2019
ANNUAL
REPORT

ADMA BIOLOGICS

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Advanced Therapies for the Immune Compromised

BECAUSE PATIENTS ARE COUNTING ON US

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To Our Valued Stockholders:

By all accounts, 2019 was a transformative year for ADMA Biologics, with unprecedented accomplishments. Our two lead intravenous immune globulin products, BIVIGAM® and ASCENIV™, both received U.S. Food and Drug Administration (FDA) approval. Moreover, each of these products achieved their first commercial sales in the U.S. during the second half of 2019. Needless to say, this is an exciting time for our company and the medical community that relies on our manufacturing, production, and commercial efforts. We remain focused on our mission to bring life-saving and sustaining therapies to the patients and physicians who need them. They are counting on us.

A strong finish and well positioned for the future

Sales from both BIVIGAM and ASCENIV contributed in 2019 to total revenues of $29.3 million, a 73% increase from 2018. The company ended the year with approximately $27 million in cash and cash equivalents. In February 2020, we further strengthened our balance sheet by completing an underwritten public offering of our common stock, which provided net proceeds to ADMA of approximately $88 million. This financing resulted in a proforma cash balance of more than $110 million.

These accomplishments would not be possible without the tireless and unwavering commitment of our leadership and their teams. I am extremely proud of the entire ADMA Biologics organization and wish to recognize their invaluable efforts, hard work and dedication in securing FDA approvals, ensuring the highest of manufacturing standards, and achieving the first sales for our life-saving plasma-derived antibody therapies. We believe in the potential of all our intravenous immune globulin and hyperimmune globulin products. As we move forward, we are prepared and well-positioned to maximize our commercial opportunities for BIVIGAM and ASCENIV in the years ahead.

Leveraging new channels for growth

As we forge ahead toward the remainder of 2020 and beyond, we are focused on several key business priorities. Among these are implementing strategies for potential manufacturing capacity expansion, enhancing control over our production supply-chain, expanding our plasma collection center network, securing new supply contracts and contract manufacturing organization opportunities, and leveraging our intellectual property estate to include additional potential specialty plasma and/or hyperimmune immunoglobulin products.

Our work has earned us widespread accolades. We were recognized by BioFlorida as the 2019 Company of the Year. We were also honored by BioNJ, who graciously presented us with the Innovator Award for ASCENIV. These accomplishments are a testament to our values as a company that is relentlessly committed to delivering novel products for the immune deficient patient community and patients at risk for infectious diseases.

With three FDA-approved products, multiple revenue categories and several meaningful goals set for 2020, we look forward to sharing our progress and achievements with you throughout the year ahead.

On behalf of the entire ADMA Biologics team, I thank you, our stockholders, for your continued support. Your investment in ADMA helps to advance our mission to save lives. Wishing everyone health and safety during this trying time.

Sincerely,

Adam S. Grossman
Founder, President and Chief Executive Officer

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

☐ **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 Global Market**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ No ☐

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

☐ Large Accelerated Filer ☒ Accelerated Filer ☐ Non-accelerated Filer ☒ 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 ☒

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates was $158,690,677 as of June 30, 2019 (the last business day of the registrant's most recently completed second fiscal quarter), based on a total of 41,005,343 shares of common stock held by non-affiliates and a closing price of $3.87 as reported on the Nasdaq Capital Market on June 28, 2019.

As of March 10, 2020, there were 86,345,313 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.

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 Section 27A of the Securities Act of 1933, as amended (the ‘‘Securities Act’’) and Section 21E of the Securities Exchange Act of 1934, as amended (the ‘‘Exchange Act’’), and such forward-looking statements involve risks and uncertainties. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as ‘‘may,’’ ‘‘should,’’ ‘‘could,’’ ‘‘would,’’ ‘‘expect,’’ ‘‘plan,’’ ‘‘anticipate,’’ ‘‘believe,’’ ‘‘estimate,’’ ‘‘predict,’’ ‘‘potential,’’ ‘‘project,’’ ‘‘continue,’’ ‘‘will,’’ or the negative thereof, or other variations or comparable terminology, although some forward-looking statements are expressed differently. The forward-looking statements included herein represent management’s current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. These statements include statements about:

- our ability to manufacture BIVIGAM on a commercial scale and commercialize this product as a result of the approval of the Prior Approval Supplement for BIVIGAM by the U.S. Food and Drug Administration (the ‘‘FDA’’) on May 9, 2019;
- our ability to manufacture ASCENIV on a commercial scale and commercialize this product as a result of the FDA approval of ASCENIV’s Biologics License Application on April 1, 2019;
- our plans to develop and expand our commercial infrastructure and to manufacture and commercialize our current 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, and the labeling or nature of any such approvals;
- the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals for our product candidates;
- our dependence upon third-party manufacturers and vendors and their compliance with applicable regulatory requirements;
- our ability to obtain adequate quantities of FDA-approved source plasma with proper specifications;
- our plans to increase our supplies of source plasma, which include plasma collection center expansion and reliance of third-party supply agreements as well as any extensions to such agreements;
- the potential indications for our products and product candidates;
- potential investigational new product applications;
- the acceptability of any of our products, including Nabi-HB, BIVIGAM and ASCENIV, for any purpose, including FDA-approved indications, by physicians, patients or payers;
- our plans to evaluate the clinical and regulatory paths to grow the ASCENIV franchise through expanded FDA-approved uses;
- Federal, state and local regulatory and business review processes, timing and Company compliance with such governmental and regulatory agencies of our business and regulatory submissions;
- concurrence by the FDA with our conclusions concerning our products and product candidates;
- the comparability of results of our hyperimmune and immune globulin products to other comparably run hyperimmune and immune globulin clinical trials;
- the potential for ASCENIV and BIVIGAM to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease, Primary Humoral Immunodeficiency Disease (‘‘PIDD’’ or ‘‘PI’’) or other immune deficiencies or any other condition for which the products may be prescribed or evaluated;
- 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;

- our intellectual property position and the defense thereof, including our expectations regarding the scope of patent protection with respect to ASCENIV or other future pipeline product candidates;
- our manufacturing capabilities, third-party contractor capabilities and vertical integration strategy;
- our plans related to the expansion of our manufacturing capacity, yield improvements, supply chain robustness, distribution and other collaborative agreements and the success of such endeavors;
- our estimates regarding revenues, expenses, capital requirements, timing to profitability and the need for and availability of additional financing;
- possible or likely reimbursement levels for our currently marketed products;
- estimates regarding market size, projected growth and sales of our existing products as well as our expectations of market acceptance of ASCENIV and BIVIGAM;
- future domestic and global economic conditions or performance; and
- expectations for future capital requirements.

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 ''ASCENIV™,'' ''BIVIGAM®'' and ''Nabi-HB®,'' 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 ™ symbols, but the absence of 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.

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 an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and others at risk for 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 three products with U.S. Food and Drug Administration (the ''FDA'') approval, all of which are currently marketed and commercially available: (i) BIVIGAM (Immune Globulin Intravenous, Human), an Intravenous Immune Globulin (''IVIG'') product indicated for the treatment of Primary Humoral Immunodeficiency (''PI''), also known as Primary Immunodeficiency Disease (''PIDD''), and for which we received FDA approval on May 9, 2019 for the commercial re-launch of the product and commenced the commercial re-launch in August 2019; (ii) ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), previously referred to as RI-002, an IVIG product indicated for the treatment of PI, for which we received FDA approval on April 1, 2019 and commenced first commercial sales in October 2019; and (iii) Nabi-HB (Hepatitis B Immune Globulin, Human), which is indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen (''HBsAg'') and other listed exposures to Hepatitis B. We seek to develop a pipeline of plasma-derived therapeutics, including a product based on our most recently approved patent application under U.S. Patent No. 10,259,865 related to methods of treatment and prevention of S. pneumonia infection for an immunoglobulin manufactured to contain standardized antibodies to numerous serotypes of S. pneumonia. 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.

We manufacture our products at an FDA-licensed, 400,000-liter annual capacity plasma fractionation and purification facility located in Boca Raton, Florida (the ''Boca Facility''). Based on current production yields, we believe this facility has the potential to produce quantities of our immune globulin (''IG'') products capable of generating up to $250 million in annual revenue as we ramp-up production over the next three to five years.

Through ADMA Bio Centers, we currently operate one FDA-approved source plasma collection facility in the U.S., which provides us with a portion of our blood plasma for the manufacture of our products and product candidates. We intend to open five to 10 additional plasma collection centers in the U.S. during the next three to five 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. and in other locations outside the U.S. where we are approved under supply agreements or in the open ''spot'' market.

We also sell plasma-derived intermediate fractions to certain customers, which are generated as part of our FDA-approved manufacturing process for IVIG products. In January 2020, we announced our entry into a five-year manufacturing and supply agreement to produce and sell these intermediate by-products, which are used as the starting raw material to produce other plasma-derived biologics. In addition, from time to time we provide contract manufacturing services for certain third-party clients.

Recent Developments

On February 11, 2020, we completed an underwritten public offering of 23,500,000 shares of our common stock for gross proceeds of $82.3 million. On February 21, 2020, we sold an additional 3,525,000 shares pursuant to the underwriters' exercise of their option to purchase additional shares of our common stock for additional gross proceeds of $12.3 million. We received net proceeds, after underwriting discounts and other expenses associated with the offering, of approximately $88.5 million.

In January 2020, we announced our entry into a five-year manufacturing and supply agreement with a third-party customer to produce and sell plasma-derived intermediate fractions from our FDA-approved IG manufacturing process.

Our Products

BIVIGAM

BIVIGAM is a plasma-derived IVIG that 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 human Immunoglobulin G antibodies indicated for the treatment of PI, a group of genetic disorders. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These PIs are a group of genetic disorders. Based on recent estimates, these disorders are no longer considered to be very rare, with as many as one in every 1,200 people in the United States having some form of PI.

BPC had originally received FDA approval for BIVIGAM on December 19, 2012, prior to our acquisition of BTBU, and product sales had commenced in the first quarter of 2013. On May 9, 2019, the FDA approved our Prior Approval Supplement (the ''PAS'') for the use of our IVIG manufacturing process, thereby enabling us to re-launch and commercialize this product in the United States. We resumed production of BIVIGAM during the fourth quarter of 2017 after the closing of the Biotest Transaction and commercial production is ongoing, using our FDA-approved IVIG manufacturing process under U.S. Department of Health and Human Services (''HHS'') License No. 2019. The commercial re-launch and first commercial sales commenced in August of 2019.

ASCENIV

ASCENIV is a plasma-derived IVIG that contains naturally occurring polyclonal antibodies, which are proteins that are used by the body's immune system to neutralize microbes, such as bacteria and viruses and prevent against infection and disease. We manufacture ASCENIV under a HHS License No. 2019 using a process known as fractionation. As part of our proprietary manufacturing process for ASCENIV, we leverage our unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and plasma from donors tested to have high levels of neutralizing titers to RSV using our proprietary microneutralization assay. We are able to identify the high titer plasma that meets our internal specifications for ASCENIV with our patented testing assay. This type of high titer plasma is typically found in less than 10% of the total donor collection samples we test.

ASCENIV is approved for the treatment of PIDD, a class of inherited genetic disorders that causes a deficient or absent immune system in adults and adolescents (12 to 17 years of age). Our pivotal Phase 3 clinical trial in 59 PIDD patients met the primary endpoint of no Serious Bacterial Infections reported during 12 months of treatment. Secondary efficacy endpoints further demonstrated the benefits of ASCENIV in the low incidence of infection, therapeutic antibiotic use, days missed from work/school/daycare and unscheduled medical visits and hospitalizations. We believe this clinical data together with the FDA approval for the treatment of PIDD better positions ADMA to further evaluate ASCENIV in immune-compromised patients infected with or at-risk for RSV infection. We plan to work with the FDA and the immunology and infectious disease community to design a clinical trial to evaluate the use of ASCENIV in this patient population in the near future. Commercial sales of ASCENIV commenced in October of 2019.

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 of infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection in specific, listed settings. 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. In early 2018, we received authorization from the FDA for the release of our first commercial batch of Nabi-HB for commercial distribution in the U.S. and continue to manufacture under HHS License No. 2019.

Evaluation of ASCENIV in PIDD Patients

PIDD or PI, 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 $6.8 billion in 2018, and approximately $14 billion in 2025 based upon anticipated compounded annual growth rate of approximately 11%.

ASCENIV 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.

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

RI-002 demonstrated positive results in the Phase III study in patients with PIDD, meeting its primary endpoint of no SBIs reported. RI-002 was administered in a total of 793 infusions with zero serious adverse events to 59 patients in nine treatment centers throughout the U.S. These results, included in our BLA, exceed 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 Immune Globulin (''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 ASCENIV is comparable to that of other immunoglobulins.

Rationale for the Potential Evaluation of ASCENIV 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 that are present in ASCENIV are expected to prevent infections in immune-compromised patients.

In October 2019, we announced the successful treatment of ASCENIV in two children through our compassionate use program. The two immunocompromised children admitted to the Mayo Clinic each were diagnosed with T-cell lymphoblastic lymphoma. Both patients were undergoing delayed intensification chemotherapy and each were diagnosed with RSV Lower Respiratory Tract Infection (''LRTI''). Both children were treated with ASCENIV™ under an emergency United States Food and Drug Administration (''FDA'') Investigational New Drug protocol.

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.

Based on these results, we intend to evaluate ASCENIV for the treatment of RSV patients 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. When stored under proper conditions, this plasma may have a shelf-life of up to 10 years. Source plasma is collected at any one of over 700 FDA-licensed donation centers located throughout the U.S., using a process known as 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, a significant risk associated with 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. We incorporate these processes into the manufacturing process ensures that our products comply with the requirements of the FDA and are safe and efficacious.

Once our drug-substance is produced in the Boca Facility, the product is further processed by certain third party fill-finish providers as well as through labeling, packaging and DSCSA serialization requirements. The end-to-end production cycle can take approximately nine to 12 months for a batch of FDA released drug product.

Sales and Commercialization of Our Products

Currently, BIVIGAM, ASCENIV and Nabi-HB are sold primarily through independent distributors, drug wholesalers acting as sales agents, specialty pharmacies and other alternate site providers. In the U.S., independent distributors or third-party drug wholesalers ship our products 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.

Commercialization efforts to generate increased market awareness for Nabi-HB include attending and presenting at medical conferences, as well as sponsoring medical education symposiums. We have also hired a small, specialty sales force to market BIVIGAM and ASCENIV to hospitals, physician offices/clinics, and other specialty treatment organizations as applicable. 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 and regional distributors to assist with order fulfillment for BIVIGAM and ASCENIV for use by healthcare professionals and hospitals.

Pharmaceutical Pricing and Reimbursement of Our Products

All sales in the U.S. of BIVIGAM, ASCENIV and Nabi-HB 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 the U.S. that 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 intend 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 international locations where we are approved under supply agreements or in the open ''spot'' market.

Acquisition Transaction with Biotest Pharmaceuticals Corporation

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 included two FDA-licensed products, Nabi-HB and BIVIGAM, and the Boca Facility (the ''Biotest Transaction''). Immediately following the acquisition, the Biotest Assets were contributed into ADMA BioManufacturing.

In connection 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, consisting 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 that offering.

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''), which shares are currently held by the Biotest Divestiture Trust (the ''Biotest Trust'') and registered for resale under an effective Registration Statement on Form S-3, and 8,591,160 shares in the form of our then-authorized non-voting common stock, $0.0001 par value per share (the ''NV Biotest Shares''). The NV Biotest Shares were convertible into our Common Stock upon the occurrence of certain specified events. As part of the purchase price to acquire the Biotest Assets, we also transferred ownership of two of our plasma collection facilities to BPC on January 1, 2019.

On May 14, 2018, we entered into a Share Transfer, Amendment and Release Agreement with BPC, Biotest AG, Biotest U.S. Corporation and 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''). In connection with the U.S. Government-required divestiture of all of BPC's U.S. assets as a result of 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'').

Prior to the closing of the Biotest Transaction, the BTBU was our third-party manufacturer for ASCENIV. In the third quarter of 2015, the FDA accepted for review our BLA for ASCENIV (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 ASCENIV submitted in our RI-002 BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of ASCENIV. The FDA identified in the RI-002 CRL, among other things, certain outstanding inspection issues and deficiencies related to chemistry, manufacturing and control (''CMC'') matters 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 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. During the second quarter of 2019, we received FDA approval of the respective submissions for both ASCENIV and BIVIGAM, and the transfer of the BIVIGAM and Nabi-HB licenses from BPC to us was completed on July 2, 2019.

Our Strategy

Our goal is to be a leader in manufacturing, marketing and developing 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:

- **Continue to expand the commercial production of our IG products, as well as the commercial presence, penetration and sales of BIVIGAM and ASCENIV for the treatment of patients with PI**. We plan to enhance our recruiting initiatives and expand our existing specialty commercial sales force to market BIVIGAM and ASCENIV to home healthcare infusion facilities, 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 and third-party reimbursement. We may also use a network of national distributors to fulfill orders for BIVIGAM and ASCENIV.
- **Increase marketing efforts around Nabi-HB.** We plan to increase our marketing efforts and attend relevant medical conferences during 2020, raising awareness of the risks associated with Hepatitis B and the benefits and efficacy of Nabi-HB in its indicated populations.
- **Expand ASCENIV's FDA-approved uses**. Having received approval by the FDA for ASCENIV as a treatment for PIDD, we plan to evaluate the clinical and regulatory paths to grow the ASCENIV franchise through expanded FDA-approved uses. We believe that there may be patient populations beyond PIDD that would derive clinical benefit from ASCENIV, 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 ASCENIV for the treatment of RSV.
- **Increase the Boca Facility's manufacturing capacity, operating efficiency and gross margins.** During 2020, we plan to execute on our capacity optimization plan to increase the Boca Facility's manufacturing capacity, operating efficiency and gross margins. We also plan to strengthen our supply chain capabilities to potentially unlock efficiencies, improve production yields and provide more control and visibility for timing of commercial product releases.
- **Expand and develop our pipeline with additional specialty plasma and/or hyperimmune immunoglobulin products**. 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.
- **Develop and expand ADMA Bio Centers**. Over the next three to five years, we plan on expanding our plasma collection network through opening an additional five to 10 plasma collection facilities throughout the U.S. to potentially bolster our long-term raw material supply and prepare for production ramp-up and growth to capitalize on the global growing IVIG and source plasma markets, including obtaining FDA licenses for each new plasma collection center and regulatory approval in additional jurisdictions.
- **Secure new supply contracts for potential contract manufacturing organization ("CMO") opportunities.** We are exploring new potential CMO and business development opportunities with our multi-faceted revenue generation platform, while continuing to fulfill our newly secured, long-term CMO supply agreement to produce and sell plasma-derived intermediate fractions.

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. Industry reports indicate the U.S. market for IG in 2018 was $6.8 billion and is expected to grow to $13.9 billion by 2025 based upon a compounded annual growth rate of 10.9%.

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.

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 known as ‘‘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 700 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 2018. 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 $30 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 go through the fractionation process. 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 biologics manufacturing process is time consuming and complex. The time for collection, manufacturing and release of a batch of IG is estimated at 7 to 12 months, which is not unique to just ADMA as other fractionators report similar production timelines.

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 (‘‘CBER’’).

Immune Globulins

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

Immune globulins can be administered in three ways: intramuscularly, intravenously or subcutaneously. IVIG principally contains antibodies and, as such, provides passive immunization for individuals who are immune-deficient or who have been exposed to various infectious agents. IVIG is used therapeutically in a variety of immunological diseases/deficiencies, such as PIDD, idiopathic thrombocytopenic purpura, Guillain-Barré syndrome, Kawasaki disease, bone marrow transplant, and chronic inflammatory demyelinating polyneuropathy. We are aware that other companies are also evaluating IVIG in a clinical 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 $6.8 billion in 2018, and approximately $14 billion in 2025 based upon anticipated compounded annual growth rate of approximately 11%. 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, secondary immune deficiencies, 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 the U.S. which provides us with a portion of our blood plasma for the manufacture of our current products and product candidates. Over the next three to five years, we plan to open five to 10 plasma collection centers throughout the U.S., as well as enter into additional third-party contracts to procure normal source and high-titer plasma.

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 ASCENIV, up to a specified cumulative maximum amount.

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 ASCENIV. 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 for ASCENIV. 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 two formerly-owned ADMA Bio Centers facilities to be used in BPC's proprietary products' manufacturing (the ''Amended and Restated Plasma Supply Agreement''). 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 provide, 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.

Marketing, Sales and Market Research

We market and sell our products through our specialty sales force, distribution relationships and other customary industry methods. We 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 ASCENIV. We are in the process of hiring 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 have substantial prior direct marketing, sales and distribution experience with plasma-derived drugs, specialty immune globulins and other biological products. 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 ASCENIV.

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

For the year ended December 31, 2019, three customers represented an aggregate of 70% of our consolidated revenues, with BioCARE, Inc. (''BioCare''), Biolife Plasma Services, L.P. (''Biolife'') and Sanofi Pasteur S.A. (''Sanofi'') representing approximately 26%, 24%, and 20%, respectively, of our consolidated revenues.

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, Octapharma, Kedrion and BPL. There are four producers of plasma-derived products in the U.S. consisting of: CSL Behring, Grifols Biologicals, Takeda and ADMA Biologics. 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 healthcare systems vary from country to country, local companies may have greater knowledge of local healthcare systems, more established infrastructures and have existing regulatory approvals or a better understanding of the local regulatory process, allowing them to market their products more quickly. Moreover, plasma therapy generally faces competition from non-plasma products and other courses of treatments. For example, recombinant Factor VIII products compete with plasma-derived products in the treatment of Hemophilia A.

Intellectual Property

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

During the third quarter of 2017, U.S. Pat. App. Serial No. 14/790,872, entitled ‘‘Compositions and Methods for the Treatment of Immunodeficiency,’’ encompassing immunotherapeutic methods of using immune globulin compositions proprietary to 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.

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.

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 ASCENIV, *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 our 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 good manufacturing practices (''cGMP'') to be used in the clinical trials and providing manufacturing information need in regulatory filings;
- submission of a BLA to the FDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product candidate is produced, and potentially other involved facilities as well, to assess compliance with cGMP regulations and other applicable regulations; and
- the FDA review and approval of a BLA prior to any commercial marketing, sale or shipment of the product.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

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 60 days of an end-of-phase 2 meeting or as may be agreed between the sponsor and the FDA. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers. The FDA and the sponsor must reach agreement on the PSP.

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

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, 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 Prescription Drug User Fee Act (''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 was the case with ASCENIV, 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.

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.

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 existing 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 existing ADMA Bio Centers 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.

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 healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the Patient Protection and Affordable Care Act (''ACA'') and the companion Healthcare and Education Reconciliation Act (which together are referred to as 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 healthcare 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, 2019, we had a total of 314 employees, comprised of 313 full-time employees and one part-time employee. 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 as part of the build-out of our 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 plasma collection center, once approved, will have a license with the FDA and may obtain additional certifications from other regulatory agencies.

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 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 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 our plasma-derived immune globulins which include: Nabi-HB, BIVIGAM, ASCENIV, intermediate fractions and the contract manufacturing of plasma-derived products for a third-party. On May 9, 2019 we received approval from the FDA for BIVIGAM, and the commercial re-launch of this product commenced in August 2019. On April 1, 2019, the FDA approved ASCENIV, formerly referred to as RI-002, and the first commercial sales of this product took place in October 2019. In October 2019, we generated initial sales of our plasma-derived intermediate fractions.

Our long-term liquidity depends upon our ability to grow our commercial programs, expand our commercial operations at the Boca Facility, improve our supply-chain capabilities, improve production yields, provide more control and visibility for timing of commercial product releases, raise additional capital, fund and successfully implement our research and development and commercial programs, establish and build out a commercial sales force, medical affairs organization and commercial infrastructure and meet our ongoing obligations.

We currently anticipate, based upon our projected revenue and expenditures, as well as the additional funds we are able to draw-down under the Credit Agreement and Guaranty (the ''Perceptive Credit Agreement'') between us and Perceptive Credit Holdings II, LP (''Perceptive''), that our current cash, cash equivalents and accounts receivable, will be sufficient to fund our operations into the second quarter of 2021. This time frame may change based upon how quickly we are able to execute on our commercialization efforts and operational initiatives. However, if the assumptions underlying our estimated revenues and expenses prove to be incorrect, we may have to raise additional capital sooner than we currently expect. We expect that we will not be able to generate a sufficient amount of product revenue to achieve profitability before 2021 and, as a result, we expect that we will need 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 commercialization efforts as well as product development activities. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, resulting in significant dilution of stockholders' interests and, in such event, the value and potential future market price of our common stock may decline. In addition, if we raise additional funds through license arrangements or through the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or assets or grant licenses on terms that are not favorable to us.

We 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 into fiscal 2021, and we may never achieve or maintain profitability. For the years ended December 31, 2019 and 2018, we incurred net losses of $48.3 million and $65.7 million, respectively. From our inception in 2004 through December 31, 2019, we have incurred an accumulated deficit of $264.7 million. We expect that we will not be able to generate a sufficient amount of product revenue to achieve profitability before 2021 and, as a result, we expect that we will need to finance our operations through additional equity or debt financings or corporate collaboration and licensing agreements. 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:

- expand commercialization and marketing efforts;
- implement additional internal systems, controls and infrastructure;
- hire additional personnel;
- expand and build out our plasma center network; and
- expand production capacity at the Boca Facility.

As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our securities.

We contract with third parties for the filling, packaging, testing and labeling of the drug substance we manufacture. This reliance on third parties carries the risk that the services upon which we rely may not be performed in a timely manner or according to our specifications, which could delay the availability of our finished drug product and could adversely affect our commercialization efforts and our revenues.

Third-party fill/finish providers may not perform as agreed or in accordance with FDA requirements. Any significant problem that our fill/finish providers experience could delay or interrupt our supply of finished drug product until the service provider cures the problem or until we locate, negotiate for, validate and receive FDA approval for an alternative provider (when necessary), if one is available. Failure to obtain the needed fill/finish services could have a material and adverse effect on our business, financial condition, results from operations and prospects.

Although in the future we plan to build our own fill/finish suite within the Boca Facility, we also intend to continue to utilize third parties to supplement our fill/finish process for final drug substance and we may, in any event, never be successful in developing our own fill/finish suite. Our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify contract fill/finishers on acceptable terms or at all because the number of potential service providers is limited and the FDA must inspect and qualify any contract manufacturers for current cGMP compliance as part of our marketing application;
- a new fill/finisher would have to be educated in, or develop substantially equivalent processes for, the production of our products and product candidates;
- our contracted fill/finishers' resources and level of expertise with plasma-derived biologics may be limited, and therefore they may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to deliver our finished drug product;
- our third-party fill/finishers might be unable to timely provide finished drug product in sufficient quantity to meet our commercial needs;
- contract manufacturers may not be able to execute our inspection procedures and required tests appropriately;
- contract manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations, and we do not have control over third-party providers' compliance with these regulations;

- our third-party fill-finishers could breach or terminate their agreements with us; and
- our contract fill/finishers may have unacceptable or inconsistent drug product quality success rates and yields, and we have no direct control over our contract fill/finishers' ability to maintain adequate quality control, quality assurance and qualified personnel.

Each of these risks could delay or prevent the completion of our finished drug product and the release of finished drug product by the FDA, which could result in higher costs or adversely impact the commercialization of our products. In addition, our contract fill/finishers and our other third-party vendors may source their materials and supplies globally, and are therefore subject to supply disruptions in the event of fire, weather related events such as hurricanes, wind and rain, other acts of God or force majeure events or global health occurrences and emergencies.

The estimates of market opportunity and forecasts of market and revenue growth included in this Form 10-K may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business could fail to grow at similar rates, if at all.

Market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. In particular, the size and growth of the overall U.S. IVIG and source plasma markets are subject to significant variables that can be difficult to measure, estimate or quantify. Our business depends on, among other things, successful commercialization of our existing products, market acceptance of such products and ensuring that our products are safe and effective. Further, there can be no assurance that we will be able to generate the revenue that we believe our products and plasma facilities are capable of generating. As a result, we may not be able to accurately forecast or predict revenue. For these reasons, the estimates and forecasts in this Form 10-K relating to revenue generation and growth may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and forecasted growth, our business could fail to grow at similar rates, if at all.

Even though we operate under our own FDA-issued license, we may not be able to officially resolve or receive a final close-out letter with respect to the Warning Letter issued to Biotest's License #1792 for the Boca Facility.

Prior to the closing of the Biotest Transaction, BTBU was our third-party manufacturer for ASCENIV, formerly referred to as RI-002. In response to our Biologics License Application (''BLA'') submission for RI-002 in 2015 (the ''RI-002 BLA''), in July 2016 the FDA issued a Complete Response Letter (''CRL'') for RI-002 (the ''RI-002 CRL''). The RI-002 CRL did not specify or request the need for any addition clinical trials or data; however, the RI-002 CRL reaffirmed the issues set forth in a November 2014 warning letter (the ''Warning Letter'') that the FDA had issued to BPC related to certain compliance and other inspection issues and deficiencies identified at the Boca Facility. The FDA identified in the RI-002 CRL, among other things, certain outstanding inspection issues and deficiencies related to chemistry, manufacturing and control (''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 could not grant final approval of our RI-002 BLA until, among other things, these deficiencies were resolved. In response to the Warning Letter, in December 2016, BTBU temporarily suspended the production of BIVIGAM 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, 2018, and until August 2019.

Following the completion of the Biotest Transaction, we gained control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility, and our highest priority was to remediate the outstanding compliance issues at the Boca Facility as indicated in the Warning Letter. We worked with a leading consulting firm with extensive experience in remediating compliance and inspection issues related to quality management systems that managed 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 Official Action Indicated (''OAI'') to Voluntary Action Indicated (''VAI''), and this inspection of the Boca Facility has been successfully closed out as indicated on the FDA's website inspection database. The FDA subsequently approved ASCENIV in April 2019 and BIVIGAM in May 2019, and, on July 2, 2019, notified us that the licenses for BIVIGAM and Nabi-HB had been revoked from BPC's U.S. License No. 1792, with respect to

which the Warning Letter was issued, and transferred and issued to our U.S. License No. 2019. The commercial re-launch and first commercial sales of BIVIGAM under our ownership occurred in August 2019. Commercial sales of ASCENIV commenced in October 2019. Although we received FDA approval of our RI-002 BLA on April 1, 2019 and the FDA has transferred the BIVIGAM and Nabi-HB licenses to us, neither we nor BPC has received a ''Warning Letter close-out letter'' from the FDA. We believe that we have successfully closed out the April 2018 FDA inspection of the Boca Facility, and we believe that as result of the FDA's transfer of the BIVIGAM and Nabi-HB licenses to us, we have neither a right nor an obligation to close out the Warning Letter, which applied to BPC's U.S. License No. 1792. Consequently, we may not be able to officially close out the Warning Letter issued to Biotest under their license #1792 related to the Boca Facility.

There can be no assurance that the FDA will not in the future determine that our efforts to remediate the underlying concerns at the Boca Facility that resulted in the Warning Letter and the CRL in July 2016 have not been effective. Additionally, we are unable to control the timing of FDA inspections, responses, meeting requests, teleconference requests, requests for clarifications and similar regulatory communications, as well as whether or not the FDA will change its requirements, guidance or expectations. If the FDA determines that we have not remediated the issues identified in the Warning Letter or any other inspection issues and deficiencies, any failure of ours to address or provide requested documentation of corrections for these issues could disrupt our business operations and the timing of our commercialization efforts and could have a material adverse effect on our financial condition and operating results.

Business interruptions could adversely affect our business.

Our operations, including our headquarters located in Ramsey, NJ, the Boca Facility and our plasma collection facilities, 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, global health occurrences and emergencies, product liability claims and events beyond our control. While we maintain several insurance policies with reputable carriers that provide partial coverage for a variety of these risks, including replacing or rebuilding a part of our facilities, these policies are subject to the insurance carriers' final determination of compensation to us and we may not have adequate coverage if we need to rebuild or replace our inventory, infrastructure, business income or our entire facility. 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.

If we are unsuccessful in obtaining regulatory approval for any of our product candidates or if 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.

Product candidates require 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. The conduct of preclinical studies and clinical trials is subject to numerous risks and results of the studies and trials are highly uncertain. 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. Furthermore, delays or setbacks can occur at any stage of the process, and we could encounter problems that cause us to abandon our product development programs and related INDs or biologics license applications, or to 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.

We cannot be certain as to what type and how many clinical trials the FDA, or equivalent foreign regulatory agencies, will require us to conduct before we may successfully gain approval to market any of our product candidates that still require FDA approval. Prior to approving a new drug or biologic, the FDA generally requires that the effectiveness of the product candidate (which is not typically fully investigated until Phase 3) be demonstrated in two adequate and well-controlled clinical trials. However, if the FDA or an equivalent foreign regulatory authority determines that our Phase 3 clinical trial results do not demonstrate a statistically significant, clinically meaningful benefit with an acceptable safety profile, or if a relevant regulator requires us to conduct additional Phase 3 clinical trials in order to gain approval, we will incur significant additional development costs and commercialization of these products would be prevented or delayed and our business would be adversely affected.

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 our product candidates, we may be required to terminate development of such product candidates. If we fail to obtain regulatory approval to market and sell our product candidates, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished and the capital necessary to fund our operations will increase.

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.

We cannot be certain that the clinical trial results of our product candidates will support our product candidates' 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 our clinical trials and product testing for our product candidates may be performed outside of the U.S., and therefore, may not be performed in accordance with standards normally required by the FDA and other regulatory agencies.

If we do not obtain and maintain the necessary U.S. or international regulatory approvals to commercialize a product candidate, we will not be able to sell that product candidate, which would make it difficult for us to recover the costs of researching and developing such product candidate.

If we are not be able to generate revenue from our products and product candidates, 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 any product candidate we may acquire or develop in the future. In order to obtain FDA approval of any 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 a 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, or may require additional CMC or other data and information, and the development and provision of this data and information may be time-consuming and expensive. There are numerous FDA personnel assigned to review different aspects of a BLA, and uncertainties can be presented by

their ability to exercise judgment and discretion during the review process. 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 product candidate's 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 any 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.

Although we have received approval from the FDA to market ASCENIV as a treatment for PIDD, our ability to market or seek approval for ASCENIV for alternative indications could be limited, unless additional clinical trials are conducted successfully and the FDA approves a BLA or other required submission for review.

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. Although we have received approval from the FDA to market ASCENIV as a treatment for PIDD, we cannot be sure whether we will be able to obtain FDA approval for any desired future indications for ASCENIV.

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. 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.

With the approval of ASCENIV, there can be no assurance that we will be successful in developing and expanding commercial operations or balancing our research and development activities with our commercialization activities.

With the approval of ASCENIV, we plan to commercialize this product, while also continuing our research and development activities. There can be no assurance that we will be able to successfully manage the balance of our research and development operations with our planned commercialization activities. Potential investors and stockholders should be aware of the problems, delays, expenses and difficulties frequently encountered by companies balancing development of product candidates, which can include problems such as unanticipated issues relating to clinical trials and receipt of approvals from the FDA and foreign regulatory bodies, with

commercialization efforts, which can include problems related to managing manufacturing and supply, reimbursement, marketing challenges, development of a comprehensive compliance program, and other related and additional costs. For example, the raw material plasma we collect and procure to manufacture ASCENIV using our patented proprietary microneutralization assay is comprised of plasma collected from donors which contains high titer antibodies to RSV. This high titer plasma which meets our internal specifications for the manufacture of ASCENIV that we are able to identify with our patented testing assay amounts to less than 10% of the total donor collection samples we test. Our product candidates will require significant additional research and clinical trials, and we will need to overcome significant regulatory burdens prior to commercialization in the U.S. and other countries. In addition, we may be required to spend significant funds on building out our commercial operations. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any of our product candidates, generate any significant revenues or ever achieve and maintain a substantial level of sales of our products.

We depend on third-party researchers, developers and vendors to develop, manufacture and test products and product candidates, 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, contract fill/finishers 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.

Our products, and any additional products for which we may obtain marketing approval in the future, could be subject to post-marketing restrictions or withdrawal from the market and we could be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products following approval.

Our products, and any additional products for which we may obtain marketing approval in the future, could be subject to post-marketing restrictions, new FDA guidance, or other regulatory actions, such as withdrawal from the market. Such products, as well as the manufacturing processes, post-marketing studies and measures, labeling, advertising and promotional activities for such products, among other things, are subject to ongoing regulatory compliance requirements, and oversight, review, and inspection by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, adherence with labeling and promotional requirements and restrictions, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding safeguarding the drug supply chain as well as the distribution of samples to physicians and recordkeeping. For example, the FDA's approval of our PAS to allow for the commercial relaunch of BIVIGAM requires us to conduct specified post-marketing studies related to our manufacturing controls and processes, and submit specified post-marketing reports to the FDA. If, during the post marketing period (after marketing approval) previously unknown adverse events or other potential concerns regarding our products or their manufacturing processes emerge, or we are observed in any way to fail to comply with the numerous regulatory requirements to which we are subject, those circumstances may yield various results, including:

- restrictions on such products or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct further post-marketing studies or clinical trials;
- warning letters or untitled letters;

- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payers;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Historically, a few customers have accounted for a significant amount of our total revenue and accounts receivable and the loss of any of these customers could have a material adverse effect on our business, results of operations and financial condition.

For the year ended December 31, 2019, three customers represented an aggregate of 70% of our consolidated revenues, with BioCare, Biolife and Sanofi representing approximately 26%, 24%, and 20%, respectively, of our consolidated revenues. For the year ended December 31, 2018, BPC, McKesson Corporation (''McKesson'') and AmerisourceBergen Corporation (''AmerisourceBergen'') represented 56%, 16% and 15%, respectively, of our consolidated revenues.

At December 31, 2019, BioCare represented 77% of our consolidated accounts receivable and McKesson represented 13% of our consolidated accounts receivable. At December 31, 2018, BPC, AmerisourceBergen and Cardinal Health, Inc. (''Cardinal Health'') accounted for 59%, 23% and 12%, respectively, of our consolidated accounts receivable.

The loss of any key customers 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. 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, and we fulfilled our commitment under our supply agreement with Sanofi during the year ended December 31, 2019. Moreover, we anticipate deriving increased revenue from BioCare over the next few years. 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 BioCare, Biolife, McKesson, Cardinal Health or AmerisourceBergen could negatively affect revenue derived from such customer, which in turn would 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 failure to obtain product approval, 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 us, physicians, payers and patients may not accept and use it. Acceptance and use of our products depends 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 or 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.

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, product candidates and label expansion of existing products, 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 label expansion activities for Nabi-HB, BIVIGAM and ASCENIV. 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 commercialization of ASCENIV, 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 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, healthcare 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 healthcare 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 HHS 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 $5.0 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 went 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. 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.

We may neither be successful in integrating the Biotest Assets into our business nor realize the strategic and financial benefits currently anticipated from the Biotest Transaction.

The Biotest Transaction involves the integration of two businesses that previously have operated independently with principal offices in two distinct locations. We continue to expend 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. 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.

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.

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, which exposes us to liabilities that are not within our control and we cannot predict the extent

to which these liabilities may arise in the future. Any liabilities that may arise could have a material adverse effect on our business, financial condition, results of operations and stock price.

The Master Purchase and Sale Agreement, dated as of January 21, 2017 (the ''Master 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 Master Purchase Agreement. In connection with the Share Transfer, Amendment and Release Agreement among us, BPC, Biotest AG, Biotest US Corporation and The Biotest Divestiture Trust (the ''Biotest Trust'') (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. 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 Master 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.

In addition, while the Master 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 were 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.

The Perceptive Credit Facility is subject to acceleration in specified circumstances, which may result in Perceptive taking possession and disposing of any collateral.

On February 11, 2019 (the ''Perceptive Closing Date''), we entered into the Perceptive Credit Agreement with Perceptive Credit Holdings II, LP, as the lender and administrative agent (''Perceptive''). The Perceptive Credit Agreement, as amended, provides for a senior secured term loan facility in a principal amount of up to $85.0 million (the ''Perceptive Credit Facility''), comprised of (i) a term loan made on the Perceptive Closing Date in the principal amount of $45.0 million, as evidenced by our issuance of a promissory note in favor of Perceptive on the Perceptive Closing Date (the ''Perceptive Tranche I Loan''), (ii) a term loan in the principal amount of $27.5 million evidenced by our of a promissory note in favor of Perceptive on May 3, 2019

(the ''Perceptive Tranche II Loan''); and (iii) an additional commitment in the principal amount of up to $12.5 million (the ''Perceptive Tranche III Loan,'' and together with the Perceptive Tranche I Loan and the Perceptive Tranche II Loan, the ''Perceptive Loans'') to be drawn-down at our sole option no later than March 31, 2020. The Perceptive Loans each have a maturity date of March 1, 2022, subject to acceleration pursuant to the Perceptive Credit Agreement, including upon an Event of Default (as defined in the Perceptive Credit Agreement). The Perceptive 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 Perceptive Loans of 4% per annum, the occurrence of an Event of Default could result in, among other things, the termination of commitments under the Perceptive 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 Perceptive 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 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.

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 products 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 U.S. Patent and Trademark Office. 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 our products 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, time-consuming and no assurance can be given that we will prevail. In addition, any such litigation may divert our management's attention from our core business and reduce the resources available for our clinical development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome. There is no assurance that ASCENIV, 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 IG. 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.

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 cyberattacks, 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.

If we are unable to hire and retain a substantial number of qualified personnel, our ability to sustain and 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, quality control, 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 that 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 building 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.

The FDA had identified issues in the Warning Letter resulting from their prior inspections while the Boca Facility was under BPC's operational control. We engaged a leading consulting firm with extensive experience in remediating compliance and inspection issues related to quality management systems that managed 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. 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 to 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 and maintain 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.

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 Statute), 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 HHS 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 Statute 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 healthcare 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 Statute that applies to Medicare and Medicaid, and other healthcare fraud provisions, leading to the possibility of greatly increased qui tam suits by relators for perceived violations. Violations or allegations of violations of the foregoing restrictions could materially and adversely affect our business.

We 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 Statute 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 healthcare laws, and mitigate potential liability in the event of noncompliance, regulatory authorities such as the HHS Office of Inspector General (the ''OIG'') have recommended the adoption and implementation of a comprehensive healthcare 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. We will need to adopt healthcare compliance and ethics programs that would incorporate the OIG's recommendations and train our employees. Such a program may be expensive and may not provide assurance 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.

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 now FDA-approved 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. In June 2018, we filed a drug substance PAS with the FDA for BIVIGAM to include the ADMA improvements for BIVIGAM and to seek FDA authorization which would enable us to resume commercial scale manufacturing and re-launch 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. On May 9, 2019, we received FDA approval for 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 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.

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, testing, 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, test, 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 the timing of receiving the testing results, 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 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, or if there were a reemergence of an infectious disease, the regulatory and public health authorities could impose precautions to limit the transmission of the disease that would impair our ability to procure plasma, manufacture our products or both. Such precautionary measures could be taken before there is conclusive medical or scientific evidence that a disease poses a risk for plasma-derived products. In recent years, new testing and viral inactivation methods have been developed that more effectively detect and inactivate infectious viruses in collected plasma. There can be no assurance, however, that such new testing and inactivation methods will adequately screen for, and inactivate, infectious agents in the plasma used in the production of our products.

We could become supply-constrained and our financial performance would suffer if we cannot obtain adequate quantities of FDA-approved source plasma with proper specifications 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. Therefore, even if we are able to construct new plasma collection centers to complement our Kennesaw, GA plasma collection facility, 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 facility. This strategy is dependent upon our ability to maintain a cGMP compliant environment in our plasma facility and to expand production and attract donors to our facility. There is no assurance that the FDA will inspect and license any of our unlicensed plasma collection facilities which we may, in the future, construct, 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 facility 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 facilities, 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 facilities held by us from time to time.

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.

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.

The new biosimilar pathway established as part of 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 shows 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 has since approved a number of biosimilars. 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 HHS 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.

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 HHS, 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 U.S. 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 U.S. 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.

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, 2019 and 2018, we had negative cash flows from operations of approximately $76.2 million and $62.7 million, respectively. We expect to continue to spend substantial amounts on procurement of raw material plasma and other raw materials necessary to scale up our manufacturing operations, commercial product launches, capacity expansion at the Boca Facility, building additional plasma collection facilities, product development, quality assurance, regulatory affairs and conducting clinical trials for our product candidates and purchasing clinical trial materials, some of which may be required by the FDA. We expect that we will not be able to generate a sufficient amount of product revenue to achieve profitability before 2021 and, as a result, we expect that we will need to finance our operations through additional equity or debt financings or corporate collaboration and licensing agreements. We currently anticipate, based upon our projected revenue and expenditures, as well as the additional funds we are able to draw down under the Perceptive Credit Facility, that our current cash, cash equivalents and accounts receivable will be sufficient to fund our operations, as currently conducted, into the second quarter of 2021. In order to have sufficient cash to fund our operations thereafter, we will need to raise additional equity or debt financing before the end of the second quarter of 2021. This time frame may change based upon how quickly we are able to execute on our operational initiatives and the various financing options that may be available to us in 2021. 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 commercialization efforts or our product development activities.

We may not have cash available to us in amounts sufficient to enable us to make interest or principal payments on our indebtedness when due.

The Perceptive Credit Facility provides for term loans of up to an aggregate principal amount of $85.0 million, of which we have drawn down $72.5 million, all of which remains outstanding. We became eligible, subject to certain conditions, to draw-down the remaining $12.5 million upon the FDA approval of the PAS on May 9, 2019, provided that such draw-down must occur no later than March 31, 2020. Borrowings under the Perceptive Credit Facility bear interest at a rate per annum equal to 7.5% plus the greater of (i) one-month LIBOR and (ii) 3.5%; provided, however, that upon, and during the continuance of, an Event of Default, the interest rate will automatically increase by an additional 400 basis points. We are required to make monthly payments of interest during the term of the Perceptive Credit Facility, with all principal and unpaid interest due at maturity. The Perceptive Credit Facility has a maturity date of March 1, 2022, subject to acceleration pursuant to the Perceptive Credit Agreement, including upon an Event of Default. All of our obligations under the Perceptive Credit Facility are secured by a first-priority lien and security interest in substantially all of our and our subsidiaries' tangible and intangible assets, including intellectual property, and all of the equity interests in our subsidiaries.

In addition, we have $15.0 million in principal amount of indebtedness outstanding under an unsecured subordinated note issued by ADMA BioManufacturing to Biotest on June 6, 2017, which note bears interest at a rate of 6.0% per annum and matures on June 6, 2022. We are obligated to make semi-annual interest payments to Biotest, with all principal and unpaid interest due at maturity.

Our current cash, cash equivalents and accounts receivable will not be sufficient to repay all of our current outstanding debt obligations as they mature. If we are unable to obtain additional financing and are otherwise unable to become profitable and generate cash from operations in the amounts necessary to repay our outstanding debt obligations when due, our creditors would be able to accelerate all of the amounts due and, in the case of the Perceptive Credit Facility, seek to enforce their security interests, which could lead to our creditors taking immediate possession of and selling substantially all of our assets with no return provided to our stockholders.

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 and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents 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 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, 2019, we had federal and state NOLs of $175.1 million and $116.2 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 of 1986, as amended (the ''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 Code imposes limitations on a company's ability to use NOLs upon certain changes in such ownership. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs. The Biotest Transaction on June 6, 2017 resulted in a change in ownership of ADMA under Section 382 and, as a 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.

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

The TCJA, among other things, reduced the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limited the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limited the deduction for net operating losses generated after December 31, 2017 to 80% of current year taxable income and eliminated net operating loss carrybacks, provided immediate deductions for certain new investments instead of deductions for depreciation expense over time and modified or repealed 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 a decision by federal, state or local business regulatory authority;
- the timing of acceptance, third-party reimbursement and sales of BIVIGAM and ASCENIV;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors or third-party vendors;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

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

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

As of March 10, 2020, most of our 86,345,313 outstanding shares of Common Stock, as well as a substantial number of shares of our Common Stock underlying outstanding warrants, were available for sale in the public market, subject to certain restrictions with respect to sales of our Common Stock by our affiliates,

either pursuant to Rule 144 under the Securities Act, or under effective registration statements. Sales of a substantial number of shares of our Common Stock, or the perception that such sales may occur, could cause the market price of our Common Stock to decline or adversely affect demand for our Common Stock.

Our affiliates control a substantial amount of our shares of Common Stock. Provisions in our Second 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 February 29, 2020, Perceptive, our directors and executive officers and their affiliates beneficially owned approximately 27% of the outstanding shares of our Common Stock. Additionally, on November 14, 2018, the standstill provisions contained in that certain Stockholders Agreement, dated as of June 6, 2017, by and between us and BPC, as amended by the Biotest Transfer 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. This 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.

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 of Directors (the ''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. For example, the Perceptive Credit Agreement prohibits 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 Global 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 the Nasdaq Global Market under the symbol ''ADMA.'' If we fail to adhere to Nasdaq's strict listing criteria, including with respect to stock price, our market capitalization and

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

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

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

We will continue to incur increased costs now that we are no longer an "emerging growth company."

Effective January 1, 2019, we ceased to be an ''emerging growth company'' as defined by the Jumpstart Our Business Startups Act (the ''JOBS Act''). The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for qualifying public companies. As an ''emerging growth company,'' we took advantage of certain benefits afforded to ''emerging growth companies'' under Section 7(a)(2)(B) of the Securities Act, which included delaying the adoption of new or revised accounting standards applicable to public companies until such standards would otherwise apply to private companies. As an emerging growth company, we were also exempt from the requirement to have our independent registered public accounting firm provide an attestation report on our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act.

Consequently, we have, and will continue to, incur increased costs related to our compliance with Section 404 of the Sarbanes-Oxley Act. For example, in 2018, our Audit Committee retained the services of BDO, a Sarbanes-Oxley advisor, to assist with our internal controls over financial reporting and information technology relating to Section 404. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our Common Stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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

Our Certificate of Incorporation authorizes the issuance of up to 10,000,000 shares of ''blank check'' preferred stock, with such designation rights and preferences as may be determined from time to time by the Board. Currently, our Certificate of Incorporation authorizes the issuance of up to 150,000,000 shares of Common Stock. As of December 31, 2019, there were 82,913,134 shares remaining available for issuance, after giving effect to 7,768,511 shares of our Common Stock that were subject to outstanding stock options, warrants or other convertible securities as of December 31, 2019 that may be issued by us without stockholder approval.

Item 1B. Unresolved Staff Comments

Not Applicable.

Item 2. Properties

Our headquarters are located in approximately 4,200 square feet of space at 465 State Route 17, Ramsey, NJ. We currently operate under a shared services agreement with Areth, LLC (''Areth'') for the office, warehouse space and certain related services. This agreement expires on September 30, 2020 and provides for automatic one-year renewals unless ADMA gives written notice of termination to Areth 60 days prior to the end of the term. Areth is a company controlled by Dr. Jerrold B. Grossman, our Vice Chairman, and Adam S. Grossman, our President and Chief Executive Officer, and we pay Areth monthly fees for the use of such office space and for other information technology, general warehousing and administrative services. Rent under the shared services agreement is $10,000 per month.

ADMA Bio Centers' plasma collection facility is located in Kennesaw, GA. This facility has approximately 12,000 square feet of space, and total rent for this facility is currently approximately $23,000 per month. The Kennesaw, GA lease expires April 1, 2026. ADMA Bio Centers also leases approximately 2,500 square feet of office space in Roswell, GA. Monthly rent for this space is approximately $3,000, and the lease expires November 30, 2023.

As part of the Biotest Transaction, we acquired the Boca Facility, which consists of two buildings aggregating more than 120,000 square feet residing on approximately 14.6 acres of land in Boca Raton, FL. All of our plasma fractionation and drug product manufacturing are conducted at the Boca Facility, which also contains administrative office space for our ADMA BioManufacturing subsidiary and for our centralized corporate functions.

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

Item 3. Legal Proceedings

We are and may become subject to certain legal proceedings and claims arising in connection with the normal course of our business. Neither the Company nor any of its subsidiaries are a party to any material pending legal proceedings, other than ordinary routine litigation incidental to our business.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our Common Stock had been listed on the Nasdaq Capital Market (''Nasdaq'') under the symbol ''ADMA'' since November 10, 2014. As of October 22, 2019, our Common Stock has been listed on the Nasdaq Global Market.

Holders

As of December 31, 2019, there were nine record holders of our Common Stock, based upon information received from our transfer agent. However, this number does not include beneficial owners whose shares were held of record by nominees or broker dealers. As of February 1, 2020, we estimate that there are more than 6,000 beneficial owners of our Common Stock.

Dividend Policy

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

Stock Performance Graph

Not applicable.

Sale of Unregistered Securities

During the year ended December 31, 2019, we had no sales of unregistered securities that have not been previously disclosed in a Current Report on Form 8-K or Quarterly Reports on Form 10-Q.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our securities during the three months ended December 31, 2019.

Item 6. Selected Financial Data

Not applicable.

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

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

OVERVIEW

Our Business

ADMA Biologics, Inc. (the "Company," "ADMA," "we," "us" or "our") is an end-to-end commercial biopharmaceutical and specialty immunoglobulin company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and others at risk for 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 three products with U.S. Food and Drug Administration (the "FDA") approval, all of which are currently marketed and commercially available: (i) BIVIGAM (Immune Globulin Intravenous, Human), an IVIG product indicated for the treatment of PI, also known as PIDD, and for which we received FDA approval on May 9, 2019 for the commercial re-launch of the product and commenced the commercial re-launch in August 2019; (ii) ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), previously referred to as RI-002, an IVIG product indicated for the treatment of PI, for which we received FDA approval on April 1, 2019 and commenced first commercial sales in October 2019; and (iii) Nabi-HB (Hepatitis B Immune Globulin, Human), which is indicated for the treatment of acute exposure to blood containing HBsAg and other listed exposures to Hepatitis B. We seek to develop a pipeline of plasma-derived therapeutics, including a product based on our most recently approved patent application under U.S. Patent No. 10,259,865 related to methods of treatment and prevention of S. pneumonia infection for an immunoglobulin manufactured to contain standardized antibodies to numerous serotypes of S. pneumonia. 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 currently operate one FDA-approved source plasma collection facility in the U.S., which provides us with a portion of our blood plasma for the manufacture of our products and product candidates. We intend to open five to 10 additional plasma collection centers in the U.S. during the next three to five 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. and in other locations outside the U.S. where we are approved under supply agreements or in the open "spot" market.

We also sell plasma-derived intermediate fractions to certain customers, which are generated as part of our FDA-approved manufacturing process for IVIG products. In January 2020, we announced our entry into a five-year manufacturing and supply agreement to produce and sell these intermediate by-products, which are used as the starting raw material to produce other plasma-derived biologics. In addition, from time to time we provide contract manufacturing services for certain historical clients.

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 included two FDA-licensed products, Nabi-HB and BIVIGAM, and an FDA-licensed plasma fractionation facility located in Boca Raton, FL (the "Boca Facility") (the "Biotest Transaction").

Our Products

BIVIGAM

BIVIGAM is a plasma-derived IVIG that 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 human Immunoglobulin G antibodies indicated for the treatment of PI, a group of genetic disorders. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These PIs are a group of genetic disorders. Based on recent estimates, these disorders are no longer considered to be very rare, with as many as one in every 1,200 people in the United States having some form of PI.BPC had originally received FDA approval for BIVIGAM on December 19, 2012, prior to our acquisition of BTBU, and product sales had commenced in the first quarter of 2013. On May 9, 2019, the FDA approved the Prior Approval Supplement (the ‘‘PAS’’) for the use of our IVIG manufacturing process, thereby enabling us to re-launch and commercialize this product in the United States. We resumed production of BIVIGAM during the fourth quarter of 2017 after the closing of the Biotest Transaction and commercial production is ongoing, using our FDA-approved IVIG manufacturing process under U.S. Department of Health and Human Services (‘‘HHS’’) License No. 2019. The commercial re-launch and first commercial sales commenced in August of 2019.

ASCENIV

ASCENIV is a plasma-derived IVIG that contains naturally occurring polyclonal antibodies, which are proteins that are used by the body’s immune system to neutralize microbes, such as bacteria and viruses and prevent against infection and disease. We manufacture ASCENIV under a HHS License No. 2019 using a process known as fractionation. As part of our proprietary manufacturing process for ASCENIV, we leverage our unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and plasma from donors tested to have high levels of neutralizing titers to RSV using our proprietary microneutralization assay. We are able to identify the high titer plasma that meets our internal specifications for ASCENIV with our patented testing assay. This type of high titer plasma is typically found in less than 10% of the total donor collection samples we test.

ASCENIV is approved for the treatment of PIDD, a class of inherited genetic disorders that causes a deficient or absent immune system in adults and adolescents (12 to 17 years of age). Our pivotal Phase 3 clinical trial in 59 PIDD patients met the primary endpoint of no Serious Bacterial Infections reported during 12 months of treatment. Secondary efficacy endpoints further demonstrated the benefits of ASCENIV in the low incidence of infection, therapeutic antibiotic use, days missed from work/school/daycare and unscheduled medical visits and hospitalizations. We believe this clinical data together with the FDA approval for the treatment of PIDD better positions ADMA to further evaluate ASCENIV in immune-compromised patients infected with or at-risk for RSV infection. We plan to work with the FDA and the immunology and infectious disease community to design a clinical trial to evaluate the use of ASCENIV in this patient population in the near future. Commercial sales of ASCENIV commenced in October of 2019.

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 of infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection in specific, listed settings. 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. In early 2018, we received authorization from the FDA for the release of our first commercial batch of Nabi-HB for commercial distribution in the U.S. and continue to manufacture under HHS License No. 2019.

RESULTS OF OPERATIONS

Critical Accounting Policies and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our consolidated financial statements, which have been prepared in accordance with Accounting Principles Generally Accepted in the United States of America (''U.S. GAAP''). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate these estimates and assumptions, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates. Significant estimates include the realizable value of accounts receivable, valuation of inventory, assumptions used in the fair value of awards granted under our equity incentive plans and warrants issued in connection with the issuance of notes payable and the valuation allowance for our deferred tax assets.

Some of the estimates and assumptions we have to make under U.S. GAAP require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summary of accounting policies and their application are considered to be critical to understanding our business operations, financial condition and results of operations. For a detailed discussion on the application of these and our other accounting policies, see Note 2 to the Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Revenue Recognition

Revenues for the years ended December 31, 2019 and 2018 are comprised of (i) revenues from the sale of our three FDA-approved immunoglobulin products, (ii) product revenues from the sale of human plasma collected from our Plasma Collection Centers business segment, (iii) product revenues from the sale of intermediate fractions, (iv) contract manufacturing revenue from a contract assumed from BPC in the Biotest Transaction; and (v) license revenues attributable to the out-licensing of ASCENIV in December 2012 to Biotest to market and sell this product in Europe and selected countries in North Africa and the Middle East. Biotest has provided us with certain services and financial payments in accordance with the related Biotest license agreement and is obligated to pay us certain amounts in the future if certain milestones are achieved. Deferred revenue is recognized over the term of the Biotest license. Deferred revenue is amortized into income for a period of approximately 22 years, the term of the Biotest license agreement.

Product revenue is recognized when the customer is deemed to have control over the product. Control is determined based on when the product is shipped or delivered and title passes to the customer. Revenue is recorded in an amount that reflects the consideration we expect to receive in exchange. Revenue from the sale of immunoglobulin products is generally recognized when the product reaches the customer's destination, and is recorded net of distributor fees, estimated rebates, price protection arrangements and customer incentives, including prompt pay discounts, wholesaler chargebacks and other wholesaler fees. These estimates are based on historical experience and certain other assumptions, and we believe that such estimates are reasonable. For revenues associated with contract manufacturing and sales of our intermediates, control transfers to the customer and the performance obligation is satisfied when the customer takes possession of the product from the Boca Facility or a third-party warehouse that is utilized by the Company.

Product revenues from the sale of human plasma collected at our plasma collection centers are recognized at the time control of the product has been transferred to the customer, which generally occurs at the time of shipment. Product revenues are recognized at the time of delivery if we retain control of the product during shipment. Payments received from customers where the foregoing revenue recognition criteria have not been satisfied are recorded as deferred revenue, which is reflected as a liability in our consolidated balance sheets.

Accounts Receivable

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

Cost of Product Revenue

Cost of product revenue includes expenses related to process development as well as scientific and technical operations when these operations are attributable to marketed products. When the activities of these operations are attributable to new products in development, the expenses are classified as research and development expenses. Costs of production for ASCENIV and BIVIGAM prior to their FDA approval dates of April 1, 2019 and May 9, 2019, respectively, were not capitalized into inventory but were instead expensed as incurred. In addition, expenses associated with remediating the issues at the Boca Facility that were identified by the FDA prior to the closing of the Biotest Transaction of approximately $0.2 million and $1.5 million for the years ended December 31, 2019 and 2018, respectively, were expensed as incurred and are reflected in cost of product revenue in the accompanying consolidated statements of operations.

Stock-Based Compensation

All equity-based payments, including grants of stock options, are recognized at their estimated fair value at the grant date, and compensation expense is recognized on a straight-line basis over the grantee's requisite vesting period. For the purpose of valuing stock options granted to our employees, directors and officers, we use the Black-Scholes option pricing model. We granted options to purchase an aggregate of 1,508,000 and 1,167,044 shares of Common Stock during the years ended December 31, 2019 and 2018, respectively. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of the grant with a term consistent with the expected term of our awards. The expected term of the options granted is in accordance with SEC Staff Accounting Bulletins 107 and 110, and is based on the average between vesting terms and contractual terms. The expected dividend yield reflects our current and expected future policy for dividends on our Common Stock. The expected stock price volatility for our stock options was calculated by examining the historical volatility of our Common Stock since our Common Stock became publicly traded in the fourth quarter of 2013. We will continue to analyze the expected stock price volatility and expected term assumptions and will adjust our Black-Scholes option pricing assumptions as appropriate. In accordance with Accounting Standards Update (''ASU'') No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, we have elected not to establish a forfeiture rate, as stock-based compensation expense related to forfeitures of unvested stock options is fully reversed at the time of forfeiture.

Research and Development Expenses

Our research and development (''R&D'') costs consist of clinical research organization costs, costs related to clinical trials, post-marketing commitment studies for BIVIGAM, wages, benefits and stock-based compensation for employees directly related to research and development activities and, prior to April 1, 2019, assay development and testing, storage and transportation costs for high-titer plasma used in the manufacture of ASCENIV. All research and development costs are expensed as incurred.

Impairment of Long-Lived Assets

We assess the recoverability of our long-lived assets, which include property and equipment and definite-lived intangible assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's carrying value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the years ended December 31, 2019 and 2018, we determined that there was no impairment of our long-lived assets.

Goodwill is not amortized, but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. We have the option to perform a qualitative assessment of goodwill to determine whether it is more likely than not that the fair value of the reporting unit associated with the goodwill is less than its carrying amount, including goodwill and other intangible assets. If we conclude that this is the case, then we must perform a goodwill impairment test by comparing the fair value of the reporting unit to its carrying value. An impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value, with the impairment loss recognized not to exceed the total amount of goodwill allocated to that reporting unit. We did not recognize any impairment charges related to goodwill for the years ended December 31, 2019 and 2018.

Recent Accounting Pronouncements

In July 2017, the Financial Accounting Standards Board (the ''FASB'') issued Accounting Standards Update (''ASU'') No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815)*'' (''ASU 2017-11''). ASU 2017-11 changed the classification analysis of certain equity-linked financial instruments (or embedded features within such instruments) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (''EPS'') in accordance with ASC 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. In addition, convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features in ASC 470-20, ''*Debt—Debt with Conversion and Other Options.*'' ASU 2017-11 became effective for us on January 1, 2019, and this update did not have a significant impact on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842) (''ASU 2016-02''), which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance became effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. We adopted ASU 2016-02 on January 1, 2019 using the option to recognize the cumulative-effect adjustment, if any, as of the date of application, which was also January 1, 2019. As a result, there was no restatement of comparative periods. We recognized right-to-use assets of approximately $1.4 million and corresponding lease liabilities of approximately $1.6 million at the date of adoption. We also elected the ''package of practical expedients,'' which permits us to not reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs. In addition, we elected the short-term lease recognition exemption for all or embedded leases that qualify.

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

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

We adopted the new revenue recognition standard and related updates effective January 1, 2018, using the modified retrospective method of adoption. Adoption of the new revenue recognition guidance did not have a material impact on our consolidated financial statements.

Year Ended December 31, 2019 Compared to December 31, 2018

The following table presents a summary of the changes in our results of operations for the year ended December 31, 2019 as compared to the year ended December 31, 2018:

	Year Ended December 31,		
	2019	2018	Increase (Decrease)
Revenues	$ 29,349,083	$ 16,985,290	$12,363,793
Cost of product revenue (exclusive of amortization expense shown below)	39,504,238	42,194,635	(2,690,397)
Gross loss	(10,155,155)	(25,209,345)	15,054,190
Research and development expenses	2,343,848	3,926,120	(1,582,272)
Plasma center operating expenses	2,169,629	7,805,619	(5,635,990)
Amortization of intangibles	844,938	844,938	—
Selling, general and administrative expenses	25,910,757	22,502,922	3,407,835
Loss from operations	(41,424,327)	(60,288,944)	18,864,617
Interest expense	(8,993,379)	(5,522,783)	(3,470,596)
Loss on extinguishment of debt	(9,962,495)	—	(9,962,495)
Gain on transfer of plasma center assets	11,527,421	—	11,527,421
Other income, net	573,463	68,282	505,181
Net loss	$(48,279,317)	$(65,743,445)	$17,464,128

Revenues

We recorded total revenues of $29.3 million for the year ended December 31, 2019, as compared to $17.0 million for the year ended December 31, 2018. The increase in total revenue of $12.4 million is primarily due to increased revenue generated by our Boca Facility manufacturing operations in 2019 totaling $15.4 million, which includes sales of our immunoglobulin products, including ASCENIV and BIVIGAM, for which we received FDA approval in 2019, and the related intermediate fractions, as well as contract manufacturing revenue, partially offset by $3.0 million decrease in plasma center revenues due to the transfer of two of our plasma collection centers to BPC on January 1, 2019 as part of the purchase price for the Biotest Transaction. Immunoglobulin production revenues derived from contract manufacturing were generally related to an agreement we assumed from BPC as part of the Biotest Transaction. This contract expired at the end of 2019.

Cost of Product Revenue

Cost of product revenue was $39.5 million for the year ended December 31, 2019, as compared to $42.2 million for the year ended December 31, 2018, a decrease of $2.7 million. The decrease is mainly attributable to the decrease in pre-approval production expenses for ASCENIV and BIVIGAM in 2019 in the amount of $5.2 million, partially offset by cost of product revenue related to contract manufacturing and the sale of intermediate byproducts in the amount of $2.7 million not present in 2018.

Research and Development Expenses

R&D expenses totaled $2.3 million for the year ended December 31, 2019, as compared to $3.9 million for the year ended December 31, 2018. As a result of the FDA approval of ASCENIV on April 1, 2019, we no longer charge the RSV assay and other testing, storage and transportation costs for high-titer plasma used in the manufacture of ASCENIV to R&D expense, but instead reflect those costs as part of the cost of the raw material plasma. We expect R&D expenses to increase in 2020 as we seek to leverage our existing patents to develop new therapies, as well as the existence of certain FDA commitments related to the approvals of ASCENIV and BIVIGAM in 2019.

Plasma Center Operating Expenses

Plasma center operating expenses were $2.2 million for the year ended December 31, 2019, as compared to $7.8 million for the year ended December 31, 2018. Plasma center operating expenses consist of certain general and administrative plasma center costs, including rent, maintenance, utilities, compensation and benefits for

center and administrative staff, advertising and promotion expenses and computer software fees related to donor collections. The decrease in plasma center operating expenses is attributable to the transfer of two of our plasma collection centers to BPC on January 1, 2019, as well as increased plasma collections at our existing plasma collection facility, which are recorded as inventory. We expect plasma operating expenses to increase in the next few years as we plan to build an additional five to 10 plasma collection centers over the next three to five years.

Selling, General and Administrative Expenses

SG&A was $25.9 million for the year ended December 31, 2019, an increase of $3.4 million as compared to the year ended December 31, 2018. The increase reflects professional services of $1.8 million in 2019 related to enhancements to our information technology and customer support infrastructure necessary to support our overall growth and commercialization plans, as well as $0.9 million of higher employee related expenses due to increased headcount, increased marketing expenses of $0.4 million resulting from new product launches and $0.3 million of increased insurance expense.

Amortization of Intangibles

Amortization expense for intangible assets acquired in the Biotest Transaction was $0.8 million for the years ended December 31, 2019 and 2018.

Loss from Operations

Our operating loss was $41.4 million for the year ended December 31, 2019, as compared to $60.3 million for the year ended December 31, 2018. The decrease was mainly due to the increase in revenues and to decreases in cost of product revenue and other operating expenses aggregating to $6.5 million.

Interest Expense

Interest expense was $9.0 million for the year ended December 31, 2019, as compared to $5.5 million for the year ended December 31, 2018. The increase reflects a higher average debt principal balance carried in 2019 as compared to 2018 due to the senior debt refinancing transaction in February 2019 and the amendment to our senior credit facility in May 2019 (see ‘‘Liquidity and Capital Resources’’), which resulted in additional debt principal of $42.5 million.

Loss on Extinguishment of Debt

In connection with the refinancing of our senior credit facility in 2019, we incurred a loss on the extinguishment debt for the retirement of our previously existing credit facility, consisting of a $6.5 million prepayment penalty, and the write-off of $3.5 million of unamortized debt discount related to the previous credit facility.

Gain on Transfer of Plasma Center Assets

As part of the purchase price for the Biotest Assets, we agreed to transfer two of our plasma collection centers to BPC effective January 1, 2019. We had estimated the combined fair value of the two facilities to be $12.6 million, and we recorded a liability in our financial statements for this amount as of the date of the Biotest Transaction. On January 1, 2019, the two plasma collection facilities were transferred to BPC and we recorded a gain on this transfer in the amount of $11.5 million, which reflects the derecognition of the obligation to transfer ownership of the two facilities net of the carrying value of the assets associated with these facilities, primarily property and equipment and inventory, in the amount of $1.1 million.

Net Loss

Net loss was $48.3 million for the year ended December 31, 2019, as compared to $65.7 million for the year ended December 31, 2018. The reduction in net loss of $17.5 million was due to the decrease in operating loss and the gain on transfer of plasma center assets, partially offset by the loss on extinguishment of debt and the increased interest expense.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2019, we had working capital of $71.8 million, including cash and cash equivalents of $26.8 million, and stockholders' equity of $26.2 million, as compared to working capital of $34.9 million, including cash and cash equivalents of $22.8 million, and stockholders' equity of $19.8 million as of December 31, 2018. We have had limited revenue from operations, incurred an accumulated deficit of $264.7 million since inception and had negative cash flows from operations of $76.2 million and $62.7 million for the years ended December 31, 2019 and 2018, respectively. We have funded our operations to date primarily from the sale of our equity and debt securities, acquisition proceeds from the Biotest Transaction and loans from our primary stockholders.

We expect to continue to spend substantial amounts on procurement of raw material plasma and other raw materials necessary to scale up our manufacturing operations, commercial product launches, capacity expansion at the Boca Facility, building additional plasma collection facilities, product development, quality assurance, regulatory affairs and conducting clinical trials for our product candidates and purchasing clinical trial materials, some of which may be required by the FDA. We expect that we will not be able to generate a sufficient amount of product revenue to achieve profitability before 2021 and, as a result, we expect that we will need to finance our operations through additional equity or debt financings or corporate collaboration and licensing arrangements. Based upon our current projected revenue and expenditures, including capital expenditures and continued implementation of our commercialization and expansion activities, we currently believe that our cash, cash equivalents, projected revenue and accounts receivable, along with the proceeds received from the February 2020 public offering of our common stock discussed below and the additional $12.5 million we are able to access under the Perceptive Credit Facility, as defined below, will be sufficient to fund our operations, as currently conducted, into the second quarter of 2021. In order to have sufficient cash to fund our operations thereafter, we will need to raise additional capital before the end of the second quarter of 2021. These estimates and timeframe may change based upon the success of our commercial manufacturing ramp-up activities, the acceptability and reimbursement of BIVIGAM and ASCENIV by physicians, patients or payers, and the various financing options that may be available to us. Other than the $12.5 million commitment currently available under the Perceptive Credit Facility through March 31, 2020 as discussed below, we currently have no firm commitments for additional financing, and there can be no assurances that we will be able to secure additional financing on terms that are acceptable to us, or at all. Furthermore, if our assumptions underlying our estimated expenses and revenues are incorrect, we may have to raise additional capital sooner than currently anticipated.

Our long-term liquidity depends upon our ability to raise additional capital, fund capacity expansion and commercial programs and generate sufficient revenues from our products, several of which have only recently achieved commercial status, to cover our operating expenses and meet our obligations on a timely basis. Failure to secure any necessary financing in a timely manner and on commercially reasonable terms could have a material adverse effect on our business plan and financial performance and we could be forced to delay or discontinue our capacity expansion, commercialization, product development or clinical trial activities, delay or discontinue the approval efforts for any of our product candidates, or potentially cease operations. In addition, we could also be forced to reduce or forgo sales and marketing efforts and forgo attractive business opportunities. Due to numerous risks and uncertainties associated with FDA approvals related to the commercialization of our products, ongoing remediation, compliance requirements and capacity expansion efforts at the Boca Facility, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures required to fund our commercialization and other development activities. Our current estimates may be subject to change as circumstances regarding our business requirements evolve.

We may decide to raise capital through public or private equity offerings or debt financings, or obtain a bank credit facility or enter into corporate collaboration and licensing arrangements. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders and, in such event, the market value of our Common Stock may decline. The incurrence of additional indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations or other financing alternatives. In addition, we are exploring additional contract manufacturing arrangements and other business development opportunities, which may provide additional liquidity to us.

In February 2020, we completed an underwritten public offering of 27,025,000 shares of our Common Stock and received net proceeds, after underwriting discounts and other expenses associated with the offering, of approximately $88.5 million. The proceeds from this offering are expected to be used (i) for the procurement

of raw materials for the manufacturing of BIVIGAM and ASCENIV; (ii) to support the ongoing commercial sales of BIVIGAM and ASCENIV; (iii) to expand the manufacturing capacity of our Boca Facility and enhance our supply chain capabilities; (iv) to expand our plasma collection facility network; (v) for research and development and business development opportunities; and (vi) for general corporate purposes and other capital expenditures.

On May 21, 2019, we issued 12,937,500 shares of our Common Stock in an underwritten public offering for gross proceeds of $51.75 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. The net proceeds of $48.4 million from the offering have been used (i) to support the commercial launch of ASCENIV, which commenced in October 2019, (ii) for the commercial re-launch of BIVIGAM, (iii) to expand the manufacturing capacity of the Boca Facility, (iv) for the procurement of raw materials for the manufacturing of ASCENIV and BIVIGAM, (v) to expand our plasma collection facility network; and (vi) for general corporate purposes and other capital expenditures.

On February 11, 2019 (the ''Perceptive Closing Date''), we and all of our subsidiaries entered into the Perceptive Credit Agreement with Perceptive. The Perceptive Credit Agreement provided for the Perceptive Credit Facility in a principal amount of up to $72.5 million, comprised of (i) the Perceptive Tranche I Loan in the principal amount of $45.0 million, and (ii) the Perceptive Tranche II Loan in the principal amount of up to $27.5 million, but no less than $10.0 million. The Perceptive Credit Facility has a maturity date of March 1, 2022 (the ''Perceptive Maturity Date''), subject to acceleration pursuant to the Perceptive Credit Agreement, including upon an Event of Default (as defined in the Perceptive Credit Agreement).

On the Perceptive Closing Date, we used $30.0 million of the Perceptive Tranche I Loan to terminate and pay in full all of the outstanding obligations under our previously existing credit agreement with Marathon Healthcare Finance Fund, L.P. (''Marathon'') (the ''Marathon Credit Facility'') that we entered into in October 2017. We also used proceeds from the Perceptive Tranche I Loan to (i) pay a deferred facility fee to Marathon of $2.8 million, (ii) pay a prepayment penalty to Marathon of $6.5 million, (iii) pay outstanding accrued interest to Marathon of $0.7 million and (iv) pay certain fees and expenses incurred in connection with the Perceptive Credit Facility of approximately $1.5 million. In addition, on the Perceptive Closing Date, Marathon released to us the $4.0 million of cash held in a debt service reserve account, per the terms of the Marathon Credit Facility.

As consideration for the Perceptive Credit Agreement, we issued to Perceptive, on the Perceptive Closing Date, a warrant to purchase 1,360,000 shares of our Common Stock (the ''Perceptive Warrant''). The Perceptive Warrant has an exercise price equal to $3.28 per share, which is equal to the trailing 10-day volume weighted average price (''VWAP'') of our Common Stock on the business day immediately prior to the Perceptive Closing Date multiplied by 1.15. We valued the Perceptive Warrant at $2.7 million as of the Perceptive Closing Date, and it has an expiration date of February 11, 2029.

On May 3, 2019, as a result of the FDA's approval of ASCENIV, we accessed the additional $27.5 million available under the Perceptive Credit Facility through the issuance of a promissory note evidencing the Perceptive Tranche II Loan. The proceeds from the Perceptive Tranche II Loan were used to support the commercial launches of ASCENIV and BIVIGAM, including the procurement of raw material inventory, and for working capital and general corporate purposes.

Also on May 3, 2019, we and Perceptive entered into an amendment to the Perceptive Credit Agreement (the ''Perceptive Amendment'') whereby Perceptive agreed to an additional commitment under the Perceptive Credit Facility in the principal amount of up to $12.5 million (the ''Perceptive Tranche III Loan'' and, together with the Initial Perceptive Loans, the ''Perceptive Loans''). The Perceptive Tranche III Loan was subject to the satisfaction of certain conditions, including, but not limited to, FDA approval of the BIVIGAM PAS, which we received on May 9, 2019, and no Material Adverse Changes (as defined in the Perceptive Credit Agreement) having occurred since December 31, 2018; provided that the Perceptive Tranche III Loan would not be made later than March 31, 2020. The Perceptive Tranche III Loan has terms that are substantially identical to those of the Initial Perceptive Loans. The Perceptive Tranche III Loan required us to pay certain proceeds of the Perceptive Tranche II Loan to Perceptive on May 3, 2019 as a facility fee. In addition, we issued a warrant (the ''Perceptive Tranche III Warrant'' and, together with the Perceptive Warrant, the ''Perceptive Warrants'') to purchase 250,000 shares of our Common Stock to Perceptive with an exercise price equal to $4.64 per share,

which represents the trailing 10-day VWAP of our Common Stock as of May 2, 2019. The Perceptive Tranche III Warrant has an expiration date of May 3, 2029. The Perceptive Warrants were issued in reliance on an exemption from registration under Section 4(2) of the Securities Act.

Borrowings under the Perceptive Credit Agreement bear interest at a rate per annum equal to 7.5% plus the greater of (i) one-month LIBOR and (ii) 3.5%; provided, however, that upon, and during the continuance of, an Event of Default, the interest rate will automatically increase by an additional 400 basis points. Under the terms of the Perceptive Credit Facility, we pay accrued interest to Perceptive on the last day of each month of approximately $0.7 million per month. The rate of interest in effect as of the Perceptive Closing Date and as of December 31, 2019 was 11.0%.

On the Perceptive Maturity Date, we will pay Perceptive the entire outstanding principal amount underlying the Perceptive Loans and any accrued and unpaid interest thereon. Prior to the Perceptive Maturity Date, there are no scheduled principal payments on the Perceptive Loans. We may prepay outstanding principal on the Perceptive Loans at any time and from time to time upon three business days' prior written notice, subject to the payment to Perceptive of, (A) any accrued but unpaid interest on the prepaid principal amount plus (B) a redemption premium amount equal to (i) 5.0% of the prepaid principal amount, if prepaid on or prior to the first anniversary of the Perceptive Closing Date, (ii) 4.0% of the prepaid principal amount, if prepaid after the first anniversary of the Perceptive Closing Date and on or prior to the second anniversary of the Perceptive Closing Date, or (iii) 3.0% of the prepaid principal amount, if prepaid after the second anniversary of the Perceptive Closing Date and on or prior to the third anniversary of the Perceptive Closing Date.

All of our obligations under the Perceptive Credit Agreement are secured by a first-priority lien and security interest in substantially all of our tangible and intangible assets, including intellectual property and all of the equity interests in our subsidiaries. The Perceptive Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings. The negative covenants restrict or limit our ability to, among other things and subject to certain exceptions contained in the Perceptive Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to our business activities; make certain Investments or Restricted Payments (each as defined in the Perceptive Credit Agreement); change our fiscal year; pay dividends; repay other certain indebtedness; engage in certain affiliate transactions; or enter into, amend or terminate any other agreements that have the impact of restricting our ability to make loan repayments under the Perceptive Credit Agreement. In addition, we must (i) at all times prior to the Maturity Date maintain a minimum cash balance of $3.0 million; and (ii) as of the last day of each fiscal quarter commencing with the fiscal quarter ending June 30, 2019, report revenues for the trailing 12-month period that exceed the amounts set forth in the Perceptive Credit Agreement, which range from $7.0 million for the fiscal quarter ending June 30, 2019 to $55.0 million for the fiscal quarter ending December 31, 2021. At December 31, 2019, we were in compliance with all of the covenants under the Perceptive Credit Facility.

On June 18, 2018, we completed an underwritten public offering of 9,623,430 shares of our Common Stock for gross proceeds of $46.0 million. We received net proceeds from this offering, after underwriters' commissions and other offering expenses, of $42.9 million. The net proceeds were used (i) for continued remediation and ongoing improvement and enhancements at the Boca Facility, (ii) to submit the PAS for, and re-launch of, BIVIGAM, (iii) to resubmit the RI-002 BLA, (iv) for expenses associated with obtaining FDA approval of our Kennesaw, GA plasma collection facility; and (v) for general corporate purposes, including capital expenditures.

Cash Flows

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

	Year Ended December 31,	
	2019	2018
Net cash used in operating activities	$(76,193,504)	$(62,678,682)
Net cash used in investing activities	(3,811,838)	(2,095,600)
Net cash provided by financing activities	80,002,625	42,921,560
Net change in cash and cash equivalents	(2,717)	(21,852,722)
Cash and cash equivalents, including restricted cash - beginning of year	26,754,852	48,607,574
Cash and cash equivalents, including restricted cash - end of year	$ 26,752,135	$ 26,754,852

Net Cash Used in Operating Activities

Cash used in operations for the year ended December 31, 2019 was $76.2 million, an increase of $13.5 million from the same period of a year ago, mainly due to increases in inventory in preparation for the initial commercial sales and the commercial launches of ASCENIV and BIVIGAM. The following table illustrates the primary components of our cash flows from operations:

	Year Ended December 31,	
	2019	2018
Net loss	$(48,279,317)	$(65,743,445)
Non-cash expenses, gains and losses	5,588,584	6,753,203
Changes in accounts receivable	(2,077,478)	2,487,713
Changes in inventories	(34,650,132)	(5,987,988)
Changes in prepaid expenses and other current assets	(773,174)	(540,509)
Changes in accounts payable and accrued expenses	4,080,553	386,504
Other	(82,540)	(34,160)
Cash used in operations	$(76,193,504)	$(62,678,682)

Net Cash Used in Investing Activities

Net cash used in investing activities for the years ended December 31, 2019 and 2018 was $3.8 million and $2.1 million, respectively, consisting of capital expenditures at the Boca Facility. Although we have no specific material commitments for capital expenditures as of December 31, 2019, we expect our total capital expenditures will be between $10.0 million and $20.0 million for fiscal 2020.

Net Cash Provided by Financing Activities

Cash provided by financing activities during the year ended December 31, 2019 was $80.0 million, which is comprised of the net proceeds received from our May 2019 equity offering in the amount of $48.4 million and the $31.6 million of net proceeds received from the refinancing of our senior credit facility and the subsequent Perceptive Tranche II Loan. Net cash provided by financing activities for the year ended December 31, 2018 of $42.9 million reflects the net proceeds received from our June 2018 equity offering.

Effect of Inflation

Inflation or changing prices did not have a significant impact on our net sales, revenues or net loss for the years ended December 31, 2019 or 2018.

Off-Balance Sheet Arrangements

None.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

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

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019. The term ''disclosure controls and procedures,'' as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Management's annual report on internal control over financial reporting (as defined in Rule 13a- 15(f) under the Exchange Act) is included with the financial statements reflected in Item 8 of this Annual Report on Form 10-K and is incorporated herein by reference.

Attestation Report of the Registered Public Accounting Firm

CohnReznick LLP, our independent registered public accounting firm, which has audited the consolidated financial statements included in this Annual Report on Form 10-K, has also issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2019. Their report is included with the financial statements contained in Item 8 of this Annual Report on Form 10-K and is incorporated herein by reference.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required to be disclosed by this Item with respect to our executive officers is incorporated into this Annual Report on Form 10-K by reference from the section entitled ''Executive Officers and Director and Officer Compensation: Executive Officers'' contained in our definitive proxy statement for our 2020 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2019.

Information required to be disclosed by this Item about our Board of Directors (the ''Board'') is incorporated into this Annual Report on Form 10-K by reference from the section entitled ''Proposal No. 1: Election of Directors'' contained in our definitive proxy statement for our 2020 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2019.

Information required to be disclosed by this Item about the Section 16(a) compliance of our directors and executive officers is incorporated into this Annual Report on Form 10-K, as applicable, by reference from the section entitled ''Delinquent Section 16(a) Reports'' contained in our definitive proxy statement for our 2020 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2019.

Information required to be disclosed by this Item about our Board, the Audit Committee of our Board, our audit committee financial expert, our Code of Ethics and Business Conduct Standards, and other corporate governance matters is incorporated into this Annual Report on Form 10-K by reference from the section entitled ''Corporate Governance'' contained in our definitive proxy statement for our 2020 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2019.

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

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

Item 11. Executive Compensation

Information required to be disclosed by this Item is incorporated into this Annual Report on Form 10-K by reference from the section entitled ''Executive Officers and Director and Officer Compensation'' contained in our definitive proxy statement for our 2020 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2019.

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

Information required to be disclosed by this Item is incorporated into this Annual Report on Form 10-K by reference from the sections entitled ''Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters'' contained in our definitive proxy statement for our 2020 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2019.

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

The information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the section entitled ''Certain Relationships and Related Transactions, and Director Independence'' contained in our definitive proxy statement for our 2020 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2019.

Item 14. Principal Accounting Fees and Services

The information required to be disclosed by this Item is incorporated into this Annual Report on Form 10-K by reference from the section entitled ‘‘Audit and Other Fees’’ contained in our definitive proxy statement for our 2020 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2019.

PART IV

Item 15. Exhibits, Financial Statement Schedules

Financial Statement Schedules

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

(1) Consolidated Financial Statements.

(2) Financial Statement Schedules.

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

(3) Exhibits.

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

Item 16. Form 10-K Summary

None.

SIGNATURES

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

ADMA Biologics, Inc.

Date: March 12, 2020

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

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

Signature	Title	Date
/s/ Adam S. Grossman Adam S. Grossman	President and Chief Executive Officer (Principal Executive Officer) and Director	March 12, 2020
/s/ Brian Lenz Brian Lenz	Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2020
/s/ Steven A. Elms Steven A. Elms	Chairman of the Board of Directors	March 12, 2020
/s/ Dr. Jerrold B. Grossman Dr. Jerrold B. Grossman	Vice Chairman of the Board of Directors	March 12, 2020
/s/ Bryant E. Fong Bryant E. Fong	Director	March 12, 2020
/s/ Dov A. Goldstein, M.D. Dov A. Goldstein, M.D.	Director	March 12, 2020
/s/ Lawrence P. Guiheen Lawrence P. Guiheen	Director	March 12, 2020
/s/ Eric I. Richman Eric I. Richman	Director	March 12, 2020

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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Management's Annual Report on Internal Control Over Financial Reporting

The Management of ADMA Biologics, Inc. (the ''Company'') is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America (''U.S. GAAP'') and includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures of our company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our company's assets that could have a material effect on the financial statements.

Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with U.S. GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of its internal control over financial reporting as of December 31, 2019. In making this assessment, management used the criteria set forth in the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2019 based on those criteria.

Our independent registered public accounting firm, which has audited the consolidated financial statements included in this Annual Report on Form 10-K, has also issued an audit report on the effectiveness of our internal control over financial reporting as of December 31, 2019. Their report appears on page F-3 of this Annual Report on Form 10-K.

/s/ Adam S. Grossman
President and Chief Executive Officer
March 12, 2020

/s/ Brian Lenz
Executive Vice President and Chief Financial Officer
March 12, 2020

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control over Financial Reporting

We have audited ADMA Biologics, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (''COSO''). In our opinion, ADMA Biologics, Inc. and subsidiaries (the ''Company'') maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (the ''PCAOB''), the consolidated balance sheets as of December 31, 2019 and 2018, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended of the Company, and the related notes, and our report, dated March 12, 2020, expressed an unqualified opinion.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ CohnReznick LLP
Roseland, New Jersey
March 12, 2020

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ADMA Biologics, Inc. and subsidiaries (the ''Company'') as of December 31, 2019 and 2018, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the ''consolidated financial statements''). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 12, 2020, expressed an unqualified opinion.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Change in Accounting Principle

As discussed in Notes 2 and 12 to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standard Codification Topic 842, *Leases*.

/s/ CohnReznick LLP

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

Roseland, New Jersey

March 12, 2020

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2019 and 2018

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,752,135	$ 22,754,852
Accounts receivable, net	3,469,919	1,392,441
Inventories	53,064,734	18,616,169
Prepaid expenses and other current assets	2,533,593	1,766,163
Total current assets	85,820,381	44,529,625
Property and equipment, net	31,741,317	30,115,730
Intangible assets, net	3,159,474	4,004,412
Goodwill	3,529,509	3,529,509
Assets to be transferred under purchase agreement	—	1,153,508
Restricted cash	—	4,000,000
Deposits and other assets	2,840,044	1,543,737
TOTAL ASSETS	$ 127,090,725	$ 88,876,521
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,174,591	$ 5,900,394
Accrued expenses and other current liabilities	4,481,395	3,551,835
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	229,073	29,983
Total current liabilities	14,027,893	9,625,046
Senior notes payable, net of discount	68,291,163	26,440,830
End of term liability, notes payable	—	2,760,000
Deferred revenue, net of current portion	2,261,532	2,404,365
Subordinated note payable, net of discount	14,908,053	14,874,184
Obligation to transfer assets under purchase agreement	—	12,621,844
Lease obligations, net of current portion	1,302,361	119,080
Other non-current liabilities	106,574	260,734
TOTAL LIABILITIES	100,897,576	69,106,083
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred Stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common Stock - voting, $0.0001 par value, 150,000,000 and 75,000,000 shares authorized, 59,318,355 and 46,353,068 shares issued and outstanding	5,932	4,635
Additional paid-in capital	290,903,772	236,203,041
Accumulated deficit	(264,716,555)	(216,437,238)
TOTAL STOCKHOLDERS' EQUITY	26,193,149	19,770,438
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 127,090,725	$ 88,876,521

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Years Ended December 31, 2019 and 2018

	Years Ended December 31,	
	2019	**2018**
REVENUES:		
Product revenue	$ 29,206,249	$ 16,842,456
License revenue	142,834	142,834
Total revenues	29,349,083	16,985,290
OPERATING EXPENSES:		
Cost of product revenue (exclusive of amortization expense shown below)	39,504,238	42,194,635
Research and development	2,343,848	3,926,120
Plasma center operating expenses	2,169,629	7,805,619
Amortization of intangible assets	844,938	844,938
Selling, general and administrative	25,910,757	22,502,922
Total operating expenses	70,773,410	77,274,234
LOSS FROM OPERATIONS	(41,424,327)	(60,288,944)
OTHER INCOME (EXPENSE):		
Interest income	800,785	195,403
Interest expense	(8,993,379)	(5,522,783)
Loss on extinguishment of debt	(9,962,495)	—
Gain on transfer of plasma center assets	11,527,421	—
Other expense	(227,322)	(127,121)
Other expense, net	(6,854,990)	(5,454,501)
NET LOSS	$(48,279,317)	$(65,743,445)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.89)	$ (1.45)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic and Diluted	54,348,136	45,188,899

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
Years Ended December 31, 2019 and 2018

	Common Stock				Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Voting		Non-Voting				
	Shares	Amount	Shares	Amount			
Balance at December 31, 2017	36,725,499	$3,673	8,591,160	$ 859	$191,022,018	$(150,693,793)	$ 40,332,757
Stock-based compensation	—	—	—	—	2,223,288	—	2,223,288
Issuance of common stock, net of offering expenses	9,623,430	962	—	—	42,943,869	—	42,944,831
Retirement of non-voting common stock	—	—	(8,591,160)	(859)	859	—	—
Stock options exercised	4,139	—	—	—	13,007	—	13,007
Net loss	—	—	—	—	—	(65,743,445)	(65,743,445)
Balance at December 31, 2018	46,353,068	4,635	—	—	236,203,041	(216,437,238)	19,770,438
Stock-based compensation	—	—	—	—	2,650,777	—	2,650,777
Warrants issued in connection with note payable	—	—	—	—	3,579,115	—	3,579,115
Issuance of common stock, net of offering expenses	12,937,500	1,294	—	—	48,395,794	—	48,397,088
Stock options exercised	27,787	3	—	—	75,045	—	75,048
Net loss	—	—	—	—	—	(48,279,317)	(48,279,317)
Balance at December 31, 2019	59,318,355	$5,932	—	$ —	$290,903,772	$(264,716,555)	$ 26,193,149

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2019 and 2018

	Years Ended December 31,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(48,279,317)	$(65,743,445)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,258,148	3,446,398
Loss on disposal of fixed assets	207,071	122,190
Stock-based compensation	2,650,777	2,223,288
Amortization of debt discount	1,180,348	1,104,161
Loss on extinguishment of debt	9,962,495	—
Gain on transfer of plasma center assets	(11,527,421)	—
Amortization of license revenue	(142,834)	(142,834)
Changes in operating assets and liabilities:		
Accounts receivable	(2,077,478)	2,487,713
Inventories	(34,650,132)	(5,987,988)
Prepaid expenses and other current assets	(773,174)	(540,509)
Deposits and other assets	107,974	(208,594)
Accounts payable	3,274,200	(20,480)
Accrued expenses	806,353	406,984
Other current and non-current liabilities	(190,514)	174,434
Net cash used in operating activities	(76,193,504)	(62,678,682)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(3,811,838)	(2,095,600)
Net cash used in investing activities	(3,811,838)	(2,095,600)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	(30,000,000)	—
Payment of end of end of term fee	(2,760,000)	—
Proceeds from issuance of common stock, net of offering expenses	48,397,088	42,944,831
Proceeds from the exercise of stock options	75,048	13,007
Payment of debt refinancing fees	(6,499,867)	—
Proceeds from issuance of note payable	72,500,000	—
Payment of debt issuance costs	(1,679,661)	—
Payments on finance lease obligations	(29,983)	(16,581)
Payments of leasehold improvement loan	—	(19,697)
Net cash provided by financing activities	80,002,625	42,921,560
Net decrease in cash and cash equivalents	(2,717)	(21,852,722)
Cash and cash equivalents, including restricted cash - beginning of year	26,754,852	48,607,574
Cash and cash equivalents, including restricted cash - end of year	$ 26,752,135	$ 26,754,852

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

1. ORGANIZATION AND BUSINESS

ADMA Biologics, Inc. (''ADMA'' or the ''Company'') is an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and others at risk for certain infectious diseases. The Company's targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons.

ADMA operates through its wholly-owned subsidiaries ADMA BioManufacturing, LLC (''ADMA BioManufacturing'') and ADMA Bio Centers Georgia Inc. (''ADMA Bio Centers''). ADMA BioManufacturing was formed in January 2017 to facilitate the acquisition of the Biotest Therapy Business Unit (''BTBU'') from Biotest Pharmaceuticals Corporation (''BPC'' and, together with Biotest AG, ''Biotest'') as more fully described below. BTBU had been the Company's third-party manufacturer for its then-lead pipeline product candidate, ASCENIV, previously referred to as ''RI-002.'' ADMA Bio Centers is the Company's source plasma collection business with a plasma collection facility located in the U.S., which holds an approved license with the U.S. Food and Drug Administration (the ''FDA''). Effective January 1, 2019, in connection with the Biotest Transaction (as defined below), the Company transferred two of its FDA-approved plasma collection facilities to BPC.

The Company has three FDA-approved products, all of which are currently marketed and commercially available: (i) BIVIGAM (Immune Globulin Intravenous, Human), an Intravenous Immune Globulin (''IVIG'') product indicated for the treatment of Primary Humoral Immunodeficiency (''PI''), also known as Primary Immunodeficiency Disease (''PIDD''), and for which we received FDA approval on May 9, 2019 for the commercial re-launch of the product and commenced the commercial re-launch in August 2019; (ii) ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), previously referred to as RI-002, an IVIG product indicated for the treatment of PI, for which we received FDA approval on April 1, 2019 and commenced first commercial sales in October 2019; and (iii) Nabi-HB (Hepatitis B Immune Globulin, Human), which is indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen (''HBsAg'') and other listed exposures to Hepatitis B. The Company seeks to develop a pipeline of plasma-derived therapeutics, and its 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.

On June 6, 2017, ADMA completed the acquisition of certain assets (the ''Biotest Assets'') of BTBU, which included the FDA-licensed BIVIGAM and Nabi-HB immunoglobulin products, and an FDA-licensed plasma fractionation manufacturing facility located in Boca Raton, FL (the ''Boca Facility'') (the ''Biotest Transaction''). In addition to its commercially available immunoglobulin products, the Company provides contract manufacturing services for certain clients and generates revenues from the sale of intermediate by-products that result from the immunoglobulin production process. Immediately following the closing of the Biotest Transaction, the Biotest Assets were contributed into ADMA BioManufacturing.

As of December 31 2019, the Company had working capital of $71.8 million, including $26.8 million of cash and cash equivalents. Based upon the Company's current projected revenue and expenditures, including capital expenditures and continued implementation of the Company's commercialization and expansion activities, as well as certain other assumptions, the Company's management currently believes that its cash, cash equivalents, projected revenue and accounts receivable, along with the net proceeds received from the February 2020 public offering of the Company's common stock (see Note 17) and the additional $12.5 million it is able to access under its senior credit facility, will be sufficient to fund ADMA's operations, as currently conducted, into the second quarter of 2021. In order to have sufficient cash to fund its operations thereafter, the Company expects it will need to raise additional capital before the end of the second quarter of 2021. These estimates may change based upon the success of the Company's commercial manufacturing ramp-up activities, the acceptability of BIVIGAM and ASCENIV by physicians, patients or payers and the various financing options that may be available to the Company. Other than the $12.5 million commitment currently available under its senior credit facility (see Note 7), the Company currently has no firm commitments for additional financing, and

there can be no assurance that the Company will be able to secure additional financing on terms that are acceptable to the Company, or at all. Furthermore, if the Company's assumptions underlying its estimated expenses and revenues are incorrect, it may have to raise additional capital sooner than currently anticipated.

The Company may decide to raise capital through public or private equity offerings or debt financings, or obtain a bank credit facility or enter into corporate collaboration and licensing arrangements. The sale of additional equity or debt securities, if convertible, could result in dilution to the Company's existing stockholders and, in such event, the market value of its common stock may decline. The incurrence of additional indebtedness would result in increased fixed obligations and could also result in covenants that would restrict the Company's operations or other financing alternatives. In addition, the Company is exploring additional contract manufacturing arrangements and other business development opportunities, which may provide additional liquidity to the Company.

There can be no assurance that the Company's approved products will be commercially viable, or that research and development, plant capacity expansion, plasma center build-outs or other capital improvements will be successfully completed or that any product developed in the future will be approved. The Company is subject to risks common to companies in the biotechnology and pharmaceutical manufacturing industries including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with FDA and other governmental regulations and approval requirements.

2. SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation and Basis of presentation

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

During the years ended December 31, 2019 and 2018, comprehensive loss was equal to the net loss amounts presented for the respective periods in the accompanying consolidated statements of operations.

Use of estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the realizable value of accounts receivable, valuation of inventory, assumptions used in the fair value of awards granted under the Company's equity incentive plans and warrants issued in connection with the issuance of notes payable and the valuation allowance for the Company's deferred tax assets.

Cash and cash equivalents

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

The Company regularly maintains cash and cash equivalents at third-party financial institutions in excess of the Federal Deposit Insurance Corporation insurance limit. Although the Company monitors the daily cash balances in the operating accounts and adjusts the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on the Company's business, if one or more of the financial institutions with which the Company has deposits fails or is subject to other adverse conditions in the financial or credit

markets. To date, the Company has not experienced a loss or lack of access to its deposited cash or cash equivalents; however, the Company cannot provide assurance that access to its cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets in the future.

Restricted cash

Restricted cash at December 31, 2018 consists of cash held in a reserve account as required by the terms of the Company's then-senior lending agreement (see Note 7).

Accounts receivable

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

Inventories

Inventories, including plasma intended for resale and plasma intended for internal use in the Company's manufacturing, commercialization or research and development activities, are carried at the lower of cost or net realizable value determined by the first-in, first-out method. Due to previous uncertainties surrounding certain prior submissions made to the FDA, all costs related to the production of BIVIGAM and ASCENIV prior to their FDA approval dates of May 9, 2019 and April 1, 2019, respectively, have been charged to cost of product revenue in the accompanying consolidated statements of operations.

Property and equipment

Assets comprising property and equipment (see Note 5) are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the asset's estimated useful life. Land is not depreciated. The buildings have been assigned a useful life of 30 years. Property and equipment other than land and buildings have useful lives ranging from 3 to 15 years. Leasehold improvements are amortized over the lesser of the lease term or their estimated useful lives.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill at December 31, 2019 and 2018 was $3.5 million, all of which is attributable to the Company's ADMA BioManufacturing business segment. There were no changes to the carrying amount of goodwill during the years ended December 31, 2019 and 2018.

Goodwill is not amortized, but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. The Company has the option to perform a qualitative assessment of goodwill to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill and other intangible assets. If the Company concludes that this is the case, then it must perform a goodwill impairment test by comparing the fair value of the reporting unit to its carrying value. An impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value. The impairment loss recognized would not exceed the total amount of goodwill allocated to that reporting unit. The Company's impairment analyses as of October 1, 2019 and 2018 did not result in any impairment charges related to goodwill for the years ended December 31, 2019 and 2018.

Impairment of long-lived assets

The Company assesses the recoverability of its long-lived assets, which include property and equipment and finite-lived intangible assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's carrying value is recoverable.

Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the years ended December 31, 2019 and 2018, the Company determined that there was no impairment of its long-lived assets.

Revenue recognition

Revenues for the years ended December 31, 2019 and 2018 are comprised of (i) revenues from the sale of the Company's immunoglobulin products, ASCENIV, BIVIGAM and Nabi-HB, (ii) product revenues from the sale of human plasma collected from the Company's Plasma Collection Centers business segment, (iii) contract manufacturing revenue, (iv) revenues from the sale of intermediate by-products; and (v) license and other revenues primarily attributable to the out-licensing of ASCENIV to Biotest in 2012 to market and sell this product in Europe and selected countries in North Africa and the Middle East. Biotest has provided the Company with certain services and financial payments in accordance with the related Biotest license agreement and is obligated to pay the Company certain amounts in the future if certain milestones are achieved. Deferred revenue is recognized over the term of the Biotest license. Deferred revenue is amortized into income for a period of approximately 22 years, the term of the Biotest license agreement.

Product revenue is recognized when the customer is deemed to have control over the product. Control is determined based on when the product is shipped or delivered and title passes to the customer. Revenue is recorded in an amount that reflects the consideration the Company expects to receive in exchange. Revenue from the sale of the Company's immunoglobulin products is recognized when the product reaches the customer's destination, and is recorded net of estimated rebates, price protection arrangements and customer incentives, including prompt pay discounts, wholesaler chargebacks and other wholesaler fees. These estimates are based on historical experience and certain other assumptions, and the Company believes that such estimates are reasonable. For revenues associated with contract manufacturing and the sale of intermediates, control transfers to the customer and the performance obligation is satisfied when the customer takes possession of the product from the Boca Facility or from a third-party warehouse that is utilized by the Company.

Product revenues from the sale of human plasma collected at the Company's plasma collection centers are recognized at the time control of the product has been transferred to the customer, which generally occurs at the time of shipment. Product revenues are recognized at the time of delivery if the Company retains control of the product during shipment.

Cost of product revenue

Cost of product revenue includes expenses related to process development as well as scientific and technical operations when these operations are attributable to marketed products. When the activities of these operations are attributable to new products in development, the expenses are classified as research and development expenses. Expenses associated with remediating the issues at the Boca Facility that were identified by the FDA prior to the closing of the Biotest Transaction of approximately $0.2 million and $1.5 million for the years ended December 31, 2019 and 2018, respectively, are expensed as incurred and were reflected in cost of product revenue in the accompanying consolidated statements of operations.

Research and development expenses

Research and development expenses consist of clinical research organization costs, costs related to clinical trials, post-marketing commitment studies for BIVIGAM, wages, benefits and stock-based compensation for employees directly related to research and development activities and, prior to April 1, 2019, assay development and testing, storage and transportation costs for high-titer plasma used in the manufacture of ASCENIV. All research and development costs are expensed as incurred.

Advertising and marketing expenses

Advertising and marketing expense includes cost for promotional materials and trade show expenses for the marketing of the Company's products and services and are expensed as incurred. Advertising and marketing expenses were $1.0 million and $0.8 million for the years ended December 31, 2019 and 2018, respectively.

Stock-based compensation

The Company follows recognized accounting guidance which requires all equity-based payments, including grants of stock options, to be recognized in the statement of operations as compensation expense based on their fair values at the date of grant. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line over the associated vesting period of the award based on the grant date fair value of the award. Stock options granted under the Company's equity incentive plans generally have a four-year vesting period and a term of 10 years. Pursuant to ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, the Company has elected not to establish a forfeiture rate, as stock-based compensation expense related to forfeitures of unvested stock options is fully reversed at the time of forfeiture.

Income taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or its tax returns. Under this method, deferred tax assets and liabilities are recognized for the temporary differences between the tax bases of assets and liabilities and their respective financial reporting amounts at enacted tax rates in effect for the years in which the temporary differences are expected to reverse. The Company records a valuation allowance on its deferred tax assets if it is more likely than not that the Company will not generate sufficient taxable income to utilize its deferred tax assets (see Note 11). The Company is subject to income tax examinations by major taxing authorities for all tax years since 2015 and for previous periods as it relates to the Company's net operating loss carryforwards.

Earnings (Loss) Per Share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. For purposes of computing basic and diluted loss per share, the non-voting class of common stock (see Note 8) was included in the common stock outstanding prior to its retirement in May 2018 as the characteristics of the non-voting class are substantially the same as the voting class of common stock.

Diluted net loss per share is calculated by dividing net loss attributable to common stockholders as adjusted for the effect of dilutive securities, if any, by the weighted average number of shares of common stock, including the non-voting class of common stock, and dilutive common stock outstanding during the period. Potentially dilutive common stock includes the shares of common stock issuable upon the exercise of outstanding stock options and warrants (using the treasury stock method). Potentially dilutive common stock in the diluted net loss per share computation is excluded to the extent that it would be anti-dilutive. No potentially dilutive securities are included in the computation of any diluted per share amounts as the Company reported a net loss for all periods presented. For the years ended December 31, 2019 and 2018, the following securities were excluded from the calculation of diluted loss per common share because of their anti-dilutive effects:

	For the Years Ended December 31,	
	2019	2018
Stock options	5,630,351	4,342,231
Warrants	2,138,160	528,160
	7,768,511	4,870,391

Fair value of financial instruments

The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable and accounts payable are shown at cost, which approximates fair value due to the short-term nature of these instruments. The debt outstanding under the Company's senior notes payable (see

Note 7) approximates fair value due to the variable interest rate on this debt. With respect to the subordinated note payable in the amount of $15.0 million as of December 31, 2019 and 2018 (see Note 7), that was issued to a then-principal stockholder of the Company and was issued concurrent with an acquisition transaction with such stockholder, the Company has concluded that an estimation of fair value for this note is not practicable.

Recent Accounting Pronouncements

In July 2017, the Financial Accounting Standards Board (the ''FASB'') issued Accounting Standards Update (''ASU'') No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815)*'' (''ASU 2017-11''). ASU 2017-11 changed the classification analysis of certain equity-linked financial instruments (or embedded features within such instruments) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) would no longer be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (''EPS'') in accordance with ASC 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. In addition, convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features in ASC 470-20, ''*Debt—Debt with Conversion and Other Options.*'' ASU 2017-11 became effective for the Company on January 1, 2019, and this update did not have a significant impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (''ASU 2016-02''), which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance became effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company adopted ASU 2016-02 on January 1, 2019 using the option to recognize the cumulative-effect adjustment, if any, as of the date of application, which was also January 1, 2019. The Company recognized right-to-use assets of $1.4 million and corresponding lease liabilities of approximately $1.6 million at the date of adoption (see Note 12). The Company also elected the ''package of practical expedients,'' which permits the Company to not reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. In addition, the Company elected the short-term lease recognition exemption for all leases that qualify, including the agreement under which the Company occupies certain office space as discussed in Note 9.

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

In March 2016, April 2016 and December 2016, the FASB issued ASU No. 2016-08, *Revenue From Contracts with Customers* (ASC 606): *Principal Versus Agent Considerations*, ASU No. 2016-10, *Revenue From Contracts with Customers* (ASC 606): Identifying Performance Obligations and Licensing, and ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue From Contracts with Customers, respectively, which further clarify the implementation guidance on principal versus agent considerations

contained in ASU No. 2014-09. In May 2016, the FASB issued ASU 2016-12, Revenue from Contracts with Customers, narrow-scope improvements and practical expedients which provides clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for non-cash consideration and completed contracts at transition. These standards became effective for the Company beginning in the first quarter of 2018.

ADMA adopted the new revenue recognition standard and related updates effective January 1, 2018, using the modified retrospective method of adoption. Adoption of the new revenue recognition guidance did not have a material impact on the Company's consolidated financial statements.

3. TRANSFER OF PLASMA CENTER ASSETS

As part of the purchase price for the Biotest Transaction (see Note 1), the Company transferred its Marietta, GA and Norcross, GA plasma collection centers to BPC effective January 1, 2019. The Company had estimated the combined fair value of the two facilities to be $12.6 million, and the Company recorded an obligation for this amount as of the date of the Biotest Transaction, which is reflected in non-current liabilities in the accompanying consolidated balance sheet as of December 31, 2018. On January 1, 2019, upon the transfer of the two plasma collection facilities to BPC, the Company recorded a gain in the amount of $11.5 million, which reflects the derecognition of the obligation to transfer ownership of the two facilities net of the carrying value of the assets associated with these facilities, primarily property and equipment and inventory, in the amount of $1.1 million.

4. INVENTORIES

The following table provides the components of inventories:

	December 31, 2019	December 31, 2018
Raw materials	$33,381,806	$14,019,668
Work-in-process	14,455,665	—
Finished goods	5,227,263	4,596,501
Total inventories	$53,064,734	$18,616,169

Inventories are stated at the lower of cost or net realizable value with cost being determined on the first-in, first-out method. Raw materials includes plasma and other materials used in the production of goods expected to be available for sale or which otherwise have alternative uses which provide a probable future benefit. All other activities and materials associated with the production of inventories used in research and development activities are expensed as incurred.

Work-in-process inventory primarily consists of bulk drug substance and unlabeled filled vials of the Company's immunoglobulin products. Finished goods inventory is comprised of immunoglobulin product inventory and related intermediates that are available for commercial sale, as well as plasma collected at the Company's plasma collection center which is expected to be sold to third-party customers.

5. PROPERTY AND EQUIPMENT

Property and equipment at December 31, 2019 and 2018 is summarized as follows:

	December 31, 2019	December 31, 2018
Manufacturing and laboratory equipment	$ 8,831,817	$ 8,233,203
Office equipment and computer software	1,690,248	1,608,994
Furniture and fixtures	582,088	1,163,552
Construction in process	4,285,915	845,538
Leasehold improvements	1,673,084	1,660,709
Land	4,339,441	4,339,441
Buildings and building improvements	16,063,680	15,685,325
	37,466,273	33,536,762
Less: Accumulated depreciation	(5,724,956)	(3,421,032)
Total property, plant and equipment, net	$31,741,317	$30,115,730

The Company recorded depreciation expense on property and equipment of $2.4 million and $2.6 million for the years ended December 31, 2019 and 2018, respectively, which includes $0.3 million of depreciation expense on the plasma assets to be transferred (see Note 3) for the year ended December 31, 2018.

6. INTANGIBLE ASSETS

Intangible assets at December 31, 2019 and 2018 consist of the following:

	December 31, 2019			December 31, 2018		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Trademark and other intangible rights related to Nabi-HB	$4,100,046	$1,513,112	$2,586,934	$4,100,046	$ 927,391	$3,172,655
Rights to intermediates	907,421	334,881	572,540	907,421	205,250	702,171
Customer contract	1,076,557	1,076,557	—	1,076,557	946,971	129,586
	$6,084,024	$2,924,550	$3,159,474	$6,084,024	$2,079,612	$4,004,412

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

The customer contract pertains to a contract manufacturing agreement with a third-party customer that the Company assumed upon the consummation of the Biotest Transaction. On December 22, 2017, Company and the customer entered into an amendment to this contract which reduced the number of batches the Company was committed to supply to the customer. The remaining required production volume was 13 batches over 2018 and 2019. The Company has fulfilled this obligation to the customer in its entirety as of December 31, 2019, the date of expiration of the contract, as amended.

Amortization expense related to the Company's intangible assets for the years ended December 31, 2019 and 2018 was $0.8 million. Estimated aggregate future aggregate amortization expense for the next five years is expected to be as follows:

2020	$715,352
2021	715,352
2022	715,352
2023	715,352
2024	298,064

7. NOTES PAYABLE

Senior Notes Payable

A summary of outstanding senior notes payable is as follows:

	December 31, 2019	December 31, 2018
Notes payable	$72,500,000	$30,000,000
Less:		
Debt discount	(4,208,837)	(3,559,170)
Senior notes payable	$68,291,163	$26,440,830

On February 11, 2019 (the ''Perceptive Closing Date''), the Company and all of its subsidiaries entered into a Credit Agreement and Guaranty (the ''Perceptive Credit Agreement'') with Perceptive Credit Holdings II, LP, as the lender and administrative agent (''Perceptive''). The Perceptive Credit Agreement, as amended, provides for a senior secured term loan facility in a principal amount of up to $85.0 million (the ''Perceptive Credit Facility''), comprised of (i) a term loan made on the Perceptive Closing Date in the principal amount of $45.0 million, as evidenced by the Company's issuance of a promissory note (the ''Perceptive Tranche I Note'') in favor of Perceptive on the Perceptive Closing Date (the ''Perceptive Tranche I Loan''), (ii) a term loan in the principal amount of up to $27.5 million (the ''Perceptive Tranche II Loan'') evidenced by the Company's issuance of a promissory note (the ''Perceptive Tranche II Note'') in favor of Perceptive on May 3, 2019; and (iii) a term loan in the principal amount of up to $12.5 million (the ''Perceptive Tranche III Loan,'' and together with the Perceptive Tranche I Loan and the Perceptive Tranche II Loan, the ''Perceptive Loans'') to be drawn-down at the Company's sole option no later than March 31, 2020. The Perceptive Tranche III Loan is the result of an amendment to the Perceptive Credit Agreement (the ''Perceptive Amendment'') that the Company and Perceptive entered into on May 3, 2019, and the Perceptive Tranche III Loan became available to the Company upon the approval of BIVIGAM on May 9, 2019. The Perceptive Credit Facility has a maturity date of March 1, 2022 (the ''Maturity Date''), subject to acceleration pursuant to the Perceptive Credit Agreement, including upon an Event of Default (as defined in the Perceptive Credit Agreement).

On the Perceptive Closing Date, the Company used $30.0 million of the Perceptive Tranche I Loan to terminate and pay in full all of the outstanding obligations under its previously existing credit agreement with Marathon Healthcare Finance Fund, L.P. (''Marathon'') (the ''Marathon Credit Facility''). The Company also used proceeds from the Perceptive Tranche I Loan to: (i) pay a deferred facility fee to Marathon in the amount of $2.8 million, (ii) pay a prepayment penalty to Marathon in the amount of $6.5 million, (iii) pay outstanding accrued interest to Marathon in the amount of $0.7 million, and (iv) pay certain fees and expenses incurred in connection with the Perceptive Credit Facility of approximately $1.5 million. In addition, Marathon released $4.0 million of cash to the Company that was held in a debt service reserve account per the terms of the Marathon Credit Facility, which was reflected as restricted cash in the accompanying consolidated balance sheet as of December 31, 2018. In connection with the Perceptive Amendment, the Company paid an additional facility fee to Perceptive in the amount of $0.1 million on May 3, 2019.

As a result of the Company's entering into the Perceptive Credit Agreement and terminating the Marathon Credit Facility, the Company recognized a loss on the extinguishment of debt in the amount of approximately $10.0 million, comprised of the $6.5 million prepayment penalty and the write-off of unamortized debt discount related to the Marathon Credit Facility in the amount of $3.5 million.

Borrowings under the Perceptive Credit Agreement bear interest at a rate per annum equal to 7.5% plus the greater of (i) one-month LIBOR and (ii) 3.5%; provided, however, that upon, and during the continuance of, an Event of Default, the interest rate will automatically increase by an additional 400 basis points. Accrued interest is payable to Perceptive on the last day of each month during the term of the Perceptive Credit Facility. The rate of interest in effect as of the Perceptive Closing Date and at December 31, 2019 was 11.0%.

On the Maturity Date, the Company will pay Perceptive the entire outstanding principal amount underlying the Perceptive Loans and any accrued and unpaid interest thereon. Prior to the Maturity Date, there are no scheduled principal payments on the Perceptive Loans. The Company may prepay outstanding principal on the Perceptive Loans at any time and from time to time upon three business days' prior written notice, subject to the payment to Perceptive of, (A) any accrued but unpaid interest on the prepaid principal amount plus (B) a redemption premium amount equal to (i) 5.0% of the prepaid principal amount, if prepaid on or prior to the first anniversary of the Perceptive Closing Date, (ii) 4.0% of the prepaid principal amount, if prepaid after the first anniversary of the Perceptive Closing Date and on or prior to the second anniversary of the Perceptive Closing Date, or (iii) 3.0% of the prepaid principal amount, if prepaid after the second anniversary of the Perceptive Closing Date and on or prior to the third anniversary of the Perceptive Closing Date.

All of the Company's obligations under the Perceptive Credit Agreement are secured by a first-priority lien and security interest in substantially all of the Company's tangible and intangible assets, including intellectual property and all of the equity interests in the Company's subsidiaries. The Perceptive Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings. The negative covenants restrict or limit the ability of the Company and its subsidiaries to, among other things and subject to certain exceptions contained in the Perceptive Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to the Company's or subsidiaries' business activities; make certain Investments or Restricted Payments (each as defined in the Perceptive Credit Agreement); change its fiscal year; pay dividends; repay other certain indebtedness; engage in certain affiliate transactions; or enter into, amend or terminate any other agreements that have the impact of restricting the Company's ability to make loan repayments under the Perceptive Credit Agreement. In addition, the Company must (i) at all times prior to the Maturity Date maintain a minimum cash balance of $3.0 million; and (ii) as of the last day of each fiscal quarter commencing with the fiscal quarter ending June 30, 2019, report revenues for the trailing 12-month period that exceed the amounts set forth in the Perceptive Credit Agreement, which range from $7.0 million for the fiscal quarter ending June 30, 2019 to $55.0 million for the fiscal quarter ending December 31, 2021. At December 31, 2019, the Company was in compliance with all of the covenants contained in the Perceptive Credit Agreement.

As consideration for the Perceptive Credit Agreement, the Company issued to Perceptive a warrant to purchase 1,360,000 shares of the Company's common stock (the ''Perceptive Warrant'') on the Perceptive Closing Date. The Perceptive Warrant has an exercise price equal to $3.28 per share, which was equal to the trailing 10-day volume weighted average price (''VWAP'') of the Company's common stock on the business day immediately prior to the Perceptive Closing Date multiplied by 1.15. The Company valued the Perceptive Warrant at $2.7 million as of the Perceptive Closing Date and it has an expiration date of February 11, 2029. In connection with the Perceptive Amendment, the Company issued an additional warrant (the ''Perceptive Tranche III Warrant'' and, together with the Perceptive Warrant, the ''Perceptive Warrants'') to purchase 250,000 shares of the Company's common stock to Perceptive with an exercise price equal to $4.64 per share, which represents the trailing 10-day VWAP of the Company's common stock as of May 2, 2019. The Perceptive Tranche III Warrant was valued by the Company at $0.9 million and has an expiration date of May 3, 2029. Perceptive has represented to the Company, among other things, that it is an ''accredited investor'' (as such term is defined in Rule 501(a) of Regulation D under the Securities Act) and the Company issued the Perceptive Warrants in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The Perceptive Warrants and the shares of common stock issuable thereunder may not be offered, sold, pledged or otherwise transferred in the U.S. absent registration or an applicable exemption from the registration requirements under the Securities Act.

As a result of the fees paid to Perceptive and the value of the Perceptive Warrants, the Company recognized an aggregate discount on the Perceptive Tranche I Note and Perceptive Tranche II Note in the amount of $5.3 million. The Company records debt discount as a reduction to the face amount of the debt, and the debt discount is amortized as interest expense over the life of the debt using the interest method. Based on the fair value of the Perceptive Warrants and the aggregate amount of fees and expenses associated with obtaining the Perceptive Credit Facility, the effective interest rate on the Perceptive Loans as of May 3, 2019 was approximately 14.1%.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the accompanying consolidated balance sheets and statements of cash flows:

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$26,752,135	$22,754,852
Restricted cash included in long-term assets	—	4,000,000
Total cash, cash equivalents and restricted cash as shown in the consolidated statements of cash flows	$26,752,135	$26,754,852

Subordinated Note Payable

A summary of the outstanding subordinated note payable is as follows:

	December 31, 2019	December 31, 2018
Subordinated note payable to Biotest	$15,000,000	$15,000,000
Less:		
Debt discount	(91,947)	(125,816)
Subordinated note payable	$14,908,053	$14,874,184

In connection with the acquisition of the Biotest Assets (see Note 1), ADMA BioManufacturing issued a subordinated note payable to BPC and in connection therewith received cash proceeds of $15.0 million. The note bears interest at a rate of 6.0% per annum and matures on June 6, 2022. The Company is obligated to make semi-annual interest payments, with all principal and unpaid interest due at maturity. The note is subordinate to all amounts outstanding under the Perceptive Credit Agreement. In the event of default, all principal and unpaid interest is due on demand. The subordinated note also contains several non-financial covenants with which the Company was in compliance as of December 31, 2019.

On July 20, 2018, in connection with 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, Biotest AG, BPC, ADMA BioManufacturing and the Company entered into an Assignment and Assumption Agreement whereby BPC transferred to Biotest AG all of its obligations, rights, title and interest in the subordinated note and the related loan agreements.

8. STOCKHOLDERS' EQUITY

Preferred Stock

The Company is currently authorized to issue up to 10 million shares of preferred stock, $0.0001, par value per share. There were no shares of preferred stock outstanding at December 31, 2019 and 2018.

Common Stock

As of December 31, 2019 and 2018, the Company was authorized to issue 150,000,000 and 75,000,000 shares, respectively, of its common stock, $0.0001 par value per share, and 59,318,355 and 46,353,068 shares of common stock were outstanding as of December 31, 2019 and 2018, respectively. On August 23, 2019, the Company's stockholders approved an amendment to the Company's Second Amended and Restated Certificate of Incorporation to increase the number of shares of common stock that the Company is authorized to issue from 75,000,000 to 150,000,000. After giving effect to shares reserved for the issuance of warrants and stock options, 82,913,134 shares of common stock were available for issuance as of December 31, 2019.

On May 21, 2019, the Company issued 12,937,500 shares of its common stock in an underwritten public offering for gross proceeds of approximately $51.8 million. After deducting underwriters' commissions and other expenses associated with the offering, the Company received net proceeds of $48.4 million.

During the year ended December 31, 2019, the Company issued 27,787 shares of common stock in connection with the exercise of stock options that had been granted to employees.

In June 2018, the Company completed an underwritten public offering of 9,623,430 shares of common stock for gross proceeds of $46.0 million. The Company received net proceeds from this offering, after underwriters' commissions and other offering expenses, of $42.9 million.

On May 14, 2018, the Company, ADMA BioManufacturing and ADMA Bio Centers 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 the Company, for no cash consideration, 8,591,160 shares of the Company's then-issued and outstanding non-voting common stock, $0.0001 par value per share (the ''NV Biotest Shares'') that had been issued to Biotest as part of the purchase price for the Biotest Assets. Immediately upon transfer of the NV Biotest Shares to the Company, the shares were retired and are no longer available for issuance. The retired NV Biotest Shares comprised approximately 19% of the total outstanding common stock of the Company as of May 14, 2018, and approximately 67% of the total shares issued to BPC in the Biotest Transaction. In exchange for the transfer and retirement of the NV Biotest Shares, the Company (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, which governs the Biotest Transaction, and (ii) relinquished its 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 the Company's Board of Directors (the ''Board'').

Warrants

On the Perceptive Closing Date, the Company issued the Perceptive Warrant, whereby Perceptive may purchase an aggregate of 1,360,000 shares of common stock at an exercise price of $3.28 per share. The Perceptive Warrant became exercisable on the Perceptive Closing Date, and was valued at $2.7 million. The Perceptive Warrant was valued using the Black-Scholes option-pricing model assuming an expected term of 10 years, a volatility of 61.2%, a dividend yield of 0% and a risk-free interest rate of 2.65%.

On May 3, 2019, the Company issued the Perceptive Tranche III Warrant, whereby Perceptive may purchase an aggregate of 250,000 shares of common stock at an exercise price of $4.64 per share. The Perceptive Tranche III was exercisable on the date of issuance and was valued at $0.9 million. The Perceptive Tranche III Warrant was valued using the Black-Scholes option-pricing model assuming an expected term of 10 years, a volatility of 62.3%, a dividend yield of 0% and a risk-free interest rate of 2.54%. At December 31, 2019, the Company had outstanding warrants to purchase an aggregate of 2,138,160 shares of common stock, with a weighted average exercise price of $3.81 per share and expiration dates ranging between June 2022 and May 2029.

No warrants were issued during the year ended December 31, 2018. At December 31, 2018, the Company had outstanding warrants to purchase an aggregate of 528,160 shares of common stock, with a weighted average exercise price of $4.76 per share and with expiration dates ranging between June 2022 and October 2024.

Stock Options

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

The 2014 Plan, as amended, was approved by the Board on March 15, 2017 and by the Company's stockholders on May 25, 2017. Currently, the maximum number of shares reserved for grant under the 2014 Plan is: (a) 2,334,940 shares, less any shares available as of such date for issuance under the 2007 Plan; plus (b) an annual increase as of the first day of the Company's fiscal year, beginning in 2018 and occurring each year thereafter through 2022, equal to 4% of the outstanding shares of common stock as of the end of the Company's immediately preceding fiscal year, or any lesser number of shares determined by the Board; provided, however, that no more than an aggregate of 10 million shares of common stock may be issued pursuant to incentive stock

options intended to qualify under Section 422 of the Internal Revenue Code. As of December 31, 2019, an aggregate of 1,931,709 shares were available for issuance under the 2007 Plan and the 2014 Plan. In accordance with the foregoing, on January 1, 2020 the aggregate number of shares available for issuance increased to 4,304,443.

During the years ended December 31, 2019 and 2018, the Company recorded stock-based compensation expense to employees of $2.7 million and $2.2 million, respectively. The fair value of employee options granted was determined on the date of grant using the Black-Scholes model. The Black-Scholes option valuation model was developed for use in estimating the fair value of publicly traded options, which have no vesting restrictions and are fully transferable. The Company's employee stock options have characteristics significantly different from those of traded options, and changes in the underlying Black-Scholes assumptions can materially affect the fair value estimate. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of the grant with a term consistent with the expected term of the Company's awards. The expected term of the options granted is in accordance with Staff Accounting Bulletins 107 and 110, which is based on the average between vesting terms and contractual terms. The expected dividend yield reflects the Company's current and expected future policy for dividends on the Company's common stock. For the years ended December 31, 2019 and 2018, the expected stock price volatility for the Company's stock options was calculated by examining the historical volatility of the Company's common stock since the stock became publicly traded in the fourth quarter of 2013.

The grant date fair values of stock options awarded during the years ended December 31, 2019 and 2018 were determined using the Black-Scholes option-pricing model with the following assumptions:

	Years Ended	
	December 31, 2019	December 31, 2018
Expected term	5.8-6.3 years	5.8-6.3 years
Volatility	54-63%	54-57%
Dividend yield	0.0	0.0
Risk-free interest rate	1.36-2.92%	2.40-3.11%

The 2007 Plan and 2014 Plan provide for the Board or a Committee of the Board (the ''Committee'') to grant awards to optionees and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the awards, including acceleration of the vesting of an award at any time. All options granted under the 2007 Plan and 2014 Plan are intended to be incentive stock options (''ISOs''), unless specified by the Committee to be non-qualified options (''NQOs'') as defined by the Internal Revenue Code. ISOs and NQOs may be granted to employees, consultants or Board members at an option price not less than the fair market value of the common stock subject to the stock option agreement. The following table summarizes information about stock options outstanding as of December 31, 2019 and 2018:

	Shares	Weighted Average Exercise Price
Options outstanding, vested and expected to vest at December 31, 2017	3,276,043	$5.52
Forfeited	(60,854)	$4.09
Expired	(34,489)	$8.38
Granted	1,167,044	$4.15
Exercised	(5,513)	$3.31
Options outstanding, vested and expected to vest at December 31, 2018	4,342,231	$5.16
Forfeited	(169,993)	$3.97
Expired	(19,983)	$4.60
Granted	1,508,000	$3.49
Exercised	(29,904)	$2.84
Options outstanding, vested and expected to vest at December 31, 2019	5,630,351	$4.76
Options exercisable	3,250,593	$5.57

The weighted average remaining contractual term of stock options outstanding and expected to vest at December 31, 2019 is 7.1 years. The weighted average remaining contractual term of stock options exercisable at December 31, 2019 is 6.1 years. The following table summarizes additional information regarding outstanding and exercisable options under the stock option plans at December 31, 2019:

	Stock Options Outstanding				Stock Options Exercisable			
Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$1.34 - $2.06 . . .	5,168	1.1	$1.41	$ 13,387	4,928	0.8	$1.40	$ 12,921
$2.62 - $3.98 . . .	3,827,577	8.2	$3.58	1,603,478	1,678,942	7.7	$3.68	540,127
$4.03 - $6.26 . . .	564,503	7.8	$5.09	—	360,048	7.3	$5.19	—
$6.28 - $10.80 . .	1,233,103	3.6	$8.28	—	1,206,675	3.5	$8.32	—
	5,630,351	7.1	$4.76	$1,616,865	3,250,593	6.1	$5.57	$553,048

Stock-based compensation expense for the years ended December 31, 2019 and 2018 was as follows:

	2019	2018
Research and development	$ 360,569	$ 292,736
Plasma center operating expenses	51,340	34,797
Selling, general and administrative	2,047,025	1,739,037
Cost of product revenue	191,843	156,718
Total stock-based compensation expense	$2,650,777	$2,223,288

As of December 31, 2019, the total unrecognized compensation expense related to unvested options was $4.4 million, which is expected to be recognized over a weighted-average period of 2.4 years. The Company's outstanding and exercisable options had an aggregate intrinsic value of approximately $0.6 million as of December 31, 2019.

9. RELATED PARTY TRANSACTIONS

The Company leases an office building and equipment from Areth, LLC (''Areth'') pursuant to an agreement for services effective as of January 1, 2016, as amended from time to time. Effective October 1, 2017, monthly rent on this facility was reduced to $10,000. On September 27, 2018, the agreement was amended to extend the term of the agreement through September 30, 2019. On November 7, 2019, an additional amendment was entered into between Areth and the Company to extend the term of this agreement through September 30, 2020, and to provide for automatic one-year renewals unless ADMA gives written notice of termination to Areth 60 days prior to the end of the term. Rent expense for the years ended December 31, 2019 and 2018 amounted to $120,000. Areth is a company controlled by Dr. Jerrold B. Grossman, the Vice Chairman of the Company's Board of Directors, and Adam S. Grossman, the Company's President and Chief Executive Officer. The Company also reimburses Areth for office and building related (common area) expenses, equipment and certain other operational expenses, which were not material to the consolidated financial statements for the years ended December 31, 2019 and 2018.

See Note 7 for a discussion of the Company's credit facility and related transactions with Perceptive, a holder of more than 10% of the Company's common stock.

10. COMMITMENTS AND CONTINGENCIES

General Legal Matters

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

Vendor and Licensor Commitments

Pursuant to the terms of a plasma purchase agreement with BPC dated as of November 17, 2011 (the ''2011 Plasma Purchase Agreement''), the Company agreed to purchase from BPC an annual minimum volume of source plasma containing antibodies to RSV to be used in the manufacture of ASCENIV. The Company must purchase a to-be-determined and agreed upon annual minimum volume from BPC, but may also collect high-titer RSV plasma from up to five wholly-owned ADMA plasma collection facilities. During 2015, the Company and BPC amended the 2011 Plasma Purchase Agreement to allow the Company the ability to collect its raw material RSV high-titer plasma from other third-party collection organizations, thus allowing the Company to expand its reach for raw material supply as it executes its commercialization plans for ASCENIV. 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, the parties 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 the Company 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, the Company may purchase RSV plasma from Grifols from the two plasma collection centers that were transferred to BPC on January 1, 2019 (see Note 3) at a price equal to cost plus five percent (5%) (without any additional increase due to inflation).

On June 6, 2017, the Company and BPC entered into a Plasma Supply Agreement 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, the Company and BPC entered into an amendment to the Plasma Supply Agreement to provide, 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 that is within a low double digit percentage of the price that 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, the Company and BPC entered into a Plasma Purchase Agreement (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, the Company and BPC entered into an amendment to the 2017 Plasma Purchase Agreement 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.

Post-marketing commitments

In connection with the approval of the BLA for BIVIGAM, on December 19, 2012 Biotest committed to perform two additional post-marketing studies, a pediatric study to evaluate the efficacy and safety of BIVIGAM in children and adolescents, and a post-authorization safety study to further assess the potential risk of hypotension and hepatic and renal impairment in BIVIGAM-treated patients with primary humoral immunodeficiency. These studies are still pending completion, as such ADMA has assumed the remaining obligations, and the costs of the studies will be expensed as incurred as research and development expenses. The Company currently expects both studies to be completed by the end of 2021. However, the timing of the completion of these studies is dependent upon the availability of BIVIGAM and the completion of the planned manufacturing process improvements.

In connection with the FDA's approval of ASCENIV on April 1, 2019, the Company is required to perform a pediatric study to evaluate the safety and efficacy of ASCENIV in children and adolescents. This study is required to be completed by June of 2023.

Employment contracts

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

Other commitments

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company's maximum exposure under these arrangements is unknown as of December 31, 2019. The Company does not anticipate recognizing any significant losses relating to these arrangements.

11. INCOME TAXES

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

	Year Ended December 31,	
	2019	2018
Benefit at U.S. federal statutory rate	$(10,138,657)	$(13,806,124)
State taxes - deferred	(2,010,517)	(1,443,538)
Increase in valuation allowance	11,790,031	(1,015,582)
Research and development credits	(115,086)	(223,735)
Decrease in federal net operating loss	—	12,090,203
Decrease in federal research and development credits	—	4,294,344
Other	474,229	104,432
Benefit for income taxes	$ —	$ —

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

	Year Ended December 31,	
	2019	2018
Federal and state net operating loss carryforwards	$ 42,496,374	$ 26,080,351
Federal and state research credits	630,516	525,248
Interest expense limitation carryforwards	—	1,159,422
Transaction costs	1,174,733	1,147,581
Deferred revenue	603,535	624,610
Accrued expenses and other	2,433,142	6,011,057
Total gross deferred tax assets	47,338,300	35,548,269
Less: valuation allowance for deferred tax assets	(47,338,300)	(35,548,269)
Net deferred tax assets	$ —	$ —

As of December 31, 2019, the Company had federal and state (post-apportioned basis) net operating losses (''NOLs'') of $175.1 million and $116.2 million, respectively, as well as federal research and development tax credit carryforwards of approximately $0.6 million. Approximately $115.8 million and $71.8 million of the foregoing federal and state NOLs, respectively, will expire at various dates from 2027 through 2037, if not limited by triggering events prior to such time. Under the provisions of the Internal Revenue Code, changes in ownership of the Company, in certain circumstances, would limit the amount of federal NOLs that can be utilized annually in the future to offset taxable income. In particular, Section 382 of the Internal Revenue Code imposes limitations on an entity's ability to use NOLs upon certain changes in ownership. If the Company is limited in its ability to use its NOLs in future years in which it has taxable income, then the Company will pay more taxes than if it were otherwise able to fully utilize its NOLs. The Company may experience ownership changes in the future as a result of subsequent shifts in ownership of the Company's capital stock that the Company cannot predict or control that could result in further limitations being placed on the Company's ability to utilize its federal NOLs. As of December 31, 2019, the Company performed a preliminary analysis of limitations imposed by Section 382 of the Internal Revenue Code and as a result has written off $57.6 million of federal NOLs, $4.3 million of federal research and development tax credits, and $10.9 million of state NOLs that are limited by historical ownership changes. As a result, there was a $16.9 million reduction to the Company's deferred tax assets. However, as discussed below, the Company maintains a full valuation allowance against its deferred tax assets. Therefore, the $16.9 million reduction to the Company's deferred tax assets is offset by a corresponding $16.9 million reduction to the Company's valuation allowance for its net deferred tax assets, resulting in no net impact to the Company's tax provision.

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

In accordance with U.S. GAAP, the Company is required to determine whether a tax position of the Company is more likely than not to be sustained upon examination by the applicable taxing authority, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit to be recognized is measured as the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. Derecognition of a tax benefit previously recognized could result in the

Company recording a tax liability that would reduce net assets. The amount of the liability for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position. Components of the liability are classified as either a current or a long-term liability in the accompanying consolidated balance sheets based on when the Company expects each of the items to be settled. The Company does not have any unrecognized tax benefits as of December 31, 2019 and 2018, and does not anticipate a significant change in unrecognized tax benefits during the next 12 months.

12. LEASE OBLIGATIONS

The Company leases certain properties and equipment for its ADMA Bio Centers subsidiary and certain equipment for its ADMA BioManufacturing subsidiary, which leases provide the right to use the underlying assets and require lease payments through the respective lease terms which expire at various dates through 2026. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

The Company determines if an arrangement is an operating lease at inception. Leases with an initial term of 12 months or less are not recorded on the balance sheet. All other leases are recorded on the balance sheet with assets representing the right to use the underlying asset for the lease term and lease liabilities representing the obligation to make lease payments arising from the lease. Right-to-use assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term and include options to extend or terminate the lease when they are reasonably certain to be exercised. The present value of the lease payments is determined using the Company's incremental borrowing rate as of the date of application of ASU 2016-02, or the lease commencement date. For the lease liabilities recognized upon the application of ASU 2016-02, the Company used a discount rate of 13% to determine the present value of its lease obligations. The Company's operating lease expense is recognized on a straight-line basis over the lease term and is reflected in Plasma center operating expenses and Selling, general and administrative expenses. Aggregate rent expense and cash paid for the Company's operating leases for the years ended December 31, 2019 and 2018 was $0.6 million and $1.1 million, respectively.

In connection with the adoption of ASU 2016-02 on January 1, 2019 (see Note 2), the Company recognized right to use assets of $1.4 million and lease liabilities of approximately $1.6 million. The right-to-use assets are reflected in Deposits and other assets in the accompanying consolidated balance sheet as of December 31, 2019. Including a finance lease the Company entered into in June 2018, the Company has aggregate lease liabilities of $1.5 million as of December 31, 2019, which are comprised primarily of the lease for the Company's plasma collection center in Kennesaw, GA and an administrative office lease in Roswell, GA related to the Company's ADMA Bio Centers subsidiary. The Company's operating leases have a weighted average remaining term of 5.9 years. Scheduled payments under the Company's lease obligations are as follows:

Year ended December 31, 2020	$ 407,792
2021	385,887
2022	382,287
2023	360,197
2024	313,015
Thereafter	293,897
Total payments	2,143,075
Less: imputed interest	(611,641)
Current portion	(229,073)
Balance at December 31, 2019	$1,302,361

During the year ended December 31, 2019, the Company entered into two new property leases where the Company intends to construct new plasma collection facilities. As of December 31, 2019, the Company had not taken possession of the leased property pertaining to either lease. The lease commencement date is February 1,

2020 for the first lease and the lease commencement date has not been determined for the second lease. With the exception of an advance deposit and an initial months' rent for each lease totaling approximately $41,000, no payments were made under these leases during the year ended December 31, 2019. The initial term of the first lease is for 130 months, with monthly rental payments varying between approximately $9,000 and $11,000, including common area maintenance charges. The initial term of the second lease is for 128 months with monthly rental payments varying between $11,000 and $14,000, including common area maintenance charges.

13. SEGMENTS

The Company is engaged in the manufacture, marketing and development of specialty plasma-derived biologics. The Company's ADMA BioManufacturing segment reflects the Company's immune globulin manufacturing and development operations in Florida, acquired on June 6, 2017. The Plasma Collection Centers segment consists of one FDA-licensed source plasma collection facility for the year ended December 31, 2019, and three FDA-licensed source plasma collection facilities for the year ended December 31, 2018 (see Note 3). The Corporate segment includes general and administrative overhead expenses. The Company defines its segments as those business units whose operating results are regularly reviewed by the chief operating decision maker (''CODM'') to analyze performance and allocate resources. The Company's CODM is its President and Chief Executive Officer. Summarized financial information concerning reportable segments is shown in the following tables:

Year Ended December 31, 2019

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 22,176,699	$ 7,029,550	$ 142,834	$ 29,349,083
Cost of product revenue	33,306,858	6,197,380	—	39,504,238
Loss from operations	(29,360,522)	(1,337,459)	(10,726,346)	(41,424,327)
Interest and other expense, net	(1,091,993)	13,521	(7,341,444)	(8,419,916)
Gain on transfer of plasma center assets	—	11,527,421	—	11,527,421
Loss on extinguishment of debt	—	—	(9,962,495)	(9,962,495)
Net (loss) income	(30,452,515)	10,203,483	(28,030,285)	(48,279,317)
Capital expenditures	3,772,742	39,096	—	3,811,838
Depreciation and amortization expense	2,789,498	455,412	13,238	3,258,148
Total assets	100,461,050	3,967,860	22,661,815	127,090,725

Year Ended December 31, 2018

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 6,797,548	$10,044,908	$ 142,834	$ 16,985,290
Cost of product revenue	35,485,273	6,709,362	—	42,194,635
Loss from operations	(45,633,715)	(4,470,073)	(10,185,156)	(60,288,944)
Interest and other expense, net	(1,077,624)	(967)	(4,375,910)	(5,454,501)
Net loss	(46,711,339)	(4,471,040)	(14,561,066)	(65,743,445)
Capital expenditures	1,580,684	514,916	—	2,095,600
Depreciation and amortization expense	2,608,776	814,768	22,854	3,446,398
Total assets	57,818,051	5,443,032	25,615,438	88,876,521

14. OTHER EMPLOYEE BENEFITS

The Company sponsors a 401(k) savings plan. Under the plan, employees may make contributions which are eligible for a Company discretionary percentage contribution as defined in the plan and determined by the Board of Directors. The Company recognized $0.7 million of related compensation expense for the years ended December 31, 2019 and 2018.

15. SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Supplemental cash flow information for the years ended December 31, 2019 and 2018 is as follows:

	2019	2018
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$8,112,231	$4,399,972
Noncash Financing and Investing Activities:		
Equipment acquired reflected in accounts payable and accrued liabilities	$ 514,904	$ 238,790
Equipment acquired through capital lease	$ —	$ 165,644
Warrants issued in connection with notes payable	$3,579,115	$ —

16. CONCENTRATIONS

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents and accounts receivable. At December 31, 2019, two customers accounted for 89% of the Company's total accounts receivable. At December 31, 2018, three customers accounted for approximately 95% of the Company's consolidated accounts receivable.

For the year ended December 31, 2019, three customers totaled 70% of the Company's consolidated revenues. For the year ended December 31, 2018, BPC represented 56% of the Company's consolidated revenues, and two other customers totaled 31% of the Company's consolidated revenues.

The Company purchases substantially all of its raw material plasma from Grifols. For the year ended December 31, 2019, plasma purchases from Grifols totaled approximately $28.6 million, representing approximately 82% of the Company's total inventory purchases. For the year ended December 31, 2018, plasma purchases from BPC totaled $7.8 million, or approximately 71% of the Company's total inventory purchases.

17. SUBSEQUENT EVENTS

Issuance of Common Stock

On February 11, 2020, the Company completed an underwritten public offering of 23,500,000 shares of its common stock for gross proceeds of $82.3 million. On February 21, 2020, the Company sold an additional 3,525,000 shares pursuant to the underwriters' exercise of their option to purchase additional shares of the Company's common stock for additional gross proceeds of $12.3 million. The Company received net proceeds, after underwriting discounts and other expenses associated with the offering, of approximately $88.5 million.

EXHIBIT INDEX

Exhibit No.	Description
2.1	Master Purchase and Sale Agreement, dated as of January 21, 2017, by and among Biotest Pharmaceuticals Corporation, ADMA BioManufacturing, LLC, ADMA Biologics, Inc., Biotest AG and Biotest US Corporation (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 23, 2017).
3.1	Second Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on August 23, 2019).
3.2	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 7, 2016).
4.1	Specimen Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Current Report on Form 8-K/A, filed with the SEC on March 29, 2012).
4.2	Warrant Agreement, dated December 21, 2012, issued by the Company to Hercules Technology Growth Capital, Inc. (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1, filed with the SEC on February 11, 2013).
4.3	Form of Warrant Agreement, dated May 13, 2016, issued by the Company to Oxford Finance LLC (incorporated herein by reference to Exhibit 4.6 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2016).
4.4	Warrant to Purchase Stock, dated October 10, 2017, issued by the Company to Marathon Healthcare Finance Fund, L.P. (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on October 11, 2017).
4.5	Warrant to Purchase Stock, dated February 11, 2019, issued by the Company to Perceptive Credit Holdings II, LP (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2019).
4.6	Note, dated February 11, 2019, issued by the Company to Perceptive Credit Holdings II, LP (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2019).
4.7*	Description of Capital Stock of ADMA Biologics, Inc.
10.1†	2007 Employee Stock Option Plan, as amended by Amendment No. 3 (incorporated herein by reference to Exhibit A to the Information Statement on Schedule 14C, filed with the SEC on October 29, 2012).
10.2†	Amended and Restated ADMA Biologics, Inc. 2014 Omnibus Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8, filed with the SEC on August 18, 2017).
10.3†	Amended and Restated Employment Agreement, dated January 29, 2019, by and between ADMA Biologics, Inc. and Adam Grossman (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 29, 2019).
10.4†	Amended and Restated Employment Agreement, dated January 29, 2019, by and between ADMA Biologics, Inc. and Brian Lenz (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on January 29, 2019).
10.5†	Amended and Restated Employment Agreement, dated January 29, 2019, by and between ADMA Biologics, Inc. and James Mond, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on January 29, 2019).
10.6+	Plasma Purchase Agreement, dated as of November 17, 2011, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc., as amended by First Amendment to Plasma Purchase Agreement, dated as of December 1, 2011, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc. (incorporated herein by reference to Exhibit 10.9 to Amendment No. 3 to the Company's Current Report on Form 8-K/A, filed with the SEC on June 22, 2012).

Exhibit No.	Description
10.6.1+	Second Amendment to Plasma Purchase Agreement, dated as of December 18, 2015, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc. (incorporated herein by reference to Exhibit 10.3.1 to the Company's Annual Report on Form 10-K, filed with the SEC on March 23, 2016).
10.6.2	Third Amendment to Plasma Purchase Agreement, dated as of April 8, 2016, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc. (incorporated herein by reference to Exhibit 10.3.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2016).
10.6.3	Fourth Amendment to Plasma Purchase Agreement, dated as of June 6, 2017, by and between Biotest Pharmaceuticals Corporation and ADMA Biologics, Inc. (incorporated herein by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).
10.6.4+	Fifth Amendment to Plasma Purchase Agreement, dated as of January 1, 2019, by and between Grifols Worldwide Operations Limited (as successor-in-interest to Biotest Pharmaceuticals Corporation) and ADMA Biologics, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 2, 2019).
10.7+	Plasma Supply Agreement, dated as of June 6, 2017, by and between ADMA BioManufacturing, LLC and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).
10.7.1+	Amendment #1 to the Plasma Supply Agreement, dated as of July 19, 2018, by and between Biotest Pharmaceuticals Corporation and ADMA BioManufacturing, LLC (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2018).
10.8+	Plasma Purchase Agreement, dated as of June 6, 2017, by and between ADMA BioManufacturing, LLC and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).
10.8.1+	Amendment to Plasma Purchase Agreement, dated as of July 19, 2018, by and between Biotest Pharmaceuticals Corporation and ADMA BioManufacturing, LLC (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2018).
10.9	Amended and Restated Agreement for Services, effective as of January 1, 2016, as amended, by and between ADMA Biologics, LLC and Areth LLC (incorporated herein by reference to Exhibit 10.18 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 12, 2016).
10.10	Lease, effective as of February 17, 2017, by and between Home Center Properties, LLC and ADMA Bio Centers Georgia Inc. (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K, filed with the SEC on February 24, 2017).
10.11	Purchase Agreement, dated as of June 6, 2017, by and among the Company, Biotest Pharmaceuticals Corporation and ADMA Bio Centers Georgia, Inc. (incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).
10.12	Agreement to Transfer Land, dated as of July 20, 2018, by and among Biotest Real Estate Corp., Biotest AG, Biotest Pharmaceuticals Corporation, ADMA BioManufacturing, LLC and the Company (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on July 24, 2018).
10.13	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K, filed with the SEC on February 13, 2012).
10.14	Subordinated Loan Agreement, dated as of June 6, 2017, by and among the Company, ADMA BioManufacturing, LLC and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 12, 2017).

Exhibit No.	Description
10.15	Assignment and Assumption Agreement (ADMA Loan), dated as of July 20, 2018, by and among Biotest AG, Biotest Pharmaceuticals Corporation, ADMA BioManufacturing, LLC and the Company (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 24, 2018).
10.16	Credit Agreement and Guaranty, dated as of February 11, 2019, by and among the Company, ADMA Plasma Biologics, Inc., ADMA Bio Centers Georgia Inc., ADMA BioManufacturing, LLC, and Perceptive Credit Holdings II, LP. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2019).
10.17	Security Agreement, dated as of February 11, 2019, by and among the Company, ADMA Plasma Biologics, Inc., ADMA Bio Centers Georgia Inc., ADMA BioManufacturing, LLC, and Perceptive Credit Holdings II, LP. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2019).
10.18+	License Agreement, effective as of December 31, 2012, by and between ADMA Biologics, Inc. and Biotest AG (incorporated herein by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1, filed with the SEC on February 11, 2013).
10.18.1	First Amendment to License Agreement, dated as of June 6, 2017, by and between the Company and Biotest AG (incorporated herein by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).
10.19+	Manufacturing Agreement, dated as of September 30, 2011, by and between ADMA BioManufacturing, LLC (as successor-in-interest to Biotest Pharmaceuticals Corporation) and Sanofi Pasteur S.A. (incorporated herein by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K, filed with the SEC on March 29, 2018).
10.19.1+	Amendment #2 to the Manufacturing Agreement, effective as of August 1, 2016, by and between ADMA BioManufacturing, LLC (as successor-in-interest to Biotest Pharmaceuticals Corporation) and Sanofi Pasteur S.A. (incorporated herein by reference to Exhibit 10.24.1 to the Company's Annual Report on Form 10-K, filed with the SEC on March 29, 2018).
10.19.2+	Amendment #3 to the Manufacturing Agreement, effective as of December 21, 2017, by and between ADMA BioManufacturing, LLC and Sanofi Pasteur S.A. (incorporated herein by reference to Exhibit 10.24.2 to the Company's Annual Report on Form 10-K, filed with the SEC on March 29, 2018).
10.20	Stockholders Agreement, dated as of June 6, 2017, by and between the Company and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on June 12, 2017).
10.21+	Transition Services Agreement, dated as of June 6, 2017, by and between ADMA BioManufacturing, LLC and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2017).
10.22+	Transition Services Agreement, dated as of January 1, 2019, by and between the Company and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2019).
10.23	Share Transfer, Amendment and Release Agreement, dated as of May 14, 2018, by and among the Company, ADMA BioManufacturing, LLC, ADMA Bio Centers Georgia Inc., Biotest Pharmaceuticals Corporation, Biotest AG, The Biotest Divestiture Trust and Biotest US Corporation (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2018).
10.24++	Amendment #1 to Transition Services Agreement, dated as of August 29, 2019, by and between ADMA BioManufacturing, LLC and Biotest Pharmaceuticals Corporation (incorporated by reference from Exhibit 10.1 to Current Report on Form 8-K, filed on September 5, 2019).
10.25*	Amendment 1 to the Amended and Restated Agreement for Services, effective as of September 25, 2017, by and between ADMA Biologics, LLC and Areth LLC.
10.26*	Amendment 2 to the Amended and Restated Agreement for Services, effective as of September 27, 2018, by and between ADMA Biologics, LLC and Areth LLC.

Exhibit No.	Description
10.27*	Amendment 3 to the Amended and Restated Agreement for Services, effective as of November 7, 2019, by and between ADMA Biologics, LLC and Areth LLC.
21.1*	Subsidiaries of the Company.
23.1*	Consent of CohnReznick LLP.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from ADMA Biologics, Inc. Form 10-K for the year ended December 31, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at December 31, 2019 and December 31, 2018, (ii) Consolidated Statements of Operations for the years ended December 31, 2019 and 2018 (iii) Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2019 and 2018, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018; and (v) Notes to Consolidated Financial Statements.

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

++ Portions of this exhibit and the schedules thereto have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

* Filed herewith.

** Furnished herewith.

† Management compensatory plan, contract or arrangement.

CORPORATE INFORMATION

BOARD OF DIRECTORS

Steven A. Elms, Chairman of the Board
Managing Partner, Aisling Capital

Dr. Jerrold B. Grossman, Founder and Vice Chairman of the Board
Founder and President, GenesisBPS
Founder and CEO, Technomed, Inc.

Bryant E. Fong, Director
Founding Managing Director and General Partner, Biomark Capital Fund

Dov A. Goldstein, M.D., Director
Private Investor

Lawrence P. Guiheen, Director
CEO Wellmond LLC

Adam S. Grossman, Founder, Director

MANAGEMENT TEAM

Adam S. Grossman
Founder, President and CEO

Brian Lenz, CPA
Executive Vice President, CFO

James Mond, M.D., Ph.D.
Executive Vice President, CSO & CMO

CODE OF ETHICS

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

CORPORATE HEADQUARTERS

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FLORIDA CAMPUS

5800 & 5900 Park of Commerce Blvd NW
Boca Raton, FL 33487
Phone: (561) 989-5799
Fax: (561) 989-5890

COMMON STOCK TRADING

The Company’s common stock trades on the Nasdaq Global Market under the symbol "ADMA".

ANNUAL MEETING OF STOCKHOLDERS

The Company’s Annual Meeting of Stockholders will be held virtually at 10AM ET on June 18, 2020 via webcast through the link www.virtualshareholdermeeting.com/ADMA2020.

INVESTOR RELATIONS

For additional information, please contact our Investor Relations Department at (201) 478-5552 or via email at: IR@admabio.com.

INDEPENDENT AUDITORS

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4 Becker Farm Road
Roseland, NJ 07068
Phone: (973) 228-3500

TRANSFER AGENT

Continental Stock Transfer & Trust Company
1 State Street, 30th Floor
New York, NY 10004
Phone: (800) 509-5586
www.continentalstock.com

LEGAL COUNSEL

Morgan, Lewis & Bockius LLP
502 Carnegie Center
Princeton, NJ 08540
Phone: (609) 919-6600

OUR VALUES

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

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

DYNAMIC
We are relentless in transforming groundbreaking science into meaningful action.

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

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

Company Profile

ADMA Biologics is an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and others at risk for certain infectious diseases. ADMA currently manufactures and markets three United States Food and Drug Administration (FDA) approved plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases: ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) for the treatment of primary humoral immunodeficiency (PI); BIVIGAM® (immune globulin intravenous, human) for the treatment of PI; and Nabi-HB® (hepatitis B immune globulin, human) to provide enhanced immunity against the hepatitis B virus. ADMA's mission is to manufacture, market and develop specialty plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases and management of immune compromised patient populations who suffer from an underlying immune deficiency, or who may be immune compromised for other medical reasons. ADMA has received U.S. Patents: 9,107,906, 9,714,283, 9,815,886, 9,969,793 and 10,259,865 related to certain aspects of its products and product candidates.

ADMA manufactures its immune globulin products at its FDA-licensed, 400,000-liter annual capacity plasma fractionation and purification facility located in Boca Raton, Florida. Through its ADMA BioCenters subsidiary, ADMA also operates as an FDA-approved source plasma collector in the U.S., which provides a portion of its blood plasma for the manufacture of its products.

For more information, please visit www.admabiologics.com.

Cautionary Statement regarding forward-looking information

This annual report contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 about ADMA Biologics, Inc. ("ADMA"). Forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "project," "continue," "will," or the negative thereof, or other variations or comparable terminology, although some forward-looking statements are expressed differently. The forward-looking statements included herein represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. These statements include statements about our ability to manufacture BIVIGAM on a commercial scale and commercialize this product as a result of the approval of the Prior Approval Supplement for BIVIGAM by the U.S. Food and Drug Administration ("FDA") on May 9, 2019; our ability to manufacture ASCENIV on a commercial scale and commercialize this product as a result of the FDA approval of ASCENIV's Biologics License Application on April 1, 2019; our plans to develop and expand our commercial infrastructure and to manufacture and commercialize our current 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, and the labeling or nature of any such approvals; the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals for our product candidates; our dependence upon third-party manufacturers and vendors and their compliance with applicable regulatory requirements; our ability to obtain adequate quantities of FDA-approved source plasma with proper specifications; our plans to increase our supplies of source plasma, which include plasma collection center expansion and reliance of third-party supply agreements as well as any extensions to such agreements; the potential indications for our products and product candidates; potential investigational new product applications; the acceptability of any of our products, including Nabi-HB, BIVIGAM and ASCENIV, for any purpose, including FDA-approved indications, by physicians, patients or payers; our plans to evaluate the clinical and regulatory paths to grow the ASCENIV franchise through expanded FDA-approved uses; Federal, state and local regulatory and business review processes, timing and Company compliance with such governmental and regulatory agencies of our business and regulatory submissions; concurrence by the FDA with our conclusions concerning our products and product candidates; the comparability of results of our hyperimmune and immune globulin products to other comparably run hyperimmune and immune globulin clinical trials; the potential for ASCENIV and BIVIGAM to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease, Primary Humoral Immunodeficiency Disease ("PIDD" or "PI") or other immune deficiencies or any other condition for which the products may be prescribed or evaluated; 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; our intellectual property position and the defense thereof, including our expectations regarding the scope of patent protection with respect to ASCENIV or other future pipeline product candidates; our manufacturing capabilities, third-party contractor capabilities and vertical integration strategy; our plans related to the expansion of our manufacturing capacity, yield improvements, supply chain robustness, distribution and other collaborative agreements and the success of such endeavors; our estimates regarding revenues, expenses, capital requirements, timing to profitability and the need for and availability of additional financing; possible or likely reimbursement levels for our currently marketed products; estimates regarding market size, projected growth and sales of our existing products as well as our expectations of market acceptance of ASCENIV and BIVIGAM; future domestic and global economic conditions or performance; and expectations for future capital requirements. In addition, our current expectations and assumptions could materially differ from our future results as a result (directly and indirectly) of any global health occurrences and emergencies, including COVID-19. 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. Forward-looking statements are subject to many risks, uncertainties and other factors that could cause our actual results, and the timing of certain events, to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, the risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.

ADMA BIOLOGICS

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