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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

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

For the transition period from to

Commission File Number: 001-36728

ADMA BIOLOGICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

465 State Route 17, Ramsey, New Jersey 07446
(Address of Principal Executive Offices) (Zip Code)

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates was $133,158,287 as of June 30, 2018 (the last business day of the registrant's most recently completed second fiscal quarter), based on a total of 29,525,119 shares of common stock held by non-affiliates and a closing price of $4.51 as reported on the Nasdaq Capital Market on June 29, 2018.

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

DOCUMENTS INCORPORATED BY REFERENCE

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

ADMA BIOLOGICS, INC.

PART IV

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Special Note Regarding Forward-Looking Statements

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

- the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals;
- our ability to successfully leverage the anticipated benefits and synergies from our June 6, 2017 acquisition of certain assets of Biotest Pharmaceuticals Corporation (the "Biotest Transaction"), including optimization of the combined businesses, operations and products and services, including the nature, strategy and focus of the combined company and the management and governance structure of the combined company;
- our ability to resume the manufacturing of BIVIGAM on a commercial scale and commercialize this product once the deficiencies identified in a November 2014 warning letter (the "Warning Letter") with respect to the outstanding issues at the plasma fractionation facility in Boca Raton, FL acquired in the Biotest Transaction have been resolved by us to the satisfaction of the U.S. Food and Drug Administration (the "FDA"), as well as a positive review of the optimized manufacturing process under a Prior Approval Supplement by the FDA and our ability to adequately address the FDA's questions and information request contained in a Complete Response Letter received by us on December 19, 2018;
- our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products and the success of such efforts;
- the safety, efficacy and expected timing of and our ability to obtain and maintain regulatory approvals for our current products and product candidates, including the timeframe within which we may receive approval from the FDA, if at all, of our Biologics License Application resubmission for RI-002 and the labeling or nature of any such approvals;
- our dependence upon our third-party and related-party customers and vendors and their compliance with regulatory bodies;
- our ability to obtain adequate quantities of FDA-approved plasma with proper specifications;
- our plans to increase our supplies of plasma;

- the potential indications for our product candidates;

- potential investigational new product applications;

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

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

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

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

- the potential of RI-002 and BIVIGAM to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease or other immune deficiencies;

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

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- our intellectual property position and the defense thereof, including our expectations regarding the scope of patent protection with respect to RI-002 or other future pipeline product candidates;
- our manufacturing capabilities, third-party contractor capabilities and strategy;
- our plans related to manufacturing, supply and other collaborative agreements;
- our estimates regarding expenses, capital requirements and the need for additional financing;
- possible or likely reimbursement levels for our currently marketed products and, if any, if and when RI-002 is approved for marketing;
- estimates regarding market size, projected growth and sales for our existing products as well as our expectations of market acceptance of RI-002;
- future economic conditions or performance; and
- expectations for future capital requirements.

These statements may be found under the “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” sections of this Annual Report on Form 10-K. Forward-looking statements typically are identified by the use of terms such as “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should” or “will” or the negative thereof or other variations thereof or comp terminology. You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to the factors referenced above. Any forward-looking statement included or incorporated by reference in this Annual Report on Form 10-K reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions related to our operations, results of operations, industry and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements speak only as of the dates such statements are made.

In addition to the foregoing, you should also consider carefully the statements under the section entitled “Risk Factors” and other sections of this Annual Report on Form 10-K, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements. We undertake no obligation to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

This Annual Report on Form 10-K includes our trademarks, trade names and service marks, such as “Nabi-HB®” and “BIVIGAM®” which are protected under applicable intellectual property laws and are the property of ADMA Biologics, Inc., or its subsidiaries. Solely for convenience, trademarks, trade names and service marks referred to in this Annual Report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

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PART I

Item 1. Business

Unless the context otherwise requires, references in this Business section to "ADMA," "ADMA Biologics," the "Company," "we," "us" and "our" refer to ADMA Biologics, Inc., a Delaware corporation, as well as its wholly-owned and indirectly owned subsidiaries, ADMA Plasma Biologics, Inc., a Delaware corporation, ADMA Bio Centers Georgia Inc., a Delaware corporation ("ADMA Bio Centers") and ADMA BioManufacturing, LLC, a Delaware limited liability company ("ADMA BioManufacturing").

Overview

We are a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and the prevention and treatment of certain infectious diseases. Our targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons. We currently have two products with United States Food and Drug Administration (the "FDA") Biologics License Application ("BLA") approvals: Nabi-HB, which is currently marketed and commercially available and is indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen ("HBsAg"); and BIVIGAM, for which commercial distribution has been temporarily suspended since December 2016 and for which we have submitted a Prior Approval Supplement ("PAS") to the FDA to amend the approved BLA to allow for the commercial re-launch of the product, which is indicated for the treatment of primary humoral immunodeficiency. We are also developing a pipeline of plasma-derived therapeutics, including our lead pipeline product candidate, RI-002, for the treatment of Primary Immune Deficiency Disease ("PIDD"), for which we previously submitted a BLA to the FDA and which has now been assigned a Prescription Drug User Fee Act ("PDUFA") action date of April 2, 2019. Our products and product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients with or at risk for certain infectious diseases. Through ADMA Bio Centers, we operate an FDA-approved source plasma collection facility located in Kennesaw, GA, which provides us with a portion of our blood plasma for the manufacture of our products and product candidates. We intend to open additional plasma collection centers in the U.S. during the next few years. A typical plasma collection center, such as those operated by ADMA Bio Centers, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase and market conditions at the time of sale. Plasma collected from ADMA Bio Centers' facilities that is not used to manufacture our products or product candidates is sold to third-party customers in the U.S., in other locations where we are approved globally under supply agreements or in the open "spot" market.

On June 6, 2017, we completed the acquisition of certain assets (the "Biotest Assets") of the Therapy Business Unit ("BTBU") of Biotest Pharmaceuticals Corporation ("BPC" and, together with Biotest AG, "Biotest"), which include two FDA-licensed products, Nabi-HB (Hepatitis B Immune Globulin, Human) and BIVIGAM (Immune Globulin Intravenous, Human) and a plasma fractionation facility located in Boca Raton, FL (the "Boca Facility") (the "Biotest Transaction"). The Boca Facility is FDA-licensed and certified by the German Health Authority (the "GHA"). In addition to the manufacture and sale of Nabi-HB and the manufacture of BIVIGAM and RI-002, we also provide contract manufacturing services for certain historical clients, including the potential sale of intermediate by-products. Immediately following the acquisition, the Biotest Assets were contributed into ADMA BioManufacturing.

Concurrent with the closing of the Biotest Transaction, Biotest provided us with an aggregate of $40.0 million of funding. Upon the closing of the Biotest Transaction, we received $27.5 million from Biotest, comprised of $12.5 million in cash from BPC and a $15.0 million subordinated note at 6% interest payable to Biotest with a maturity of five years. Biotest also participated in our November 2017 follow-on equity offering by investing $12.5 million of the $42.0 million of total gross proceeds from the offering (see "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this Annual Report on Form 10-K).

At the closing of the Biotest Transaction, we delivered to BPC an aggregate equity interest equal to 50%, less one share, of our then-issued and outstanding capital stock comprised of 25%, or 4,295,580 shares, of our then-issued and outstanding voting common stock, $0.0001 par value per share ("Common Stock"), and 8,591,160 shares in the form of our non-voting common stock, $0.0001 par value per share (the "NV Biotest Shares") (calculated as of immediately following the closing and on a post-closing issuance basis). The NV Biotest Shares were convertible into our Common Stock upon the occurrence of certain specified events.

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

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

Our Products

Nabi-HB

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

BIVIGAM

BIVIGAM is an intravenous immune globulin indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These primary immunodeficiencies ("PIs") are a group of genetic disorders. Initially thought to be very rare, it is now believed that as many as one in every 1,200-2,000 people has some form of PI. BIVIGAM contains a broad range of antibodies similar to those found in normal human plasma. These antibodies are directed against bacteria and viruses, and help to protect PI patients against serious infections. BIVIGAM is a purified, sterile, ready-to-use preparation of concentrated Immunoglobulin ("IgG") antibodies. Antibodies are proteins in the human immune system that work to defend against disease. FDA approval for BIVIGAM was received on December 19, 2012, and sales commenced in the first quarter of 2013. In December 2016, BPC temporarily suspended the commercial production of BIVIGAM in order to focus on the completion of planned improvements to the manufacturing process. We resumed production of BIVIGAM utilizing our optimized intravenous immunoglobulin ("IVIG") manufacturing process with two conformance lots in the fourth quarter of 2017, a third conformance lot in the first quarter of 2018 and additional production lots in the fourth quarter of 2018. During the first half of 2018, we qualified, validated and filled the BIVIGAM conformance batches and the product is currently on stability. During the second half of 2018, we filed a PAS with the FDA for BIVIGAM to include the ADMA optimization improvements for BIVIGAM and to seek FDA authorization which would enable us to resume commercial scale manufacturing and re-launch and commercialize this product in the U.S. On December 19, 2018, we announced the receipt of a Complete Response Letter ("CRL") (the "BIVIGAM CRL") from the FDA for our PAS submission for BIVIGAM drug substance, and also announced the FDA approval of our PAS submission for BIVIGAM drug product. For clarity, drug substance is the bulk immune globulin we manufacture at the Boca Facility and drug product is the result of shipping the drug substance to our third party fill-finish provider who then fills the drug into vials and prepares the product for final release testing and potential commercial release. The BIVIGAM CRL requested certain additional information and clarifications relating to chemistry, manufacturing and control ("CMC") matters contained in our PAS submission for drug substance, including complete resolution of certain manufacturing related deviations, information pertaining to how certain in-process manufacturing samples are taken, as well as updates on certain stability data previously submitted. As the information we believed necessary to address and respond to the matters raised in the BIVIGAM CRL was readily available in our files, on January 7, 2019 we announced that our responses to the BIVIGAM CRL were submitted to the FDA for further review. Subsequent to the January 7, 2019 resubmission to the FDA, we received an information request for a limited number of questions. We believe that all requests contained in the recently received FDA information request were addressable and we have responded to the FDA. To date, we have not received a formal BIVIGAM CRL resubmission acknowledgment and we have not received formal clarity on the FDA's intended review timing. We can confirm that the FDA is actively reviewing our BIVIGAM CRL resubmission and information request responses, however we cannot provide any assurance or predict with certainty the schedule for when we will, if at all, receive authorization from the FDA with respect to our PAS for BIVIGAM.

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Our Lead Pipeline Product Candidate – RI-002

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

Prior to the closing of the Biotest Transaction, the BTBU was our third-party manufacturer for RI-002. In the third quarter of 2015, the FDA accepted for review our BLA for RI-002 (the "RI-002 BLA") for the treatment of PIDD. In July 2016, the FDA issued a CRL (the "RI-002 CRL"). The RI-002 CRL reaffirmed the issues set forth in a November 2014 warning letter (the "Warning Letter") that had been issued by the FDA to Biotest related to certain issues identified at the Boca Facility, but did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in our RI-002 BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002. The FDA identified in the RI-002 CRL, among other things, certain outstanding inspection issues and deficiencies related to CMC and Good Manufacturing Practices ("GMP") at the Boca Facility and at certain of our third-party vendors, and requested documentation of corrections for a number of these issues. The FDA indicated in the RI-002 CRL that it cannot grant final approval of our RI-002 BLA until, among other things, these deficiencies are resolved. Upon the completion of the Biotest Transaction, we gained control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility. In the first quarter of 2018, we produced required conformance lots using the ADMA optimized IVIG manufacturing process, and these batches were filled and finished, have been placed on stability and are currently under FDA review. In April 2018, we completed an FDA inspection and as a result of the inspection, our Boca Facility's regulatory compliance status improved from Official Action Indicated ("OAI") to Voluntary Action Indicated ("VAI"), allowing us to submit regulatory applications to the FDA for review. Following our BLA resubmission in September 2018, in October 2018, we received a PDUFA date of April 2, 2019 for FDA action on the RI-002 BLA.

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Evaluation of RI-002 in PIDD Patients

PIDD, a genetic disorder that causes a deficient or absent immune system, is caused by hereditary or genetic defects and can affect anyone regardless of age or gender. PIDD patients are more vulnerable to infections and more likely to suffer complications from these infections. IVIG is a plasma derived product that is used to prevent serious infections in patients with PIDD. It is comprised of polyclonal antibodies, which are proteins produced by B-cells that are used by the body's immune system to neutralize foreign objects such as bacteria and viruses. It is estimated that there are about 250,000 diagnosed PIDD patients in the U.S., approximately half of whom are treated with IVIG regularly. As reported in industry journals, the U.S. sales of immune and hyperimmune globulin products for all its uses were reported to be approximately $6.2 billion in 2017.

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

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

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

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

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

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

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

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

Manufacturing and Supply of Our Products

In order to produce plasma-derived immunoglobulin products, raw material plasma is collected from human donors and then manufactured into specialized products. Historically, plasma for our products and product candidates has been collected from healthy donors at FDA-licensed plasma donation centers. Source plasma is collected at any one of over 600 FDA-licensed donation centers located throughout the U.S., using a process called automated plasmapheresis. This sterile, self-contained, automated process separates red blood cells and other cellular components in the blood, which are then returned to the donor. Source plasma obtained by plasmapheresis is tested and must be negative for antibodies to human immunodeficiency virus types 1 and 2 (HIV-1/2), HBsAg and Hepatitis C virus ("HCV"), using FDA-licensed serological test procedures.

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

Sales and Commercialization of Our Products

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

We have a PDUFA date of April 2, 2019 for RI-002 and we have been in ongoing communication with the FDA regarding the BIVIGAM PAS and the BIVIGAM CRL. We have initiated efforts to internally prepare for commercialization of our product candidates, if and when the RI-002 BLA and BIVIGAM PAS are approved, and have continued commercialization efforts to generate increased market awareness for Nabi-HB by attending and presenting at medical conferences, as well as sponsoring medical education symposiums. Upon FDA approval of either the BIVIGAM PAS or RI-002 BLA, we plan to bolster these efforts and initiatives by hiring a small, specialty sales force to market BIVIGAM upon its re-launch and, upon approval by the FDA, RI-002 to hospitals, physician offices/clinics, and other specialty treatment organizations. We also anticipate staffing our company with additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, third-party reimbursement, inventory and logistics, human resources and financial and operational management. If and when we receive FDA approval, we may also use a network of national and regional distributors to assist with order fulfillment for BIVIGAM and RI-002 for use by healthcare professionals and hospitals.

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Pharmaceutical Pricing and Reimbursement of Our Products

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

Plasma Collection Operations

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

As part of the purchase price to acquire the Biotest Assets, we transferred ownership of two of our plasma collection facilities to BPC on January 1, 2019.

Leadership

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

Our Strategy

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

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

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

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

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- **Obtain FDA approval of RI-002 as a treatment for PIDD**. In the third quarter of 2015, the FDA accepted for review the RI-002 BLA for the treatment of PIDD. In July 2016, the FDA issued the RI-002 CRL. The RI-002 CRL did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in the RI-002 BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002. In connection with our remediation efforts at the Boca Facility and receiving an inspection close-out by the FDA, we submitted the RI-002 BLA for review and in October 2018, we received an FDA target action PDUFA date of April 2, 2019.

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

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

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

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

- **Develop and expand ADMA Bio Centers**. In order to maintain partial control of our raw material supply as well as generate revenues through additional sources, we operate ADMA Bio Centers, a subsidiary that was established to operate plasma collection facilities in the U.S. Our facility in Kennesaw, GA holds an FDA license, under which we may collect normal source plasma and high-titer RSV plasma, with a portion of the plasma being sold to third-party buyers. We also plan to grow through the creation and licensing of additional plasma collection facilities in various regions of the U.S. We believe additional plasma collection facilities will allow us to cost-effectively secure additional plasma for our product manufacturing, and potentially increase revenues through the collection and sale of normal source plasma and other hyperimmune plasma to third parties.

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The Plasma Industry

Primary Immunodeficiency Disease

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

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

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

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

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

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Plasma - Background, Composition and Manufacturing

Human blood contains a number of components including:

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

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

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

Plasma is collected using a process called "plasmapheresis." During plasmapheresis, a donor's blood is drawn into a specialized medical device that separates the plasma component through centrifugation, and then returns the other blood components back into the donor's bloodstream. Plasmapheresis is performed utilizing an FDA-approved, automated device with a sterile, self-contained collection kit. The plasma that is collected is known as "normal source plasma." There are over 600 plasma donation centers in the U.S. As noted in a variety of plasma industry trade reports and related conferences, approximately 42 million liters of source plasma were collected in the U.S. in 2017. In the U.S., a donor may donate plasma a maximum of two times during any seven-day period, with at least two days in between donations. Plasma donation centers in the U.S. typically pay donors $25 to $50 per donation and some donors with rare or high antibody levels can be paid more.

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

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

Immune Globulins

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

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

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

As reported in industry journals, the U.S. sales of immune and hyperimmune globulin products for all its uses were reported to be approximately $6.2 billion in 2017, and in 2016 industry journals reported that the worldwide market for plasma-derived therapeutic drug products was approximately $21 billion. IVIG products are used to treat primary immune deficiencies, certain autoimmune diseases, and other illnesses for immune-compromised patients and certain neuropathy indications. New research and data, additional labeled indications, an aging population and emerging countries with new markets are all adding to the worldwide demand and growth of IVIG utilization.

Manufacturing and Supply

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

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

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

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

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

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

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

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Marketing, Sales and Market Research

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

On June 6, 2017, we entered into a Termination Agreement with BPC with respect to the Manufacturing Supply and License Agreement and Master Services Agreement, which included, effective as of January 21, 2017, a mutual release with respect to any claims related to or arising from any breach or default under the existing Manufacturing Supply and License Agreement and Master Services Agreement between ADMA BioManufacturing and BPC. Pursuant to our Manufacturing, Supply and License Agreement, we granted Biotest an exclusive license to market and sell RI-002 in Europe and in selected countries in North Africa and the Middle East (the “Territory”), to have access to our testing services for testing of BPC’s plasma samples using our proprietary RSV assay, and to reference (but not access) our proprietary information for the purpose of Biotest seeking regulatory approval for the RI-002 in the Territory. As consideration for the license, Biotest provided us with certain services at no charge and also compensated us with cash payments upon the completion of certain milestones. Biotest was also obligated to pay us an adjustable royalty based on a percentage of revenues from the sale of RI-002 in the Territory for 20 years from the date of first commercial sale.

Major Customers

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

Competition

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

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

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Intellectual Property

During the second quarter of 2015, U.S. Pat. App. Serial No. 14/592,721, entitled ‘Compositions and Methods for the Treatment of Immunodeficiency’, encompassing our RI-002 product, was allowed and issued August 18, 2015 as U.S. Patent No. 9,107,906. The ‘906 patent has a term at least through January 2035 and covers compositions comprising pooled plasma, as well as immunoglobulin prepared therefrom, that contains a standardized, elevated titer of RSV neutralizing antibodies as well as elevated levels of antibodies specific for one or more other respiratory pathogens, as well as methods of making and using the compositions. Our proprietary methods allow us to effectively identify and isolate donor plasma with high-titer RSV neutralizing antibodies and to standardize RI-002’s antibody profile, which we believe may enable us to garner a premium price.

During the third quarter of 2017, U.S. Pat. App. Serial No. 14/790,872, entitled ‘Compositions and Methods for the Treatment of Immunodeficiency’, encompassing immunotherapeutic methods of using immune globulin compositions proprietary to us, was allowed and issued July 25, 2017 as U.S. Patent No. 9,714,283. The ‘283 patent has a term at least through January 2035.

In November 2017, U.S. Pat. App. Serial No. 14/592,727, related to immune globulin compositions containing elevated, neutralizing antibody titers to RSV, as well as elevated antibody titers to other respiratory pathogens, was allowed and issued as U.S. Patent No. 9,815,886. The term of the issued patent extends to January 2035.

In May 2018, U.S. Patent No. 9,969,793 was issued covering methods of treating respiratory infections. The newly issued patent encompasses methods of treating upper and lower respiratory infections, including those caused by RSV, other viruses as well as bacteria utilizing ADMA’s investigational drug candidate RI-002, that contains elevated, neutralizing antibody titers to RSV as well as elevated antibody titers to other respiratory pathogens, such as influenza virus, coronavirus, parainfluenza virus, and metapneumovirus. The term of the issued patent extends to January 2035.

During the first quarter of 2019, U.S. Pat. App. Serial No. 14/790,872, entitled ‘Compositions and Methods for the Treatment of Immunodeficiency’, encompassing immunotherapeutic methods of using immune globulin compositions proprietary to us, was allowed and issued July 25, 2017 as U.S. Patent No. 9,714,283. The ‘283 patent has a term at least through January 2035.

On January 24, 2019, the U.S. Patent and Trademark Office issued a Notice of Allowance for U.S. Patent Application Serial No. 15/460,147 related to methods of treatment and prevention of *S. pneumonia* infection. The allowed claims encompass methods of preparing immune globulin via harvesting plasma from *S. pneumonia* vaccinated, healthy adult human donors and pooling the harvested plasma as the source for manufacturing a hyperimmune anti-*S pneumococcal*

immune globulin containing elevated opsonic antibodies to a plurality of *S. pneumonia* serotypes, hyperimmune anti-*S pneumococcal* immune globulin so prepared and methods of treating *S. pneumonia* infection and methods of providing immunotherapy using the hyperimmune anti-*S pneumococcal* immune globulin. This allowed Application is expected to issue as a patent in March 2019. The term of the patent, once issued, is expected to extend to March 2037.

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

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

We currently hold multiple trademarks, including but not limited to *BIVIGAM* and *Nabi-HB*. We have spent considerable resources registering the trademarks and building brand awareness and equity of the ADMA Biologics trade name, which has been used in commerce since 2006. We expect to maintain and defend our various trademarks to the fullest extent possible.

Government Regulation and Product Approval

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

U.S. Government Regulation

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

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

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

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

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

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

- submission of a BLA to the FDA;

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

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

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

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

Clinical Trials

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

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

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

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

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

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

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

Biologics License Application

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

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

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

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

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Other Regulatory Requirements

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

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

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

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

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

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

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

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

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

Regulation of ADMA Bio Centers

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

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

Foreign Regulation

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

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

Product Coverage, Pricing and Reimbursement

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

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

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

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

Employees

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

Corporate Information

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

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

Item 1A. Risk Factors

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

Risks Relating to our Business

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

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

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

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

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

Prior to the closing of the Biotest Transaction, BTBU was our third-party manufacturer for RI-002. In response to our RI-002 BLA submission in 2015, in July 2016 the FDA issued the CRL. The CRL did not specify or request the need for any addition clinical trials or data; however, the CRL reaffirmed the issues set forth in the Warning Letter issued to Biotest relating to inspection issues identified at the Boca Facility. The FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies related to CMC and GMP at the Boca Facility and at certain of our third-party vendors, and requested documentation of corrections for a number of these issues. The FDA indicated in the CRL that it cannot grant final approval of our RI-002 BLA until, among other things, these deficiencies are resolved. Following the completion of the Biotest Transaction, we now have control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility, and one of our highest priorities is to close out the Warning Letter. In June 2017, we engaged a leading consulting firm with extensive experience in remediating compliance and inspection issues related to quality management systems that manages a robust team of subject matter experts in plasma derived products and biologic drugs to assist us in addressing all identified CMC and cGMP issues and deficiencies. In April 2018, the FDA inspected the Boca Facility and in July 2018 our FDA status improved from OAI to VAI and this inspection of the Boca Facility has been successfully closed-out as indicated on the FDA's website inspection database. Upon our receiving FDA compliance status, we responded to the RI-002 CRL through resubmitting the RI-002 BLA on September 28, 2018 and the FDA assigned a PDUFA action due date of April 2, 2019. Upon approval of the RI-002 BLA by the FDA, we intend to commercialize RI-002. We cannot provide any assurances or predict with certainty the schedule for when we will, if at all, receive approval from the FDA for the RI-002 BLA. Similarly, there can be no assurances that our efforts to remediate the Warning Letter will be effective or whether the FDA will accept these efforts. Failure to timely remediate the issues identified in the Warning Letter and other inspection issues and deficiencies and/or receive approval from the FDA, as well as passing an FDA inspection within this timeline, if at all, will have a material adverse effect on our business, prospects, financial condition and results of operations. We may be issued additional 483 observations, Warning Letters or have other negative regulatory actions taken against us should we be found to be noncompliant.

We are currently not profitable and may never become profitable.

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

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

- seek regulatory approval(s);

- initiate commercialization and marketing efforts;

- implement additional internal systems, controls and infrastructure;

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- hire additional personnel;

- expand and build out our plasma center network; and

- expand production capacity at the Boca Facility.

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

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

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

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

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

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

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

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

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

Business interruptions could adversely affect our business.

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

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

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

- unforeseen safety issues;

- determination of dosing issues;

- lack of effectiveness during clinical trials;

- slower than expected rates of patient recruitment;

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

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

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

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

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

If we do not obtain the necessary U.S. or worldwide regulatory approvals to commercialize RI-002, we will not be able to sell RI-002.

If we cannot obtain regulatory approval for RI-002, we will not be able to generate revenue from this product candidate. As a result, our sources of revenue may continue to be from a product mix consisting only of plasma collection and sales revenues, revenues generated from sales of our FDA-approved commercial products, revenues generated from ongoing contract manufacturing for third parties and revenues generated from the sales of manufacturing intermediates. We cannot assure you that we will receive the approvals necessary to commercialize RI-002 or any other product candidate we may acquire or develop in the future. In order to obtain FDA approval of RI-002 or any other product candidate requiring FDA approval, our clinical development must demonstrate that the product candidate is safe for humans and effective for its intended use, and we must successfully complete an FDA BLA review. Obtaining FDA approval of any other product candidate generally requires significant research and testing, referred to as preclinical studies, as well as human tests, referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in products that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the product approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidate;

- impose costly procedures on us; and

- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject our RI-002 BLA. In addition, the FDA could determine that we must test additional subjects and/or require that we conduct further studies with more subjects. We may never obtain regulatory approval for RI-002, or any other future potential product candidate or label expansion activity. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without the ability to generate additional accretive revenues. There is no guarantee that we will ever be able to develop or acquire other product candidates. In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any products or product candidates outside the U.S. Foreign regulatory approval processes generally include all of the risks and uncertainties associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any product candidate for sale outside the U.S.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

While we are not a covered entity or business associate subject to HIPAA, even when HIPAA does not apply, according to the U.S. Federal Trade Commission (the "FTC"), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. In addition, states impose a variety of laws protecting consumer information, with certain sensitive information such as HIV/Sexually Transmitted Disease status subject to heightened standards. In addition, federal and state privacy, data security, and breach notification laws, rules and regulations, and other laws apply to the collection, use and security of personal information, including social security number, driver's license numbers, government identifiers, credit card and financial account numbers. Some state privacy and security laws apply more broadly than HIPAA and associated regulations. For example, California recently enacted legislation – the California Consumer Privacy Act, or CCPA – which goes into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Legislators have stated that they intend to propose amendments to the CCPA before it goes into effect, and the California Attorney General will issue clarifying regulations. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. We could be subject to enforcement action and litigation exposure if we fail to adhere to these data privacy and security laws.

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

We may not realize all of the strategic and financial benefits currently anticipated from the Biotest Transaction. For example, we may not realize the anticipated benefits of acquiring control of all aspects of RI-002 drug manufacturing, regulatory affairs and business operations. In addition, we may not be able to resolve the outstanding issues at the Boca Facility that resulted in the Warning Letter. As part of the remediation of the Warning Letter, in December 2016 BTBU temporarily suspended the production of BIVIGAM in order to focus on the completion of planned improvements to the manufacturing process. As a result, BIVIGAM was not available for sale or distribution throughout fiscal 2017. If we are unable to address the underlying concerns at the Boca Facility that resulted in the Warning Letter and the CRL in July 2016 that identified deficiencies and inspection issues related to certain of our third-party contract manufacturers, including BPC, and provide requested documentation of corrections for a number of these issues, we will not be able to apply for the PAS related to the manufacturing of BIVIGAM or reapply for FDA approval to market and sell RI-002, which could have a material adverse effect on us. Failure to resolve any outstanding issues or any administrative actions taken or changes made by the FDA toward our contract manufacturers, vendors or us could impact our ability to receive approval for RI-002, including the timing thereof, disrupt our business operations and the timing of our commercialization efforts and may have a material adverse effect on our financial condition and operating results. In April 2018, the FDA inspected the Boca Facility and in July 2018 our FDA status resulted improved from OAI to VAI and this inspection of the Boca Facility has been successfully closed-out as indicated on the FDA's website inspection database. Upon our receiving FDA compliance status, we responded to the RI-002 CRL through resubmitting the RI-002 BLA on September 28, 2018 and the FDA assigned a Prescription User Fee Act ("PDUFA") action due date of April 2, 2019. Upon approval of the RI-002 BLA by the FDA, we intend to commercialize RI-002. We cannot provide any assurances or predict with certainty the schedule for when we will, if at all, receive approval from the FDA for the RI-002 BLA.

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

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

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

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

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

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

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

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

As part of the consideration paid to acquire the Biotest Assets, we were required to transfer to BPC ownership of two of our licensed plasma collection facilities in the U.S. and certain related assets and liabilities. These plasma collection facilities, which were transferred on January 1, 2019, have historically been the source of substantially all of our revenue. Although we have completed construction of, and received FDA approval for our plasma collection facility in Kennesaw, GA, there can be no assurances that we will generate similar revenues as historically reported from the plasma collection facilities we transferred to BPC on January 1, 2019.

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

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

The Purchase Agreement contains indemnification undertakings by the parties thereto for certain losses, including, among other things, indemnification for any losses arising from breaches of its representations, warranties, covenants and agreements in the Purchase Agreement. In connection with the Biotest Transfer Agreement, we granted a full release to Biotest from any and all past, present or future indemnification claims arising under or in connection with the Purchase Agreement. Significant indemnification claims by BPC or its affiliates or breaches by BPC or its affiliates of any indemnity obligations which would have been owed to us under the Purchase Agreement prior to the release granted in the Biotest Transfer Agreement could have a material adverse effect on our business, financial condition, results of operations and stock price.

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

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

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

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

Our Credit Agreement and Guaranty (the "Credit Agreement") with our secured lender, Perceptive Credit Holdings II, LP ("Perceptive") is subject to acceleration in specified circumstances, which may result in Perceptive taking possession and disposing of any collateral.

On February 11, 2019, we entered into the Credit Agreement with Perceptive which provides for a senior secured term loan facility in an aggregate amount of up to $72.5 million (collectively, the "Credit Facility"), comprised of (i) a term loan in the principal amount of $45.0 million (the "Initial Term Loan"), (ii) an additional term loan to be made in the maximum principal amount not to exceed $27.5 million, but no less than $10.0 million (the "Additional Term Loan" and, together with the Initial Term Loan, the "Loans"), which Additional Term Loan availability is subject to the satisfaction of certain conditions. The Loans each have a maturity date of March 1, 2022, subject to acceleration pursuant to the Credit Agreement, including upon an Event of Default (as defined in the Credit Agreement). The Loans are secured by substantially all of our assets, including our intellectual property. Events of Default include, among others, non-payment of principal, interest, or fees, violation of covenants, inaccuracy of representations and warranties, bankruptcy and insolvency events, material judgments, cross-defaults to material contracts and events constituting a change of control. In addition to an increase in the rate of interest on the Loans of 4% per annum, the occurrence of an Event of Default could result in, among other things, the termination of commitments under the

Credit Facility, the declaration that all outstanding Loans are immediately due and payable in whole or in part, and Perceptive taking immediate possession of, and selling, any collateral securing the Loans.

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

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

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

As we move forward in clinical development we are also uncovering novel aspects of our product and are drafting patents to cover our inventions. We rely on a combination of patent rights, trade secrets and nondisclosure and non-competition agreements to protect our proprietary intellectual property, and we will continue to do so. There can be no assurance that our patent, trade secret policies and practices or other agreements will adequately protect our intellectual property. Our issued patents may be challenged, found to be over-broad or otherwise invalidated in subsequent proceedings before courts or the USPTO. Even if enforceable, we cannot provide any assurances that they will provide significant protection from competition. The processes, systems, and/or security measures we use to preserve the integrity and confidentiality of our data and trade secrets may be breached, and we may not have adequate remedies as a result of any such breaches. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. There can be no assurance that the confidentiality, nondisclosure and non-competition agreements with employees, consultants and other parties with access to our proprietary information to protect our trade secrets, proprietary technology, processes and other proprietary rights, or any other security measures relating to such trade secrets, proprietary technology, processes and proprietary rights, will be adequate, will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We could lose market exclusivity of a product earlier than expected.

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

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

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

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

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

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

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

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

Our performance is substantially dependent on the continued service and performance of our management team, who have extensive experience and specialized expertise in our business. In particular, the loss of Adam S. Grossman, our President and Chief Executive Officer, could adversely affect our business and operating results. We do not have "key person" life insurance policies for any members of our management team. We have employment agreements with each of our executive officers; however, the existence of an employment agreement does not guarantee retention of members of our management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our product candidates and diversion of management resources.

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

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is important to our operations and reputation. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate our proprietary and confidential information including e-mails and other electronic communications. In addition, an employee, contractor, or other third party with whom we do business may attempt to obtain such information, and may purposefully or inadvertently cause a breach involving such information. While we have certain safeguards in place to reduce the risk of and detect cyber-attacks, including a company-wide cybersecurity policy, our information technology networks and infrastructure may be vulnerable to unpermitted access by hackers or other breaches, or employee error or malfeasance. Any such compromise of our data security and access to, or public disclosure or loss of, confidential business or proprietary information could disrupt our operations, damage our reputation, provide our competitors with valuable information and subject us to additional costs, which could adversely affect our business.

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

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

We currently collect human blood plasma at our ADMA Bio Centers facility, and if we cannot maintain FDA approval for this facility or obtain FDA approval for additional facilities which we create or acquire rights to, we may be adversely affected and may not be able to sell or use this human blood plasma for future commercial purposes.

We intend to maintain FDA approval of our ADMA Bio Centers collection facility in Kennesaw, GA for the collection of human blood plasma and we may seek other governmental and regulatory approvals for this facility. We also plan to grow through the creation and licensing of additional ADMA Bio Centers facilities in various regions of the U.S. Collection facilities are subject to FDA and potentially other governmental and regulatory inspections and extensive regulation, including compliance with current cGMP, FDA and other government approvals, as applicable. Failure to comply with applicable governmental regulations or to receive applicable approvals for our future facilities may result in enforcement actions, such as adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of regulatory authority approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses, any of which may significantly delay or suspend our operations for these locations, potentially having a materially adverse effect on our ability to manufacture our products or offer for sale plasma collected at the affected site(s).

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

We currently operate under the Warning Letter due to issues identified by the FDA in their prior inspections while the Boca Facility was under Biotest's operational control. We engaged a leading consulting firm with extensive experience in remediating compliance and inspection issues related to quality management systems and which manages a robust team of subject matter experts in plasma derived products and biologic drugs to assist us in addressing all identified

CMC and cGMP issues and deficiencies. We continue to work with the FDA to resolve the Warning Letter classification. Although we have improved our compliance status at the Boca Facility, there are no assurances we will be able to maintain compliance with all FDA or other regulations. Our third party vendors may perform activities for themselves or other clients and we may not be privy to all regulatory findings or issues discovered by the FDA or other regulatory agencies. Such findings, which are out of our control, may adversely affect our ability to continue to work with these vendors, or our ability to release commercial drug product or perform necessary testing or other actions for us or our clients, which may be required in order to remain FDA compliant or commercialize our products.

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

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

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

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

For example, under the Anti-Kickback Law and similar state laws and regulations, the offer or payment of anything of value for patient referrals, or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease, or ordering of any time or service reimbursable in whole or in part by a federal health care program is prohibited. This places constraints on the marketing and promotion of products and on common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose products for patients, such as physicians and hospitals, and these practices can result in substantial legal penalties, including, among others, exclusion from the Medicare and Medicaid programs. Arrangements with referral sources such as purchasers, group purchasing organizations, physicians and pharmacists must be structured with care to comply with applicable requirements. Legislators and regulators may seek to further restrict the scope of financial relationships that are considered appropriate. For example HHS issued a proposed rule in February 2019, which aims to eliminate certain Anti-Kickback Statute safe harbor protection for drug rebates. Also, certain business practices, such as payments of consulting fees to healthcare providers, sponsorship of educational or research grants, charitable donations, interactions with healthcare providers that prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid any possibility of wrongfully influencing healthcare providers to prescribe or purchase particular products or as a reward for past prescribing. Under the Patient Protection and Affordable Care Act (“ACA”) and the companion Health Care and Education Reconciliation Act, which together are referred to as the “Healthcare Reform Law”, payments and transfers of value by pharmaceutical manufacturers subject to this “Sunshine Act” and its implementing regulations to U.S. –licensed physicians and teaching hospitals, must be tracked and reported, and will be publicly disclosed. Such “applicable manufacturers” are also required to report certain ownership interests held by physicians and their immediate family members. In 2018 the Sunshine Act was extended to require tracking and reporting of payments and transfers of value to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments and transfers of value made in 2021). A number of states have similar laws in place. Additional and stricter prohibitions could be implemented by federal and state authorities. Where such practices have been found to be improper incentives to use such products, government investigations and assessments of penalties against manufacturers have resulted in substantial damages and fines. Many manufacturers have been required to enter into consent decrees or orders that prescribe allowable

corporate conduct.

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

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

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

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

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

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

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

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We are subject to extensive and rigorous governmental regulation, including the requirement of FDA and other federal, state and local business regulatory approval before our products and product candidates may be lawfully marketed, and our ability to obtain regulatory approval of our products and product candidates from the FDA in a timely manner, access the public markets and obtain necessary capital in order to properly capitalize and continue our operations may be hindered by inadequate funding for the FDA, the SEC and other state and local government agencies.

Both before and after the approval of our products, our products, our operations, our facilities, our suppliers and our contract research organizations are subject to extensive regulation by federal, state and local governmental authorities in the U.S. and other countries, with regulations differing from country to country. In the U.S., the FDA regulates, among other things, the pre-clinical testing, clinical trials, manufacturing, safety, efficacy, potency, labeling, storage, record keeping, quality systems, advertising, promotion, sale and distribution of therapeutic products. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: notices of violation, untitled letters, warning letters, complete response letters, fines and other monetary penalties, unanticipated expenditures, delays in approval or refusal to approve a product or product candidate, product recall or seizure, interruption of manufacturing or clinical trials, operating restrictions, injunctions and criminal prosecution. Our products and product candidates cannot be lawfully marketed in the U.S. without FDA and other federal, state and local business regulatory approval. Any failure to receive the marketing approvals necessary to commercialize our product or product candidates could harm our business.

The regulatory review and approval process of governmental authorities is lengthy, expensive and uncertain. For example, in December 2016, BPC, the owner of BIVIGAM prior to the Biotest Transaction in June 2017, temporarily suspended the commercial production of BIVIGAM in order to focus on the completion of planned improvements to the manufacturing process. We resumed production of BIVIGAM utilizing our optimized IVIG manufacturing process with two conformance lots in the fourth quarter of 2017 and a third conformance lot in the first quarter of 2018. During the first half of 2018, we qualified and filled the BIVIGAM conformance batches and the product is on stability. During the second half of 2018, we filed a drug substance PAS with the FDA for BIVIGAM to include the ADMA optimization improvements for BIVIGAM and to seek FDA authorization which would enable us to resume commercial scale manufacturing and relaunch and commercialize this product. On December 19, 2018, we received the BIVIGAM CRL for our PAS submission for BIVIGAM drug substance. The BIVIGAM CRL requested certain additional information and clarifications relating to CMC matters contained in our PAS submission for drug substance, including complete resolution of certain manufacturing related deviations, information pertaining to how certain in-process manufacturing samples are taken, as well as updates on certain stability data previously submitted. As the information we believed necessary to address and respond to the matters raised in the BIVIGAM CRL was readily available in our files, on January 7, 2019 we announced that our responses to the BIVIGAM CRL were submitted to the FDA for further review. Subsequent to the January 7, 2019 resubmission to the FDA, we received an information request for a limited number of questions. We believe that all requests contained in the recently received FDA information request were addressable and we have responded to the FDA. To date, we have not received a formal BIVIGAM CRL resubmission acknowledgment and we have not received formal clarity on the FDA’s intended review timing. We can confirm that the FDA is actively reviewing our BIVIGAM CRL resubmission and information request responses, however we cannot provide any assurance or predict with certainty the schedule for when we will, if at all, receive authorization from the FDA with respect to our PAS for BIVIGAM.

Additionally, the ability of the FDA and other federal, state and local business regulatory agencies to review and approve products and product candidates can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA and other federal, state and local business regulatory agencies have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for products and product candidate submissions to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including in December 2018 and January 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown reoccurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions and other reporting requirements, including our drug substance PAS for BIVIGAM, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

There have been repeated attempts by Congress to repeal or change the Healthcare Reform Law. Further, on January 20, 2017, the new administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the Healthcare Reform Law that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. More recently, the United States District Court for the Northern District of Texas struck down the Healthcare Reform Law, deeming it unconstitutional given that Congress repealed the individual mandate in 2017. This decision has been stayed pending outcome of an appeal to the Fifth Circuit Court of Appeals. Although there is no immediate impact on the ACA, we will continue to evaluate the effect that the Healthcare Reform Law and its possible repeal and replacement, or potential total revocation by the Supreme Court of the United States, has on our business.

Developments in the worldwide economy may adversely impact our business.

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

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

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

Our operations have consumed substantial amounts of cash since inception. For the years ended December 31, 2018 and 2017, we had negative cash flows from operations of approximately $62.7 million and $37.3 million, respectively. We expect to continue to spend substantial amounts on product development, including commercialization activities, procuring raw material plasma, manufacturing, conducting potential future clinical trials for our product candidates and purchasing clinical trial materials from our suppliers, conducting commercial launch activities and potential post marketing studies. We currently anticipate, based upon our projected revenue and expenditures, as well as the additional $27.5 million we expect to be able to draw down under the Credit Agreement, that our current cash, cash equivalents and accounts receivable will be sufficient to fund our operations, as currently conducted, into the fourth quarter of 2019. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing by the fourth quarter of 2019. However, if we do not receive FDA approval of either the BIVIGAM PAS or the RI-002 BLA, we believe that our cash balance will be sufficient to fund our operations, as currently conducted, into the third quarter of 2019, and we will be required to raise additional capital by the third quarter of 2019. This time frame may change based upon how quickly we are able to execute on our operational initiatives and the various financing options we are exploring. However, if the assumptions underlying our estimated expenses prove to be incorrect, we may have to raise additional capital sooner than we currently expect. Until such time, if ever, as we can generate a sufficient amount of product revenue to achieve profitability, we expect to continue to finance our operations through additional equity or debt financings or corporate collaboration and licensing arrangements. If we are unable to raise additional capital as needed, we will have to delay, curtail or eliminate our product development activities, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers, as well as future commercialization efforts.

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

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

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

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

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

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

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

We have incurred substantial losses during our history. As of December 31, 2018, we had federal and state NOLs of $108.5 million and $72.3 million, respectively. These NOLs will begin to expire at various dates beginning in 2027, if not limited by triggering events prior to such time. Under the provisions of the Internal Revenue Code, changes in our ownership, in certain circumstances, will limit the amount of federal NOLs that can be utilized annually in the future to offset taxable income. In particular, Section 382 of the Internal Revenue Code ("Section 382") imposes limitations on a company's ability to use NOLs upon certain changes in such ownership. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs. The Biotest Transaction on June 6, 2017 resulted in a change in ownership of ADMA under Section 382 and as result, we were required to write off $57.6 million of federal NOLs. We may experience ownership changes in the future as a result of subsequent changes in our stock ownership that we cannot predict or control that could result in further limitations being placed on our ability to utilize our federal NOLs.

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

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

Risks Associated with our Common Stock

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

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

- sales or potential sales of substantial amounts of our Common Stock;
- our ability to successfully leverage the anticipated benefits and synergies from the Biotest Transaction, including optimization of the combined businesses, operations and products and services, including the nature, strategy and focus of the combined company and the management and governance structure of the combined company;
- delay or failure in initiating or completing preclinical or clinical trials or unsatisfactory results of these trials;
- delay in FDA approval for RI-002;

- delay in a decision by federal, state or local business regulatory authority;

- the timing of acceptance, third-party reimbursement and sales of RI-002;

- our ability to resume the manufacturing of BIVIGAM once the deficiencies identified in the CRL have been resolved by us to the satisfaction of the FDA;

- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;

- developments concerning our licensors or third-party vendors;

- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;

- conditions in the pharmaceutical or biotechnology industries;

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- governmental regulation and legislation;

- variations in our anticipated or actual operating results; and

- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

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

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

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

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

As of December 31, 2018, most of our 46,353,068 outstanding shares of Common Stock, as well as a substantial number of shares of our Common Stock underlying outstanding warrants, were available for sale in the public market, subject to certain restrictions with respect to sales of our Common Stock by our affiliates, either pursuant to Rule 144 ("Rule 144") under the Securities Act of 1933, as amended (the "Securities Act"), or under effective registration statements. Pursuant to the Stockholders' Agreement, until December 6, 2020, subject to certain limited exceptions, sales of the 10,109,534 shares of Common Stock held by the Biotest Trust (as successor-in-interest to BPC) may not exceed 15% of the issued and outstanding Common Stock of ADMA in any twelve-month period; provided, however, that if our market capitalization increases to double our market capitalization immediately following the closing of the Biotest Transaction, then the Biotest Trust may sell up to 20% of our issued and outstanding Common Stock in any twelve-month period; provided, further, that (x) if our market capitalization increases to triple our market capitalization immediately following the closing of the Biotest Transaction, or (y) upon the one-year anniversary of the Biotest Trust holding less than a 25% economic interest in us, which occurred on May 14, 2018 following the transfer of the NV Biotest Shares to us, then the Biotest Trust may sell any amount of its equity interests in us at any time (subject to applicable securities laws). Sales of a substantial number of shares of our Common Stock, or the

perception that such sales may occur, may adversely impact the market price of our Common Stock.

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

As of December 31, 2018, the Biotest Trust, our directors and executive officers and their affiliates beneficially owned approximately 36% of the outstanding shares of our Common Stock. Additionally, on November 14, 2018, the standstill provisions contained in the Stockholders Agreement, which prohibited the Biotest Trust from, among other things, acquiring more than (i) 50%, less one share, of our issued and outstanding shares of capital stock on an as-converted basis, or (ii) 30% of the issued and outstanding shares of Common Stock, terminated and are of no further force and effect. Such event could result in the Biotest Trust acquiring additional shares of our Common Stock or taking other actions with the goal of acquiring additional shares of our Common Stock.

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Provisions of our Certificate of Incorporation, our Bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our Company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. 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;
- the ability of our Board to institute a stockholder rights plan, also known as a poison pill, that would work to dilute our stock,
- classification of our Board and limitation on filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our Company; and
- authorization of the issuance of "blank check" preferred stock, with such designation rights and preferences as may be determined from time to time by the Board, without any need for action by stockholders.

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

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

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

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

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

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

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

Item 13. Certain Relationships and Related Transactions

The information required by this item is incorporated by reference to the information under the sections captioned Certain Relationships and Related Transactions and Compensation Committee Interlocks and Insider Participation contained in the 2003 Proxy Statement.

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Item 14. Controls and Procedures

Within 90 days prior to the date of filing this Report, an evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934, as amended). Based on and as of the time of such evaluation, our management, including the Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures were effective in timely alerting them to material information relating to the company required to be included in our reports filed or submitted under the Securities Exchange Act of 1934, as amended. There have been no significant changes in our internal controls or in other factors that could significantly affect internal controls and procedures subsequent to the time of such evaluation.

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PART IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

1. Consolidated Financial Statements

The following financial statements are filed as part of this Report:

2. Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable or not required, or because the required information is included in the consolidated financial statements or notes thereto.

3. Exhibits

(a) Exhibits

Exhibit Number	Description of Document
3.1(a)(6)	Certificate of Incorporation as currently in effect
3.1(b)(6)	Amendment to Certificate of Incorporation, effective as of December 21, 2001
3.2(4)	Bylaws of Introgen as currently in effect
4.1(2)	Specimen Common Stock Certificate
4.2(5)	Certificate of Designations of Series A Non-Voting Convertible Preferred Stock
10.1(1)	Form of Indemnification Agreement between Introgen and each of its directors and officers
10.2(1)	1995 Stock Plan and form of stock option agreement thereunder
10.3(3)	2000 Stock Option Plan and forms of stock option agreements thereunder
10.4(3)	2000 Employee Stock Purchase Plan and forms of agreements thereunder
10.5(1)	Form of Series C Preferred Stock Purchase Agreement among Introgen and certain investors
10.6(1)	Registration Rights Agreement, dated October 31, 1997
10.7(a)(1)	Assignment of Leases, dated November 23, 1998, by TMX Realty Corporation and Riverway Bank, and other related agreements
10.7(b)(1)	Lease Agreement, dated June 7, 1996, by and between Introgen and Plaza del Oro Business Center
10.7(c)(2)	Amendment No. 1 to Lease Agreement, effective as of May 9, 1997
10.7(d)(2)	Amendment No. 2 to Lease Agreement, effective as of July 31, 1998
10.7(e)(2)	Amendment No. 3 to Lease Agreement, effective as of June 29, 2000
10.8(a) (1)	Patent and Technology License Agreement, effective as of July 20, 1994, by and between the Board of Regents of The University of Texas System, M. D. Anderson Cancer Center and Introgen
10.8(b) (1)	Amendment No. 1 to Patent License Agreement, effective as of September 1, 1996

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Exhibit Number	Description of Document
10.9 (3)	Sponsored Research Agreement for Clinical Trial, No. CS 93-27, dated February 11, 1993, between Introgen and M. D. Anderson, as amended
10.10	[Reserved]
10.11 (3)	Sponsored Research Agreement No. SR 93-04, dated February 11, 1993 between M. D. Anderson and Introgen, as amended
10.12	[Reserved]
10.13 (3)	Sponsored Research Agreement No. SR 96-004 between Introgen and M. D. Anderson, dated January 17, 1996
10.14	[Reserved]
10.15 (3)	License Agreement, dated March 29, 1996 between Introgen and SKCC
10.16(1)	Consulting Agreement between Introgen and Jack A. Roth, M. D., effective as of October 1, 1994
10.17(1)	Consulting Agreement between EJ Financial Enterprises, Inc. and Introgen, effective as of July 1, 1994
10.18(a)(1)	Employment Agreement dated as of August 1, 1996 between Introgen and David G. Nance
10.18(b)(1)	Amendment No. 1 to Employment Agreement, effective as of August 1, 1998
10.18(c)(1)	Amendment No. 2 to Employment Agreement, effective as of February 15, 2000
10.19(1)	Service Agreement, effective as of July 1, 1994, between Introgen and Domecq Technologies, Inc.
10.20(a) (1)	Collaboration Agreement (p53 Products), effective as of October 7, 1994, between Introgen and RPR, as amended
10.20(b) (3)	Addendum No. 1 to Collaboration Agreement (p53 Products), dated January 23, 1996, between Introgen and RPR
10.20(c) (1)	1997 Agreement Memorandum, effective as of July 22, 1997, between Introgen and RPR
10.20(d) (3)	Letter Agreement, dated April 19, 1999, from Introgen to RPR regarding manufacturing process for ADVEXIN gene therapy
10.21(a) (1)	Collaboration Agreement (K-ras Products), effective as of October 7, 1994, between Introgen and RPR, as amended
10.21(b)(1)	Amendment No. 1 to Collaboration Agreement (K-ras Products), effective as of September 27, 1995, between Introgen and RPR
10.22 (3)	Collaborative Research and Development Agreement dated October 30, 1998 between Introgen, RPR and NCI
10.23 (1)	Non-Exclusive License Agreement, effective as of April 16, 1997, by Introgen and Iowa Research Foundation
10.24 (3)	Option Agreement, effective as of June 1, 1998, by Introgen and Imperial Cancer Research Technology Limited (ICRT)
10.25 (3)	Option Agreement, effective as of January 1, 1999, by Introgen and ICRT
10.26 (3)	Exclusive License Agreement, effective as of July 19, 1999, by Introgen and Corixa Corporation
10.27(a)	[Reserved]
10.27(b)(1)	Letter dated January 28, 2000, from Introgen to LXR Biotechnology (LXR), notifying LXR of its exercise of its option
10.27(c) (2)	Exclusive License Agreement, effective as of May 16, 2000, by and between Introgen and LXR
10.28 (3)	Administrative Services and Management Agreement, effective as of January 1, 1999, by and between Introgen and Gendux, Inc.
10.29 (3)	Research and Development Agreement, effective as of January 1, 1999, by and between Introgen and Gendux, Inc.

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Exhibit Number	Description of Document
10.30 (3)	Delivery Technology License Agreement, effective as of January 1, 1999, by and between Introgen and Gendux, Inc.
10.31 (3)	Target Gene License Agreement, effective as of January 1, 1999, by and between Introgen and Gendux, Inc.
10.32 (1)	Non-Exclusive License Agreement, effective as of August 17, 1998, by and between Introgen and National Institutes of Health
10.33	[Reserved]
10.34(2)	Master Lease Agreement, effective as of August 4, 1999, by and between Introgen and Finova Capital Corporation
10.35(2)	Construction Loan Agreement, effective as of July 24, 2000, by and between Introgen and Compass Bank
10.36 (5)	Restated p53 and K-ras Agreement, effective as of June 30, 2001, by and among Introgen, Aventis Pharmaceuticals Inc. (API) and Aventis Pharma S.A. (Aventis)
10.37(5)	p53 Assignment Agreement, effective as of June 30, 2001, by and among Introgen, API and Aventis
10.38(5)	K-ras Assignment Agreement, effective as of June 30, 2001, by and among Introgen, API and Aventis
10.39(5)	Registration Rights Agreement, effective as of June 30, 2001, by and among Introgen, API and RPR
10.40(5)	Voting Agreement, effective as of June 30, 2001, by and among Introgen, API and RPR
10.41(7)	Master Services Agreement, effective as of July 9, 2001, by and between Introgen and PPD Development, LLC
10.42(8)	Series A Preferred Stock Purchase Agreement, effective as of March 7, 2002, by and between Introgen and VirRx, Inc.
10.43(8)	Collaboration and License Agreement, effective as of March 7, 2002, by and between Introgen and VirRx, Inc.
21.1(1)	List of subsidiaries of Introgen
23.1	Consent of Ernst & Young LLP, independent auditors
23.2	Information Regarding Consent of Arthur Andersen LLP
24.1	Power of Attorney (See page 52)
99.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to the same-numbered exhibit filed with Introgen s Registration Statement on Form S-1 (No. 333-30582) filed with the Securities and Exchange Commission on February 17, 2000.

(2) Incorporated by reference to the same-numbered exhibit filed with Amendment No. 2 to Introgen s Registration Statement on Form S-1 (No. 333-30582) filed with the Securities and Exchange Commission on September 8, 2000.

(3) Incorporated by reference to the same-numbered exhibit filed with Amendment No. 3 to Introgen s Registration Statement on Form S-1 (No. 333-30582) filed with the Securities and Exchange Commission on October 4, 2000.

(4) Incorporated by reference to the same-numbered exhibit filed with Introgen s Quarterly Report on Form 10-Q, for the quarter ended December 31, 2000, (File No. 000-21291), filed with the Securities and Exchange Commission on February 14, 2001.

(5) Incorporated by reference to the same-numbered exhibit filed with Introgen s Annual Report on Form 10-K for the fiscal year ended June 30, 2001 (File No. 000-21291), filed with the Securities and Exchange Commission on September 19, 2001.

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(6) Incorporated by reference to the same-numbered exhibit filed with Introgen s Transition Report on Form 10-KT for the six-month transition period ended December 31, 2001 (File No. 000-21291), filed with the Securities and Exchange Commission on March 20, 2002.

(7) Incorporated by reference to the same-numbered exhibit filed with Amendment No. 1 to Introgen s Transition Report on Form 10-KT for the six-month transition period ended December 31, 2001 (File No. 000-21291), filed with the Securities and Exchange Commission on March 26, 2002.

(8) Incorporated by reference to the same-numbered exhibit filed with Introgen s Quarterly Report on Form 10-Q, for the quarter ended March 31, 2002 (File No. 000-21291), filed with the Securities and Exchange Commission on May 15, 2002.

Confidential treatment has been granted for portions of this exhibit.

Confidential treatment has been requested for portions of this exhibit.

(b) **Reports on Form 8-K**

We did not file any Current Reports on Form 8-K during the last quarter of our fiscal year ended December 31, 2002.

(c) **Exhibits**

See Item 15(3) above.

(d) **Financial Statement Schedules**

See Item 15(2) above.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934 the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized in the City of Austin, Texas, this March 31, 2003.

INTROGEN THERAPEUTICS, INC.

By: /s/ DAVID G. NANCE

David G. Nance
President, Chief Executive Officer and Director
(Principal Executive Officer)

By: /s/ JAMES W. ALBRECHT, JR.

James W. Albrecht, Jr.
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints David G. Nance and James W. Albrecht, Jr. and each of them acting individually, as his or her attorney-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report on Form 10-K has been signed on behalf of the Registrant by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
/s/ DAVID G. NANCE (David G. Nance)	President, Chief Executive Officer, and Director (Principal Executive Officer)	March 31, 2003
/s/ JAMES W. ALBRECHT, JR. (James W. Albrecht, Jr.)	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2003
/s/ JOHN N. KAPOOR, PH.D. (John N. Kapoor, Ph.D.)	Chairman of the Board and Director	March 31, 2003
/s/ WILLIAM H. CUNNINGHAM, PH.D. (William H. Cunningham, Ph.D.)	Director	March 31, 2003
/s/ CHARLES E. LONG (Charles E. Long)	Director	March 31, 2003
/s/ ROBERT L. MOORE	Director	March 31, 2003

(Robert L. Moore)		
/s/ MAHENDRA G. SHAH, PH.D.	Director	March 31, 2003
(Mahendra G. Shah, Ph.D.)		

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CERTIFICATIONS

I, David G. Nance, certify that:

1. I have reviewed this annual report on Form 10-K of Introgen Therapeutics, Inc.;

2. Based on my knowledge, this annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of Introgen as of, and for, the periods presented in this annual report;

4. Introgen s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for Introgen and we have:

(a) designed such disclosure controls and procedures to ensure that material information relating to Introgen, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b) evaluated the effectiveness of Introgen s disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and

(c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. Introgen s other certifying officer and I have disclosed, based on our most recent evaluation, to Introgen s auditors and the audit committee of Introgen s board of directors (or persons performing the equivalent function):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect Introgen s ability to record, process, summarize and report financial data and have identified for Introgen s auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in Introgen s internal controls; and

6. Introgen s other certifying officer and I have indicated in this Annual Report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

By: /s/ DAVID G. NANCE

David G. Nance
Chief Executive Officer

Date: March 31, 2003

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I, James W. Albrecht, Jr., certify that:

1. I have reviewed this annual report on Form 10-K of Introgen Therapeutics, Inc.;

2. Based on my knowledge, this annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of Introgen as of, and for, the periods presented in this annual report;

4. Introgen s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for Introgen and we have:

(a) designed such disclosure controls and procedures to ensure that material information relating to Introgen, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b) evaluated the effectiveness of Introgen s disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and

(c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. Introgen s other certifying officer and I have disclosed, based on our most recent evaluation, to Introgen s auditors and the audit committee of Introgen s board of directors (or persons performing the equivalent function):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect Introgen s ability to record, process, summarize and report financial data and have identified for Introgen s auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in Introgen s internal controls; and

6. Introgen s other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

By: /s/ JAMES W. ALBRECHT, JR.

James W. Albrecht, Jr.
Chief Financial Officer

Date: March 31, 2003

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REPORT OF INDEPENDENT AUDITORS

To the Board of Directors and Stockholders of

Introgen Therapeutics, Inc. and Subsidiaries:

We have audited the accompanying consolidated balance sheet of Introgen Therapeutics, Inc. and subsidiaries as of December 31, 2002, and the related consolidated statements of operations, stockholders equity, and cash flows for the year then ended. These financial statements are the responsibility of Introgen Therapeutics, Inc. s management. Our responsibility is to express an opinion on these financial statements based on our audit. The financial statements of Introgen Therapeutics, Inc. and subsidiaries for the six months ended December 31, 2001 and for the years ended June 30, 2001 and 2000, were audited by other auditors whose report dated January 18, 2002, expressed an unqualified opinion on those statements.

We conducted our audit in accordance with auditing standards generally accepted in the 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. 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 audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Introgen Therapeutics, Inc. and subsidiaries at December 31, 2002, and the consolidated results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Austin, Texas

January 21, 2003

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REPORT OF INDEPENDENT AUDITORS

To the Board of Directors of

Introgen Therapeutics, Inc.:

We have audited the accompanying consolidated balance sheets of Introgen Therapeutics, Inc. (a Delaware corporation), and subsidiaries as of June 30, 2000 and 2001 and December 31, 2001, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended June 30, 2001 and for the six months ended December 31, 2001. These financial statements are the responsibility of Introgen Therapeutics, Inc. s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the 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. 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 financial statements referred to above present fairly, in all material respects, the financial position of Introgen Therapeutics, Inc., and subsidiaries as of June 30, 2000 and 2001 and December 31, 2001, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2001 and the six months ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

Austin, Texas

January 18, 2002

THIS IS A COPY OF THE AUDIT REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP IN CONNECTION WITH INTROGEN THERAPEUTICS, INC. S FILING ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2001. THIS AUDIT REPORT HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP IN CONNECTION WITH THIS FILING ON FORM 10-K. SEE EXHIBIT 23.2 FOR FURTHER DISCUSSION.

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands)

	December 31,	
	2001	2002
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 37,397	$ 23,467
Short-term investments	11,428	
Prepaid expenses and other current assets	811	812
Total current assets	49,636	24,279
Property and equipment, net of accumulated depreciation of $6,406 and $8,228, respectively	10,443	8,742
Other assets	345	295
Total assets	$ 60,424	$ 33,316
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 946	$ 1,774
Accrued liabilities	4,029	1,997
Deferred revenues from affiliate		69
Current portions of capital lease obligations and notes payable	1,486	1,587
Total current liabilities	6,461	5,427
Capital lease obligations, net of current portion	957	125
Notes payable, net of current portion	8,079	7,310
Deferred revenue, long-term	361	619
Commitments and Contingencies		
Stockholders Equity:		
Series A non-voting convertible preferred stock, $.001 par value; 100 shares authorized, issued and outstanding	1	1
Common stock, $.001 par value; 50,000 shares authorized; 21,446, and 21,487 shares issued and outstanding in 2001 and 2002, respectively	21	21
Additional paid-in capital	94,544	94,430
Deferred compensation	(2,485)	(974)
Accumulated deficit	(47,515)	(73,643)
Total stockholders equity	44,566	19,835
Total liabilities and stockholders equity	$ 60,424	$ 33,316

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

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands, except per share amounts)

	Year Ended June 30,		Six Months Ended December 31,		Year Ended December 31,
	2000	2001	2000	2001	2002
			(Unaudited)		
Contract services, grant and other Revenue	$ 97	$ 684	$ 391	$ 298	$ 1,173
Collaborative research and development revenues from affiliate	6,204	3,016	3,016		
Product sales to affiliate	2,087	1,500	1,500		
Cost of product sales	1,476	2,488	2,488		
Gross margin on product sales	611	(988)	(988)		
Operating costs and expenses:					
Research and development	10,075	15,014	5,153	10,063	21,512
General and administrative	4,701	4,875	2,040	3,526	6,722
Total operating costs and expenses	14,776	19,889	7,193	13,589	28,234
Loss from operations	(7,864)	(17,177)	(4,774)	(13,291)	(27,061)
Interest income	722	1,230	783	912	596
Interest expense	(582)	(849)	(380)	(467)	(803)
Other income		354		518	1,140
Net loss	$ (7,724)	$(16,442)	$ (4,371)	$(12,328)	$(26,128)
Net loss per share, basic and diluted	$ (1.89)	$ (1.02)	$ (0.39)	$ (0.58)	$ (1.22)
Shares used in computing basic and diluted net loss per share	4,096	16,163	11,120	21,440	21,471

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

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Series A, B, C and D Convertible Preferred Stock		Series A Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Compensation	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
					(Amounts in thousands)					
Balance, June 30, 1999	6,419	$ 6		$	4,006	$ 4	$31,975	$(1,778)	$(11,021)	$ 19,187
Issuance of common stock in connection with Exercise of stock options and warrants					128		58			58
Deferred compensation relating to issuance of stock options, net of reversals							3,929	(3,929)		
Amortization of deferred compensation and stock-based compensation							574	1,497		2,071
Net loss									(7,724)	(7,724)
Balance, June 30, 2000	6,419	$ 6		$	4,134	$ 4	$36,536	$(4,210)	$(18,745)	$ 13,592
Issuance of common stock in connection with initial public offering, net of offering costs of $4,575					4,600	5	32,221			32,226
Conversion of preferred stock to common stock	(6,419)	(6)			12,326	12	(6)			
Issuance of common stock in connection with Exercise of stock options and warrants					331		204			204
Issuance of preferred stock in June 2001 in accordance stock purchase agreement with affiliate, net of offering costs of $100			100	1			24,900			24,900
Deferred compensation relating to issuance of stock options, net of reversals							720	(720)		
Amortization of deferred compensation and stock-based compensation								1,589		1,589
Net loss									(16,442)	(16,442)
Balance, June 30, 2001		$	100	$ 1	21,391	$ 21	$94,575	$(3,341)	$(35,187)	$ 56,069
Issuance of common stock in connection with Exercise of stock options and warrants					55		26			26
Deferred compensation relating to issuance of stock options, net of reversals							(57)	57		

Amortization of deferred compensation and stock-based compensation								799		799
Net loss									(12,328)	(12,328)
Balance, December 31, 2001		$	100	$ 1	21,446	$ 21	$94,544	$(2,485)	$(47,515)	$ 44,566
Issuance of common stock in connection with Exercise of stock options and warrants					41		21			21
Deferred compensation relating to issuance of stock options, net of reversals							(135)	135		
Amortization of deferred compensation and stock-based compensation								1,376		1,376
Net loss									(26,128)	(26,128)
Balance, December 31, 2002		$	100	$ 1	21,487	$ 21	$94,430	$ (974)	$(73,643)	$ 19,835

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

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended June 30,		Six Months Ended December 31,		Year Ended December 31,
	2000	2001	2000	2001	2002
			(Unaudited) (Amounts in thousands)		
Cash flows from operating activities:					
Net loss	$ (7,724)	$(16,442)	$ (4,371)	$(12,328)	$(26,128)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation	1,711	2,226	1,066	1,191	1,801
Compensation related to issuance of certain stock options	2,071	1,589	746	800	1,511
Changes in assets and liabilities:					
Decrease (increase) in receivable from affiliate			(709)		
Decrease (increase) in inventory	(110)	1,734	984		
Decrease (increase) in other assets	(908)	(437)	(371)	(294)	49
Increase (decrease) in accounts payable	(1,752)	113	582	568	829
Increase (decrease) in accrued liabilities	763	3,376	479	(372)	(2,032)
Increase (decrease) in deferred revenue	407	(917)	(155)	73	326
Net cash used in operating activities	(5,542)	(8,758)	(1,749)	(10,362)	(23,644)
Cash flows from investing activities:					
Purchases of property and equipment	(1,022)	(3,581)	(2,954)	(127)	(121)
Purchases of short-term investments	(21,585)	(83,143)	(47,076)	(19,400)	(71,734)
Maturities of short-term investments	25,224	72,343	20,075	28,749	83,184
Net cash provided by (used in) investing activities	2,617	(14,381)	(29,955)	9,222	11,329
Cash flows from financing activities:					
Proceeds from sale of preferred and common stock, net of offering costs	59	33,105	33,070	25,026	(114)
Proceeds from issuance of note payable	2,814	3,263	1,932		
Principal payments under capital lease obligations and notes payable	(305)	(818)	(387)	(689)	(1,501)
Net cash provided by financing activities	2,568	35,550	34,615	24,337	(1,615)
Net increase (decrease) in cash	(357)	12,411	2,911	23,197	(13,930)
Cash, beginning of period	2,146	1,789	1,789	14,200	37,397
Cash, end of period	$ 1,789	$ 14,200	$ 4,700	$ 37,397	$ 23,467
Supplemental disclosure of cash flow information:					
Cash paid for interest	$ 608	$ 917	$ 280	$ 459	$ 803

Supplemental disclosure of non-cash investing and financing activities:					
Purchases of equipment under capital lease obligations	$ 2,780	$	$	$	$
Retirement of fully-depreciated assets	$ 484	$	$	$	$
Receivable for issuance of preferred stock	$	$ 25,000	$	$	$
Offering costs deferred in 2000, netted against initial public offering proceeds in 2001	$	$ 776	$ 776	$	$

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

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2002
(Information pertaining to the six-month period ending December 31, 2000 is unaudited)

1. Formation and Business of the Company

Introgen Therapeutics, Inc., a Delaware corporation, and its subsidiaries (Introgen) is a leading developer of gene therapy products for the treatment of cancer and other diseases. Our lead product candidate, ADVEXIN® gene therapy, combines the p53 gene, one of the most potent members of a group of naturally occurring tumor suppressor genes, which act to protect cells from becoming cancerous, with our adenoviral delivery system. We are conducting pivotal Phase 3 clinical trials of ADVEXIN gene therapy in head and neck cancer. We have completed a Phase 2 clinical trial of ADVEXIN in non-small cell lung cancer and are conducting a Phase 2 trial of ADVEXIN gene therapy in breast cancer. We are conducting Phase 1 clinical trials, or safety trials, of ADVEXIN gene therapy in other types of cancer. We are developing additional cancer gene therapy product candidates, including those based on the mda-7 and PTEN genes, as well as associated vector technologies for delivering the gene-based products into target cells. Our INGN 241 product candidate, which combines the mda-7 gene with our proprietary gene delivery system, is undergoing safety testing in a Phase 1 clinical trial. We hold the worldwide rights for pre-clinical and clinical development, manufacturing, marketing and commercialization of ADVEXIN gene therapy. ADVEXIN gene therapy is designated by the FDA as an orphan drug under the Orphan Drug Act, which gives us seven years of marketing exclusivity for ADVEXIN gene therapy if approved by the FDA.

We are investigating other vector technologies for delivering gene-based products into targeted cells, specifically those involving replication-competent viral therapies in which viruses bind directly to cancer cells, replicate in those cells, and cause those cancer cells to die. As a supplement to our gene therapy product programs, we are evaluating the development of mebendazole, our first small molecule candidate. Pre-clinical trials suggest that mebendazole may also be an effective treatment of cancer.

We own and operate a manufacturing facility that we believe complies with the FDA s current Good Manufacturing Practices requirements, commonly known as CGMP requirements. We have produced ADVEXIN gene therapy in this facility for use in our Phase 1, 2 and 3 clinical trials and INGN 241 for use in our Phase 1 clinical trials.

We have not yet generated any significant revenues from unaffiliated third parties, nor is there any assurance of future product revenues. Our research and development activities involve a high degree of risk and uncertainty, and our ability to successfully develop, manufacture and market our proprietary products is dependent upon many factors. These factors include, but are not limited to, the need for additional financing, the reliance on collaborative research and development arrangements with corporate and academic affiliates, and the ability to develop manufacturing, sales and marketing experience. Additional factors include uncertainties as to patents and proprietary technologies, competitive technologies, technological change and risk of obsolescence, development of products, competition, government regulations and regulatory approval, and product liability exposure. As a result of the aforementioned factors and the related uncertainties, there can be no assurance of our future success.

Prior to June 30, 2001, we developed therapeutics based on p53 and on K-ras pathway inhibition under two collaboration agreements originally entered into in October 1994 with Rhône-Poulenc Rorer Pharmaceuticals Inc., which ultimately became part of Aventis Pharma, or Aventis. In June 2001, we and Aventis restructured this collaborative relationship whereby we assumed responsibility for the worldwide development of all p53 and K-ras products and acquired all worldwide marketing and commercialization rights with respect to those products. We assumed responsibility for the control and performance of ongoing clinical trials for p53- and K-ras-based products and for the development and clinical trials for new gene therapy products. Aventis licensed or transferred to us all of its patents covering the manufacture, sale, offering for sale, importation or use of ADVEXIN gene therapy and other K-ras patents, delivery patents and targeting technologies, as well as all trademarks and goodwill associated with ADVEXIN gene therapy. Aventis also

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

agreed, for a period of seven years, not to conduct any activities directed to the development or commercialization of any gene therapy products using the p53 or K-ras genes. In connection with this restructuring, Aventis purchased $25.0 million of non-voting preferred stock from us. During the quarter ended September 30, 2001, we made a one-time payment of $2.0 million to Aventis in consideration for internal costs they incurred in facilitating the transition of control and performance of these clinical trials from Aventis to us.

Since our inception in 1993, we have used our resources primarily to conduct research and development activities, primarily for ADVEXIN gene therapy and, to a lesser extent, for other product candidates. At December 31, 2002, we had an accumulated deficit of approximately $73.6 million. It is possible we will incur losses in the future that will be greater than cumulative losses incurred in prior years. We expect that cash needed for operating activities will increase as we continue to expand our research and development of various gene therapy technologies. Since inception, our only significant revenues have been payments from Aventis under the collaborative agreements discussed above for Aventis early-stage development work on ADVEXIN gene therapy and Aventis purchases of ADVEXIN gene therapy product we manufactured for Aventis use in later-stage clinical trials it previously performed. We no longer receive these revenues. We have also earned revenue from federal research grants, contract manufacturing and process development activities and interest income on cash placed in short-term investments.

Unless indicated otherwise, amounts disclosed in these footnotes are rounded to the nearest thousand.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include our accounts and all of our subsidiaries. Intercompany transactions and balances are eliminated in consolidation. In October 2001, we announced a change in the ending date of our accounting year from June 30 to December 31.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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.

Cash and Cash Equivalents

Cash and cash equivalents include amounts on deposit with financial institutions and investments with original maturities of 90 days or less.

Short-Term Investments

Our short-term investments consist of investments in short-term, investment-grade securities in the form of federal and state government obligations, commercial paper and/or corporate bonds with various maturity dates not exceeding one year. All short-term investments have been classified as held-to-maturity and are carried at amortized cost. At any point in time, amortized costs may be greater or less than fair value. If investments are sold prior to maturity, we could incur a realized gain or loss based on the fair market value of the investments at the date of sale. Additionally, we could incur future losses on investments if the investment issuer becomes impaired or the investment is downgraded.

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Property and Equipment

Property and equipment are carried at cost, less accumulated depreciation. Maintenance, repairs and minor replacements are charged to expense as incurred. Significant renewals and betterments are capitalized. Depreciation is provided generally using accelerated methods based on useful lives of fifteen years for research, manufacturing and administrative facilities and five to seven years for equipment. Interest incurred during construction of facilities is capitalized as a cost of those facilities.

Property and equipment consists of the following items (in thousands):

	December 31,	
	2001	2002
Facilities	$11,570	$11,594
Equipment	5,279	5,376
Total property and equipment	16,849	16,970
Less accumulated depreciation	(6,406)	(8,228)
Net property and equipment	$10,443	$ 8,742

As of December 31, 2001 and 2002, $3,077,000 of equipment was held under capital lease obligations and is being depreciated over the applicable lease term (see Note 7).

Federal Income Taxes

We recognize deferred tax liabilities and assets for the expected future tax consequences of events that have been recognized differently between the financial statements and tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between the financial statement carrying amounts and tax bases of liabilities and assets using enacted tax rates and laws in effect in the years in which the differences are expected to reverse. Deferred tax assets are evaluated for realization based on a more-likely-than-not criteria in determining if a valuation should be provided.

Accrued Liabilities

Accrued liabilities consist of the following significant items (in thousands):

	December 31,	
	2001	2002
Pre-clinical costs due to unrelated parties	$ 960	$ 490
Property taxes	213	314
Clinical costs due affiliate	1,163	300
Vacation	218	284
Clinical costs due unrelated parties	365	275
Legal fees	500	150
Other	610	184

Total accrued liabilities	$4,029	$1,997

In conducting our pivotal Phase 3 clinical trials of ADVEXIN gene therapy, we procure services from multiple third party vendors. The cost of these services constitutes a significant portion of the cost of these trials and of our research and development expenses in general. Some of our vendors do not necessarily bill us for their services on a regular basis and, accordingly, make it difficult for us to determine the costs we have incurred relative to their services for any given accounting period. As a result, we make significant accounting

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

estimates as to the amount of costs we have incurred relative to these vendors in each accounting period. These estimates are based on many factors, including, among others, costs set forth in our contracts with these vendors, the period of time over which the vendor has rendered the services and the rate of enrollment of patients in our clinical trials. Using these estimates, we record expenses and accrued liabilities in each accounting period that we believe fairly represent our obligations to these vendors. Actual results could differ from these estimates resulting in increases or decreases in the amount of expense recorded and the related accrual.

Revenue Recognition

Contract services revenue is recognized as the related contract services are performed. Deferred revenue is recorded for cash received for which the related expenses had not been incurred.

In accordance with the terms of the grant, grant revenue is recognized as research expenses relating to the grant are incurred, provided that the amounts received are not refundable if the research is not successful.

Collaborative research payments received prior to the restructuring of the Aventis collaboration were recognized as revenue as we performed our obligations related to such research agreements. Deferred revenue was recorded for cash received for which the related expenses had not been incurred. We have not received such payments subsequent to December 31, 2000.

Prior to the restructuring of the Aventis collaboration, we sold gene-therapy based products to Aventis at specified prices and payment terms with no rights to return delivered and accepted product. Revenue from product sales to the affiliate was recognized upon completion of production and delivery requirements and acceptance by Aventis and when collection was reasonably assured. Deferred revenue was recorded for cash received for product which had not been delivered to and accepted by Aventis. We have not sold product to Aventis subsequent to December 31, 2000.

Rental income from the sublease of laboratory space to third parties under leases that have variable monthly rent amounts over the term of the lease is recognized on a straight-line basis over the term of the lease. Any cash payments received in excess of rental income recognized is recorded as deferred revenue. Rental income is included in other income in the accompanying consolidated statement of operations.

Research and Development Costs

Research and development costs include the costs of conducting basic research, developing product applications, conducting pre-clinical investigations and performing clinical trials to obtain data for regulatory filings for product approvals. Research and development costs are expensed as incurred.

Net Loss Per Share

Net loss per share is computed using the weighted average number of shares of common stock outstanding. Due to losses incurred in all periods presented, the shares associated with stock options, warrants and non-voting convertible preferred stock are not included because they are anti-dilutive.

Stock-Based Compensation

Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation, allows companies to adopt one of two methods for accounting for stock options. We have elected the method that requires disclosure only of stock-based compensation. Because of this election, we continue to account for our employee stock-based compensation plans, using the intrinsic value method, under Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, as clarified by Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation. Accordingly,

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

deferred compensation is recorded for stock-based compensation grants based on the excess of the fair market value of the common stock on the measurement date over the exercise price. The deferred compensation is amortized over the vesting period of each unit of stock-based compensation grant, generally four years. If the exercise price of the stock-based compensation grants is equal to the estimated fair value of our stock on the date of grant, no compensation expense is recorded.

The fair value of options granted for all periods presented was estimated on the applicable grant dates using the Black-Scholes option pricing model. Significant weighted average assumptions used to estimate fair value for all years include: risk-free interest rates ranging from 4.8 percent to 6.7 percent; expected lives of seven to ten years; no expected dividends; and volatility factors ranging from 58.0 percent to 110.8 percent. Had compensation expense been determined consistent with the provisions of SFAS No. 123, our net loss would have been increased to the following pro forma amounts (in thousands, except per share information):

	Year Ended June 30,		Six Months Ended December 31,	Year Ended December 31,
	2000	2001	2001	2002
Net loss, as reported	$(7,724)	$(16,442)	$(12,328)	$(26,128)
Add: Stock-based employee compensation expense included in reported net loss	$ 1,497	$ 1,589	$ 799	$ 1,377
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	$(1,555)	$ (1,883)	$ (1,693)	$ (1,902)
Pro forma net income	$(7,782)	$(16,736)	$(13,222)	$(26,653)
Earnings per share:				
Basic and Diluted as reported	$ (1.89)	$ (1.02)	$ (0.58)	$ (1.22)
Basic and Diluted pro forma	$ (1.90)	$ (1.04)	$ (0.62)	$ (1.24)

Because SFAS No. 123 does not apply to options granted prior to July 1, 1995, the resulting pro forma compensation costs may not be representative of the costs to be expected in future years.

Other Comprehensive Loss

Our other comprehensive loss consists of net loss, as there are no other comprehensive loss items.

Recent Accounting Pronouncements

In June 2002 the FASB issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS No. 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of commitment to an exit or disposal plan. This statement is effective for exit or disposal activities initiated after December 31, 2002. We do not believe that the adoption of SFAS No. 146 will have a material impact on our financial statements.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, an Amendment of FASB Statement No. 123. This Statement amends FASB Statement No. 123, Accounting for Stock-Based Compensation, to provide alternative methods of transition for an entity that voluntarily changes to the fair value based method of accounting for stock-based employee compensation. It also amends the disclosure provisions of that Statement to require prominent disclosure about the effects on reported net

income of an entity s accounting policy decisions with respect to stock-based employee compensation. Finally, this Statement amends APB Opinion No. 28, Interim Financial Report-

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

ing, to require disclosure about those effects in interim financial information. Since we are continuing to account for stock-based compensation according to APB 25, adoption of SFAS No. 148 requires us to provide prominent disclosures about the affects of FAS 123 on reported income (loss) and will require us to disclose these affects in the interim financial statements as well.

3. Stockholders Equity

Stock Split

In August 2000, our Board of Directors approved a stock dividend to effect a stock split of 1.6 shares for every one share of common stock outstanding. An amount equal to the increased par value of the common shares has been reflected as a transfer from additional paid-in capital to common stock. Retroactive effect has been given to the stock split in stockholders equity and in all share and per share data as of the earliest date presented in the accompanying consolidated financial statements.

Initial Public Offering

In October 2000, we completed an initial public offering of 4,600,000 newly-issued shares of our common stock at a price of $8.00 per share. We received $32.2 million in cash proceeds from the initial public offering, net of underwriting discounts, commissions and other offering costs.

Convertible Preferred Stock

Simultaneous with the closing of the initial public offering, our convertible preferred stock then outstanding, consisting of 3,011,423 shares of Series A Convertible Preferred Stock, 1,757,063 shares of Series B Convertible Preferred Stock, 551,410 shares of Series C Convertible Preferred Stock and 1,100,000 shares of Series D Convertible Preferred Stock, was automatically converted into 12,326,173 shares of common stock.

Series A Non-Voting Convertible Preferred Stock

In connection with the restructuring of the Aventis collaboration and pursuant to a stock purchase agreement with Aventis executed on June 30, 2001, we issued and sold to Aventis 100,000 unregistered shares of a new class of $0.001 par value, Series A Non-Voting Convertible Preferred Stock in exchange for $25.0 million. At June 30, 2001, we had a receivable of $25.0 million from Aventis for this sale, for which we received payment in July 2001. These shares are convertible at any time, at our option or the option of Aventis, into 2,343,721 shares of our common stock. Under a voting agreement, Aventis must vote these shares in the same manner as the shares voted by a majority of the other stockholders on any corporate action put to a vote of our stockholders. This voting requirement terminates at the earliest of the tenth anniversary of the voting agreement, registration of these shares with the Securities and Exchange Commission or the sale of these shares to an Aventis non-affiliate, as defined in the voting agreement. A registration rights agreement grants the holder of a majority of the common stock issuable upon conversion of the Series A Non-Voting Convertible Preferred Stock three demand registrations and three piggyback registrations.

Employee Stock Purchase Plan

Under our 2000 Employee Stock Purchase Plan (the Stock Purchase Plan), 780,000 shares of common stock are reserved for purchase by eligible employees, at 85 percent of the appropriate market price. The Stock Purchase Plan provides for an increase on each January 1 in the number of shares available for issuance, in an amount equal to the lesser of 480,000 shares, 1.5 percent of the outstanding shares of common stock on the date of the annual increase or such lesser amount as may be determined by the Board of Directors. The Stock Purchase Plan provides that eligible employees may authorize payroll deductions of up to 10 percent of their

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

qualified compensation. The maximum number of shares that an employee may purchase in a single offering period is 10,000 shares. The Stock Purchase Plan will terminate in 2010 and may be amended or terminated by the Board of Directors. During the year ended June 30, 2001, 22,561 shares of common stock were purchased by employees under this plan. There have been no common stock purchases since that time, as we have suspended operation of the Stock Purchase Plan until further notice by the Board of Directors.

Stock Option Plans

The 2000 Stock Option Plan (the Stock Option Plan) was initiated in October 2000 and all stock option grants since that time have been under this plan. The Stock Option Plan provides for the granting of options, either incentive or non-statutory, or stock purchase rights to our employees, directors and consultants to purchase shares of our common stock. At December 31, 2002, there were 5,109,000 shares of common stock reserved for option grants under this plan. This plan provides for annual increases in the number of shares available for issuance beginning in fiscal 2001, equal to the lesser of 1,600,000 shares, five percent of the outstanding shares on the date of the annual increase, or a lesser amount as may be determined by the Board of Directors. The exercise price for all option grants shall be no less than the fair value of our common stock at the date of grant, with the exception of incentive stock options granted to holders of shares representing more than ten percent of our voting power, in which case the exercise price shall be no less than 110 percent of the fair value. In the event of a merger, reorganization or change in our controlling ownership, all options outstanding under the Stock Option Plan become fully vested and immediately exercisable unless the successor corporation assumes or substitutes other options in their place. The Stock Option Plan will terminate in 2010 and may be amended or terminated by the Board of Directors.

Prior to October 2000, stock options were granted under our 1995 Stock Plan. We no longer issue options under this plan. The terms of this plan are substantially the same as the Stock Option Plan. No shares of common stock were reserved for option grants under this plan at December 31, 2002.

We record the fair value of options issued to non-employee consultants at the fair value of the options issued. We have not incurred significant compensation expense relating to non-employee consultant grants. Any expense is recognized over the service period or at the date of issuance if the options are fully vested and no performance obligation exists.

Aggregate deferred compensation recorded related to stock options was $4,177,000 and $792,000 during the years ended June 30, 2000 and 2001, respectively, $600,000 and zero during the six months ended December 31, 2000 and 2001, and zero during the year ended December 31, 2002.

Amortization to expense of deferred compensation related to stock options was $1,497,000 and $1,589,000 during the years ended June 30, 2000 and 2001, respectively, $746,000 and $799,000 for the six months ended December 31, 2000 and 2001, respectively, and $1,377,000 during the year ended December 31, 2002.

Reversals of deferred compensation and additional paid-in capital for unamortized deferred compensation related to the forfeiture of non-vested options by terminated employees was $248,000 and $73,000 for the years ended June 30, 2000 and 2001, respectively, and $56,000 and $56,000 for the six months ended December 31, 2000 and 2001, respectively, and $134,000 during the year ended December 31, 2002. For each respective year, total amortization expense was revised to the extent amortization had previously been recorded for non-vested options.

In December 1999, we accelerated the vesting of options held by a member of the Board of Directors concurrent with the individual s resignation from our Board of Directors. We accelerated these options in recognition of the individual s contributions to the Board of Directors and recognized approximately $574,000 of compensation expense for the fair value of the previously unvested options as of the re-measurement date.

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following is a summary of option activity under these plans:

	Options Outstanding	Weighted Average Exercise Price Per Share
Balance, June 30, 1999	2,431,111	$0.47
Granted	399,306	0.94
Exercised	(108,745)	0.46
Cancelled	(124,517)	0.51
Balance, June 30, 2000	2,597,155	0.55
Granted	704,498	4.30
Exercised	(308,212)	0.42
Cancelled	(17,357)	0.74
Balance, June 30, 2001	2,976,084	1.27
Granted	379,300	4.35
Exercised	(55,238)	0.44
Cancelled	(38,350)	1.21
Balance, December 31, 2001	3,261,796	1.80
Granted	989,514	3.62
Exercised	(40,331)	0.54
Cancelled	(224,886)	3.46
Balance, December 31, 2002	3,986,093	2.18
Exercisable at December 31, 2002	2,457,447	1.28

The weighted average fair value of options granted during the years ended June 30, 2000 and 2001 was $11.18 and $5.61, respectively, for the six months ended December 31 2001 was $3.96, and for the year ended December 31, 2002 was $3.07. All options granted during the six months ended December 31, 2000 and thereafter have an exercise price equal to the fair value of our common stock as of date of grant.

The following table summarizes information about stock options outstanding as of December 31, 2002:

Options Outstanding				Options Exercisable	
Range of Exercise Price	Outstanding as of December 31, 2002	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Exercisable as of December 31, 2002	Weighted Average Exercise Price
$0.39-$1.99	2,137,107	4.92	$0.56	1,936,845	$0.53
2.00- 3.91	575,750	8.95	2.68	205,900	2.86
4.02- 5.88	1,273,236	8.65	4.64	314,702	4.86

3,986,093	6.69	2.18	2,457,447	1.28

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Federal Income Taxes

The reconciliation of the statutory federal income tax rate to our effective income tax rate is as follows:

	Year Ended June 30,		Six Months Ended December 31,		Year Ended December 31,
	2000	2001	2000	2001	2002
Federal statutory rate	(34.0)%	(34.0)%	(34.0)%	(34.0)%	(34.0)%
State taxes, net of federal benefit					(2.8)
Increase in deferred tax valuation allowance	24.8	30.6	30.8	32.9	37.1
Stock option compensation not deductible	9.1	3.3	3.1	2.2	1.8
Research and development tax credits				(1.4)	(0.2)
Other	0.1	0.1	0.1	0.3	(4.7)
	%	%	%	%	%

The components of our deferred tax assets are as follows:

	December 31,	
	2001	2002
Net operating loss carryforwards	$ 11,708,500	$ 21,602,000
Research and development tax credits	226,900	282,800
Technology license	50,200	25,900
Tax basis of property and equipment in excess of book basis	1,578,400	1,849,800
Accrued liabilities	432,500	248,900
Capital leases	137,900	
Other	209,000	35,600
Total deferred tax assets	14,343,400	24,045,000
Less Valuation allowance	(14,343,400)	(24,045,000)
Net deferred tax assets	$	$

As of December 31, 2002, we have generated net operating loss (NOL) carryforwards of approximately $58.4 million and research and development credits of approximately $283,000 available to reduce future income taxes. These carryforwards begin to expire in 2007. A change in ownership, as defined by federal income tax regulations, could significantly limit our ability to utilize these carryforwards. Our ability to utilize current and future NOLs to reduce future taxable income and tax liabilities may be limited. Additionally, because United States tax laws limit the time during which these carryforwards may be applied against future taxes, we may not be able to take full advantage of these attributes for federal income tax purposes. As we have had cumulative losses and there is no assurance of future taxable income, a valuation allowance has been established to fully offset the deferred tax asset. The valuation allowance increased $1.9 million and $5.0 million for the years ended June 30, 2000 and 2001, respectively, and $2.8 million and $4.1 million for the six months ended December 31, 2000 and 2001, respectively, and $9.7 million during the year ended December 31, 2002. These valuation allowance increases were primarily due to losses from operations.

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Notes Payable

We have notes payable with banks to finance our facilities, which are pledged as security for these notes. There are two notes with the following terms:

Note payable with an original principal balance of $6,000,000 and an outstanding balance of $5,826,000 and $5,732,000 at December 31, 2001 and 2002, respectively. Interest is fixed at 7.5 percent until November 2004, at which time it is subject to a one-time adjustment to a rate equal to the then-current rate of the five-year United States Treasury bond note plus 2 percent, with such adjusted interest rate not to exceed 8.5 percent. Interest plus principal based on a 25-year amortization period are payable monthly until November 2009, at which time the remaining outstanding principal is due and payable.

Note payable with an original principal balance of $3,263,000 and an outstanding balance of $2,938,000 and $2,332,000 at December 31, 2001 and 2002, respectively. Interest is at prime, adjustable annually. Principal and interest, fully amortized over a five-year period, is payable monthly through June 2006.

Interest was capitalized as a cost of facilities during the time those facilities to which those notes relate were under construction. Interest capitalized was $103,000 and $84,000 during the years ended June 30, 2000 and 2001, respectively, $60,000 and zero during the six months ended December 31, 2000 and 2001, respectively, and zero during the year ended December 31, 2002.

Aggregate annual maturities on notes payable as of December 31, 2002, are as follows (in thousands):

Year ending December 31,	
2003	$ 755
2004	789
2005	825
2006	434
2007	142
Thereafter	5,119
Total	$8,064

We believe the fair market value of our debt approximates its carrying value as of all balance sheet dates presented herein.

6. License and Research Agreements

Patent and Technology License Agreement With The University of Texas System

We have a license agreement with the Board of Regents of The University of Texas System (the System) and M. D. Anderson Cancer Center, a component institution of the System, whereby we have an exclusive, worldwide license to use certain technology. Beginning with the first commercial sale of a product incorporating the licensed technologies, we will pay M. D. Anderson Cancer Center, for the longer of fifteen years or the life of the patent, a royalty based on net sales by us or our affiliates or by sublicense agreement of products incorporating any of such technologies. We are obligated by the agreement to reimburse any of M. D. Anderson Cancer Center s costs that may be incurred in connection with obtaining patents related to the licensed technologies.

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

VirRx, Inc.

We are working with VirRx, Inc. (VirRx) to investigate other vector technologies for delivering gene-based products into targeted cells. We have an agreement with VirRx, which began in 2002, to purchase shares of VirRx s Series A Preferred Stock. We purchased $525,000 of this stock for cash during 2002, which we recorded as research and development expense. We have agreed to purchase an additional $150,000 of this stock for cash on the first day of each quarter through January 1, 2006. VirRx is required to use the proceeds from these stock sales in accordance with the terms of a collaboration and license agreement between us and VirRx for the development of VirRx s technologies. We may unilaterally terminate this collaboration and license agreement with 90 days prior notice at any time after March 7, 2003, which would also terminate the requirement for us to make any additional stock purchases. Provided the collaboration and license agreement remains in place, we will make additional milestone stock purchases, either for cash or through the issuance of our common stock, upon the completion of Phase 1, Phase 2 and Phase 3 clinical trials involving technologies licensed under this agreement and we will make a $5.0 million cash milestone payment to VirRx, for which we receive no VirRx stock, upon approval by the United States Food and Drug Administration of a biologics license application involving these technologies. To the extent we have already made cash milestone payments, we may receive a credit of 50% of the Phase 2 clinical trial milestone payments and 25% of the Phase 3 clinical trial milestone payments against this $5.0 million cash milestone payment. The additional milestone stock purchases and cash payment are not anticipated to be required in the near future. We have an option to purchase all outstanding shares of VirRx at any time until March 2007.

Other Technology Option and License Agreements

We have technology option and license agreements with various other third parties and, in particular, agreements related to the mda-7 and PTEN genes. These agreements require us to make milestone and license payments to these parties if and when we achieve certain prescribed clinical trial and product development milestones. We have technology option and license agreements with two additional third parties covering certain enabling technologies, both of which require annual payments of $20,000 until cancelled at our option.

Sponsored Research

We fund certain research performed by M. D. Anderson Cancer Center to further the development of technologies that could have potential commercial viability. By sponsoring and funding this research, we have the right to include certain patentable inventions arising therefrom under its patent and technology license agreement with The University of Texas System. The expense for this research was approximately $816,000 and $634,000 during the years ended June 30, 2000 and 2001, respectively, $230,000 and $632,000 during the six months ended December 31, 2000 and 2001, respectively, and $809,000 for the year ended December 31, 2002.

7. Commitments and Contingencies

Lease Commitments

We are obligated under various capital and operating leases for land, office and laboratory space and equipment that expire at various dates through September 2026. The amounts payable under capital leases were drawn under two lease lines of credit with commercial leasing companies which were used to finance equipment acquisitions. Amounts drawn under both lines are payable monthly over 48 months from the time of the draw. The lines of credit bear interest at fixed interest rates ranging from 11.3% to 13.25% at December 31, 2002. The lease lines of credit are secured by the equipment being financed.

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Operating leases consist primarily of a ground lease for the land on which our new facility is located. The annual rent due under this lease is $144,000. The primary term of this lease continues through September 2026.

Lease expense was $380,000 and $315,000 for the years ended June 30, 2000 and 2001, respectively, and $157,000 and $155,000 for the six months ended December 31, 2000 and 2001, respectively, and $303,000 for the year ended December 31, 2002. Future minimum lease payments under non-cancelable operating leases and the present value of future minimum capital lease payments as of December 31, 2002, are as follows (in thousands):

	Operating Leases	Capital Leases
Year ending December 31,		
2003	$ 279	$ 905
2004	281	128
2005	202	
2006	144	
2007	144	
Thereafter	2,707	
Total minimum lease payments	$3,757	1,033
Less amount representing interest		(76)
Capital lease obligations		$ 957

Insurance and Litigation

We are subject to numerous risks and uncertainties because of the nature and status of our operations, and we are subject to claims and legal actions arising in the normal course of business. We maintain insurance coverage for events and in amounts that we deem appropriate. Management believes that uninsured losses, if any, would not be materially adverse to our financial position or results of operations.

We were previously named as a defendant in a complaint filed by Canji, Inc against Sidney Kimmel Cancer Center (SKCC), ourselves and others. In June 2002, Canji, SKCC and we entered into an agreement to settle all claims to the litigation. As part of the agreement, SKCC agreed to reimburse us for certain costs, and we granted to Canji a limited, non-exclusive sublicense under our license of intellectual property from SKCC. The SKCC intellectual property is not material to our business.

Employment Agreement

We have an employment agreement with our President and Chief Executive Officer that provides for a base salary and bonuses through July 31, 2003.

8. Related Parties

The Chairman of our Board of Directors owns, and another member of our Board of Directors is a former employee of, a company to which we pay consulting fees of approximately $175,000 per year. We are obligated to continue paying this fee until such time as we, at our option, terminate the services of that company. As of December 31, 2002, these two individuals held options to purchase 416,000 shares of our common stock.

We have a consulting agreement with an individual primarily responsible for the creation of the technology upon which ADVEXIN gene therapy is based, who is also a stockholder. Under this consulting

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INTROGEN THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

agreement, we paid this individual fees of $150,000 and $150,000 during the years ended June 30, 2000 and 2001, respectively, $75,000 and $78,750 during the six months ended December 31, 2000 and 2001, respectively, and $171,000 during the year ended December 31, 2002. This consulting agreement provides for payments of $181,500 per annum until September 30, 2003, and $200,000 per annum thereafter through the end of its term on September 30, 2009, with such future payments subject to adjustment for inflation. We may terminate this agreement at our option upon one year s advance notice.

We sublease a portion of our facilities to M. D. Anderson Cancer Center under a lease with a non-cancelable term that expires in 2009. M. D. Anderson Cancer Center is obligated to pay us rent of approximately $76,000 per month until February 2006 and $13,053 per month thereafter. This lease began in February 2001, after which time rental income related to this lease is included in other revenue. Rental income was $354,000 for the year ended June 30, 2001, $515,000 for the six months ended December 31, 2001 and $1,104,000 for the year ended December 31, 2002.

In 2002, we entered into an agreement with Aventis Pharmaceuticals Products, Inc. (APP) under which APP provides funding for a Phase 2 clinical trial for breast cancer conducted under our supervision. APP may fund up to $795,000 for this trial of which we received $197,000 through December 31, 2002. Amounts received under this agreement are recorded as deferred revenue until the related expenses are incurred. APP is an affiliate of Aventis, one of our stockholders.

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EXHIBIT INDEX

Exhibit Number	Description of Document
23.1	Consent of Ernst & Young LLP, independent auditors
23.2	Information Regarding Consent of Arthur Andersen LLP
24.1	Power of Attorney (See page 52)
99.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002