         | \$ ---      | \$ 1,118,118 |
| Loss from operations                  | (1,297,802)                    | (3,469,078)                    | (3,142,289) | (7,909,169)  |
| Interest expense, net                 | ---                            | ---                            | (9,759)     | (9,759)      |
| Loss before income taxes              | (1,297,802)                    | (3,469,078)                    | (3,152,048) | (7,918,928)  |
| Property and equipment at cost, net   | 687,462                        | 5,967                          | 85,868      | 779,297      |
| Depreciation and amortization expense | 164,514                        | 4,558                          | 13,017      | 182,089      |
| Year ended December 31, 2011          | Plasma<br>Collection<br>Center | Research<br>and<br>Development | Corporate   | Consolidated |
| Revenues                              | \$ 761,042                     | \$ ---                         | \$ ---      | \$ 761,042   |
| Loss from operations                  | (609,676)                      | (2,581,386)                    | (1,431,894) | (4,622,956)  |
| Interest expense, net                 | ---                            | ---                            | (1,601,269) | (1,601,269)  |
| Loss before income taxes              | (609,676)                      | (2,581,386)                    | (3,033,163) | (6,224,225)  |
| Property and equipment at cost, net   | 822,265                        | 28,924                         | 9,743       | 860,932      |
| Depreciation and amortization expense | 197,274                        | 18,144                         | 4,134       | 219,552      |

The “Corporate” column includes general and administrative overhead expenses. The column for Research and Development expense includes the loss on sale of research and development inventory incurred during the year ended December 31, 2011.

Property and equipment, net, included in the “Corporate” column above includes assets related to corporate and support functions.

### 13. SUBSEQUENT EVENTS

On January 23, 2013, the Compensation Committee of the Board of Directors (the “Board”) of the Company approved the following bonuses for the Company’s executive officers in accordance with their respective employment agreements: Adam S. Grossman: \$100,000, Brian Lenz: \$77,250 and Dr. James Mond: \$52,000. In addition, the Compensation Committee approved payment of a bonus of \$25,000 to the non-executive Vice-Chairman of the Board, Dr. Jerrold B. Grossman, in accordance with the arrangement made in connection with the February 2012 private placement and merger. The aforementioned bonuses are included in accrued expenses as of December 31, 2012. The Compensation Committee furthermore approved three percent salary increases for its executive officers, effective February 4, 2013.

On February 28, 2013, the Company and Biotest extended the timeframe to finalize the terms of the in-license agreement (See Note 9), which includes the in-license of certain rights to incomplete, in-process technology, the terms of which the Company expects to finalize by the end of the second quarter of 2013. 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.



## EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u>   |
|--------------------|--|
| 2.1 (1)            | Agreement and Plan of Merger, dated February 13, 2012, among R&R Acquisition VI, Inc., ADMA Biologics, Inc. and ADMA Acquisition Sub, Inc.   |
| 2.2 (1)            | Certificate of Merger, dated February 13, 2012, merging ADMA Acquisition Sub, Inc. with and into ADMA Biologics, Inc.  |
| 3.1 (1)            | Certificate of Incorporation of R&R Acquisition VI, Inc., as amended   |
| 3.2 (8)            | Bylaws of R&R Acquisition VI, Inc.   |
| 4.1 (2)            | Specimen Common Stock Certificate  |
| 4.2 (1)            | Form of Placement Agent Warrant  |
| 4.3 (9)            | Form of Warrant Agreement with Hercules Technology Growth Capital, Inc. ("Hercules")   |
| 4.4 (9)            | Form of Secured Term Loan Promissory Note issued to Hercules   |
| 10.1** (6)         | 2007 Employee Stock Option Plan (as amended)   |
| 10.2 (1)           | Form of Securities Purchase Agreement, dated as of February 13, 2012, between ADMA Biologics, Inc. and each purchaser identified on the signature pages thereto  |
| 10.3 (1)           | Form of Registration Rights Agreement, dated as of February 13, 2012, between R&R Acquisition VI, Inc. and each of the several purchasers signatory thereto  |
| 10.4 (1)           | Amended and Restated Placement Agency Agreement, dated February 12, 2012, between ADMA Biologics, Inc. and Rodman & Renshaw, LLC   |
| 10.5 (2)           | Form of Lockup Agreement (February 13, 2012)   |
| 10.6** (1)         | Employment Agreement, dated February 13, 2012, by and between ADMA Biologics, Inc. and Adam Grossman   |
| 10.7 (1)           | Investors' Rights Agreement, dated July 17, 2007, by and among the Company and each of the investors listed on Schedule A thereto  |
| 10.8+ (5)          | Manufacturing Agreement, dated as of October 23, 2006, by and between Biotest Pharmaceuticals Corporation ("Biotest") and ADMA Biologics, Inc., as amended as of October 23, 2011 and as of December 2, 2011                                       |
| 10.9+ (5)          | Plasma Purchase Agreement, dated as of November 17, 2011, between Biotest and ADMA Biologics, Inc., as amended as of December 1, 2011  |
| 10.10 (2)          | Agreement for Services between the Company and Areth Inc., dated July 23, 2007   |
| 10.11 (1)          | Agreement of Lease between the Company and C1VF I-GA1W15-W23, LLC (DCT Holdings), effective June 1, 2008 and confirmed on November 13, 2008, for the premises located at 6290 Jimmy Carter Boulevard, Suite 206-208, Norcross, Georgia, as amended |
| 10.12 (1)          | Form of Indemnification Agreement  |
| 10.13 ** (3)       | Employment Agreement, dated as of April 30, 2012, by and between ADMA Biologics, Inc. and Brian Lenz   |
| 10.14 (4)          | Modification and Release Agreement dated June 15, 2012, between ADMA Biologics, Inc and Rodman & Renshaw, LLC  |
| 10.15+ (7)         | Testing Services Agreement, dated June 7, 2012, between ADMA and Quest Diagnostics Clinical Laboratories, Inc.   |
| 10.16+ (7)         | Plasma Supply Agreement, dated June 22, 2012, between ADMA and Biotest   |
| 10.17** (7)        | Employment Agreement, dated July 18, 2012, by and among the Company and James Mond.  |
| 10.18 (9)          | Loan and Security Agreement, dated as of December 21, 2012 by and among ADMA, ADMA Plasma Biologics, Inc., ADMA Bio Centers Georgia Inc. and Hercules  |
| 10.19 (9)          | Equity Rights Letter, dated December 21, 2012, from ADMA to Hercules   |
| 10.20+ (9)         | Manufacturing, Supply and License Agreement, dated as of December 31, 2012, by and between Biotest and ADMA  |
| 10.21+ (9)         | License Agreement, dated December 31, 2012, by and between ADMA and Biotest Aktiengesellschaft   |
| 16.1 (1)           | Letter from Sherb & Co, LLP regarding change in certifying accountants   |

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|          |   |
|----------|---|
| 21.1 (2) | Subsidiaries of Registrant  |
| 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, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets at December 31, 2012 and December 31, 2011, (ii) Statements of Operations for the years ended December 31, 2012 and 2011 (iii) Statements of Changes in Stockholders' Equity (Deficiency) for the years ended December 31, 2012 and 2011, (iv) Statements of Cash Flows for the years ended December 31, 2012 and 2011 and (v) Notes to the Financial Statements.*** |

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

\*\* Management compensatory plan, contract or arrangement.

\*\*\* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

- (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/A filed with the Commission on March 29, 2012.
- (3) Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the Commission on May 3, 2012.
- (4) Incorporated herein by reference to the Company's Current Report on Form 8-K filed with the Commission on June 21, 2012.
- (5) Incorporated herein by reference to Amendment No. 3 to the Company's current report on Form 8-K filed with the Commission on June 22, 2012.
- (6) Incorporated herein by reference to Exhibit A to the Information Statement on Schedule 14C filed with the Commission on October 29, 2012.
- (7) Incorporated herein by reference to Amendment No. 4 to the Company's registration statement on Form S-1 (333-180449) filed with the Commission on August 10, 2012.
- (8) Incorporated herein by reference to Exhibit 3.2 to R&R Acquisition VI, Inc.'s registration statement on Form 10-SB, as filed with the Securities and Exchange Commission on July 10, 2006.
- (9) Incorporated herein by reference to the Company's registration statement on Form S-1 (333-186579) filed with the Securities and

Exchange Commission on February 2, 2013.

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Adam S. Grossman, certify that:

1. I have reviewed this annual report on Form 10-K of ADMA Biologics, Inc. for the year ended December 31, 2012;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 6, 2013

/s/ Adam S. Grossman

Name: Adam S. Grossman

Title: President and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Lenz, certify that:

1. I have reviewed this annual report on Form 10-K of ADMA Biologics, Inc. for the year ended December 31, 2012;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 6, 2013

/s/ Brian Lenz

Name: Brian Lenz

Title: Chief Financial Officer  
(Principal Financial Officer)



CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of ADMA Biologics, Inc., a Delaware corporation (the "Company") on Form 10-K for the year ended December 31, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Adam S. Grossman, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 6, 2013

/s/ Adam S. Grossman

Name: Adam S. Grossman

Title: President and Chief Executive Officer  
(Principal Executive Officer)





CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of ADMA Biologics, Inc., a Delaware corporation (the "Company") on Form 10-K for the year ended December 31, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian Lenz, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 6, 2013

/s/ Brian Lenz

Name: Brian Lenz

Title: Chief Financial Officer  
(Principal Financial Officer)

