ADMA BIOLOGICS

ADVANCED THERAPIES FOR THE IMMUNE COMPROMISED

2020 ANNUAL REPORT

ADMA BIOLOGICS

BECAUSE PATIENTS ARE COUNTING ON US

To Our Valued Stockholders:

The 2020 pandemic was unprecedented and difficult for many. I am, however, pleased to report that our dedicated ADMA team members delivered on their commitments to stockholders, customers and most importantly the patients who were treated with our life saving plasma-derived therapeutics.

Despite the pandemic-induced adversity that our industry and the world faced, 2020 was a year of many achievements for ADMA, which included record revenue, expansion of our plasma collection center network and delivering on all of our manufacturing and regulatory objectives as a part of our supply chain enhancement initiatives. Our strong commercial execution during the year allowed us to provide first-time peak revenue guidance of $250 million or more expected to be achieved in 2024 and additionally enabled us to confidently commit to achieving profitability by no later than the first quarter of 2024. Moreover, we proudly achieved these operational milestones while acting decisively to enact all the medically recommended safeguards and operating protocols for our patients, employees and customers, which we believe will enable our Company to continue to effectively navigate pandemic-related headwinds in the periods ahead.

2020: A Foundational Year for ADMA Biologics

In the first full calendar year of commercial launch of our two Intravenous Immune Globulin ("IVIG") products, BIVIGAM® and ASCENIV®, ADMA executed on its operating strategy and significantly strengthened the Company's balance sheet. ADMA generated 2020 total revenues of $42.2 million, representing a substantial 44% increase over 2019. The Company additionally ended 2020 with $81.5 million of inventories compared to $53.1 million of inventories for 2019, which we believe provides a solid basis to support our anticipated quarter-over-quarter revenue growth in 2021 and beyond. During the year, the Company refinanced its senior secured term loan, which among other things, lowered our overall effective cost of capital, consolidated our previously subordinated debt and importantly provided for a two-year extension of the interest-only period through March 2024, which we believe will allow ADMA to reach profitability prior to maturity.

At ADMA, we believe it is incumbent upon healthcare companies like ours to strive to further serve patients and society during extraordinary situations like the COVID-19 pandemic. Accordingly, we proudly contributed to the collaborative efforts of the CoVIg-19 plasma alliance, an unprecedented industry partnership formed in response to the global COVID-19 pandemic. We additionally developed the ImmunoRank™ Neutralization MICRO-ELISA to detect the presence and levels of SARS-CoV-2 neutralizing antibodies.

I am extremely proud of the entire ADMA Biologics organization and wish to recognize their invaluable efforts, hard work and dedication. Our team's 2020 success was further recognized in the form of several third-party accolades, including receiving the BioNJ Innovator of the Year award, inclusion on the Deloitte Fast 500 list as well as in 2021 our CEO being voted a Top 10 Biotech CEO by Healthcare Technology Report. It is our employees' unified and unwavering commitment that enabled all of our achievements during 2020. The totality of our 2020 accomplishments places our Company in a strong position to execute on our ongoing operating targets and advance towards our goals of generating substantial revenues and profitability.

2021: Continuing Commercial Execution and Progressing Towards Vertical Integration

We expect 2021 to be defined by continued commercial execution in addition to a series of value-creating FDA decisions during the year across all business segments.

These anticipated FDA decisions include: increased IVIG production capacity scale, in-house capabilities with our Vanrx aseptic fill-finish machine, and the expansion of our plasma center collection network. Upon FDA approval, ADMA expects to realize significant operating efficiencies and improved gross margins beginning potentially as early as mid-2021, which will ultimately support durable profitability with enhanced in-house control of our most critical manufacturing and operating functions.

ADMA enters 2021 from a position of operational strength across its value chain, within its immune globulin end-markets and in the context of our improving financial position and asset value. We look forward to executing on all of our commitments in 2021, and in doing so, we anticipate creating meaningful value for our stockholders.

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 and we wish you health and safety during these unprecedented times.

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, 2020**

☐ **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	Trading Symbol	Name of each exchange on which registered
Common stock, par value $0.0001 per share	ADMA	**Nasdaq Global Market**
Preferred Share Purchase Right	-	**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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

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 common stock held by non-affiliates was $184,142,642 as of June 30, 2020 (the last business day of the registrant's most recently completed second fiscal quarter), based on a total of 62,847,318 shares of common stock held by non-affiliates and a closing price of $2.93 as reported on the Nasdaq Global Market on June 30, 2020.

As of March 16, 2021, there were 121,275,357 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," 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 continue as a going concern;
- our ability to manufacture BIVIGAM and ASCENIV on a commercial scale and commercialize these products as a result of their approval by the U.S. Food and Drug Administration (the "FDA") in 2019;
- our plans to develop, manufacture, market, launch and expand our commercial infrastructure 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 our third-party customers and vendors and their compliance with applicable regulatory requirements;
- our belief that we have addressed the delays experienced with final drug product Good Manufacturing Practices ("GMP") release testing by our third-party vendors by adding additional release testing laboratories to our FDA-approved consortium listed in our drug approval documents;
- our ability to obtain adequate quantities of FDA-approved plasma with proper specifications;
- our plans to increase our supplies of source plasma, which include plasma collection center expansion, our ability to obtain and maintain regulatory compliance and receive FDA approvals of new plasma collection centers and reliance on 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 BIVIGAM, ASCENIV and Nabi-HB, 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 and timing by 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 or 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 and efficiencies of our manufacturing capacity, yield improvements, supply-chain robustness, in-house fill-finish capabilities, 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;
- effects of the coronavirus COVID-19 pandemic on our business, financial condition, liquidity and results of operations, and our ability to continue operations in the same manner as previously conducted prior to the macroeconomic effects of the COVID-19 pandemic;
- 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 "BIVIGAM®," "ASCENIV™" 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 BioCenters Georgia Inc., a Delaware corporation ("ADMA BioCenters") 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 and commenced commercial sales in August 2019; (ii) ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), 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. pneumoniae*. 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 these products at our 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 and our ongoing supply chain enhancement and capacity expansion initiatives, we believe this facility has the potential to produce quantities of our immune globulin ("IG") products of more than $250 million in annual revenue beginning in 2024 as well as achieving profitability during the first quarter of 2024, as we ramp-up production over the next three to five years.

Through our ADMA BioCenters subsidiary, we currently operate as an FDA-approved source plasma collection organization in the U.S. This business unit, which we refer to as our Plasma Collection Centers business segment, provides us with a portion of our blood plasma for the manufacture of our products and product candidates, and also allows us to sell certain quantities of source plasma to customers for further manufacturing. As a part of our planned supply chain robustness initiative, we opened two new plasma collection centers during 2020, and we now have seven plasma collection centers in various stages of development and approval, including three that are fully operational and collecting plasma. With respect to our fully operational plasma collection centers, two hold FDA licenses and the third has a Biologics License Application ("BLA") pending an FDA decision expected in the fourth quarter of 2021. In addition, one of our FDA-approved plasma collection centers also has approvals from the Korean Ministry of Food and Drug Safety ("MFDS"), as well as FDA approval to implement a Hepatitis B immunization program. After giving effect to the progress we made in 2020 with our plasma collection network expansion, we believe we remain on track to achieve our goal of having 10 or more plasma collection centers in operation by 2024. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase and market conditions at the time of sale. Plasma collected from ADMA BioCenters' 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 sell plasma-derived intermediate fractions to certain customers, which are generated as part of our FDA-approved manufacturing process for IG and 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 and testing services for certain third-party clients.

We also provide laboratory contracting services to certain customers and anticipate providing contract filling, labeling and packing services upon FDA approval and implementation of our in-house fill-finish capabilities through our Vanrx SA25 Workcell aseptic filling machine.

Recent Developments

On August 5, 2020, we entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC ("Jefferies"), pursuant to which we could offer and sell, from time to time, at our option, through or to Jefferies, up to an aggregate of $50 million of shares of the Company's common stock (see "Liquidity and Capital Resources"). On November 5, 2020, we and Jefferies amended the Sale Agreement to provide for an increase in the aggregate offering amount under the Sale Agreement such that, as of November 5, 2020, the Company could sell shares having an additional aggregate offering price of up to $20 million. On February 3, 2021, we entered into an additional amendment to the Sale Agreement to provide for an additional increase in the aggregate offering amount under the Sale Agreement to allow us to sell shares having an additional aggregate offering price of up to $35.4 million.

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.

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 commence commercial sales of this product in the United States. We resumed production of BIVIGAM during the fourth quarter of 2017 and commercial production is ongoing, using our FDA-approved IVIG manufacturing process under FDA License No. 2019. Commercial sales for this product 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 FDA License No. 2019 using a process known as fractionation. The Centers for Medicare and Medicaid Services ("CMS") has issued a permanent, product-specific J-code for ASCENIV. Under the Healthcare Common Procedure Coding System ("HCPCS"), the J-code (J1554) will become effective April 1, 2021 and will replace the currently issued C-code for ASCENIV (C9072), which can continue to be utilized in the interim for reimbursement purposes. 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 antibody titers to respiratory syncytial virus ("RSV") using our proprietary microneutralization testing assay. We are able to identify the high titer or "hyperimmune" plasma that meets our internal and required specifications for ASCENIV with our patented testing methods and 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 Primary Immune Deficiency Disorder ("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 or potentially other respiratory viral pathogens. 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. The FDA approved Nabi-HB on March 24, 1999. 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 we continue to manufacture Nabi-HB under FDA License No. 2019. We are currently working on bringing fill-finish capabilities for Nabi-HB in-house and anticipate a potential FDA decision during 2021.

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 $8.1 billion in 2019 and are expected to reach approximately $13.9 billion in 2025 based upon an anticipated compounded annual growth rate of approximately 11%.

ASCENIV, formerly known as RI-002, 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.

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 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 suffering with RSV 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 or other respiratory viral pathogens in immunocompromised patients.

Plasma Collection Operations

ADMA BioCenters has seven source plasma collection facilities in various stages of operations or development. We are actively operating and collecting plasma at three source plasma collection facilities located in the U.S., two of which have an FDA license (of which one facility has received approvals from MFDS and FDA approval to implement a Hepatitis B immunization program), while a BLA for our third facility is pending FDA approval. In addition, we have four additional plasma collection facilities that are under various stages of construction and development. Source plasma that is collected from our FDA-licensed facilities provides us with a portion of our blood plasma for the manufacture of our products and product candidates. After giving effect to the progress we made in 2020 with our plasma collection network expansion, we believe we remain on track to achieve our goal of having 10 or more plasma collection centers operating in the U.S. by 2024. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase, and market conditions at the time of sale. Plasma collected from ADMA BioCenters' 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 BPC Plasma, Inc. (formerly Biotest Pharmaceuticals Corporation ("BPC"), 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.

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**. Subject to the restrictions surrounding COVID-19, 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. We have implemented and continue to implement virtual customer engagement programs to adapt and change with the current restrictions in place due to COVID-19.

- **Increase marketing efforts around Nabi-HB.** Subject to the restrictions surrounding COVID-19, we plan to increase our marketing efforts and attend relevant virtual or in-person medical conferences during 2021, 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 potentially 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 or other potential respiratory viral pathogens.

- **Increase the Boca Facility's manufacturing capacity, operating efficiency and gross margins.**During 2021, we plan to execute on the capacity optimization efforts we put in place during 2020 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. During 2020, we successfully implemented several manufacturing and supply chain enhancements, including the purchase and installation of a new Vanrx SA25 Workcell aseptic filling machine. Both the capacity expansion and fill finish projects are pending FDA approval, which is anticipated to occur in the middle of 2021.

- **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 our plasma collection center network**. We plan on expanding our plasma collection network with the goal of having 10 or more plasma collection facilities operating in the U.S. by 2024 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, contract testing 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 2019 was $8.1 billion and is expected to grow to $13.9 billion by 2025 based upon a compounded annual growth rate of 11%.

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 900 plasma donation centers in the U.S. As noted in a variety of plasma industry trade reports and related conferences, approximately 45 million liters of source plasma were collected in the U.S. in 2019. 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 $50 to $100 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 to potentially expand the label for our existing products.

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 $8.1 billion in 2019, and are expected to reach approximately $13.9 billion in 2025 based upon an 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 of Our Products

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. 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 900 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-approved 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, which 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. During 2020, we successfully implemented several manufacturing and supply chain enhancements, including the purchase and installation of a new Vanrx SA25 Workcell aseptic filling machine and the manufacturing of four conformance batches of BIVIGAM at an increased scale. These initiatives are designed to reduce operating costs, improve margins and provide for faster production cycle turnaround time, ultimately providing increased control and independence from third-party vendors and contractors. ADMA submitted the appropriate applications to the FDA during the fourth quarter of 2020 and upon FDA approval expects to begin benefitting from these initiatives as early as mid-2021.

ADMA BioCenters operates two 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. We also have a third plasma collection facility where we currently collect plasma for which a BLA is pending with the FDA. In addition, we have four additional plasma collection facilities that are under various stages of construction and development. After giving effect to the progress we made in 2020 with our plasma collection network expansion, we believe we remain on track to achieve our goal of having 10 or more plasma collection centers in operation by 2024. In addition, we intend to enter into additional third-party contracts to procure normal source and high-titer plasma.

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 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 two additional 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.

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 servicing both acute and ambulatory infusion centers and the home health infusion setting 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.

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 expanding our current specialty sales force consisting 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.

Subject to restrictions surrounding the COVID-19 pandemic, 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. In addition, we have been 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

Pursuant to our Manufacturing, Supply and License Agreement effective as of January 21, 2017, 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.

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. BIVIGAM and Nabi-HB 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. CMS has issued a permanent, product-specific-J-code for ASCENIV. Under the HCPCS, the J-code (J1554) will become effective April 1, 2021 and will replace the currently issued C-code for ASCENIV (C9072), which can continue to be utilized in the interim for reimbursement purposes.

Major Customers

For the year ended December 31, 2020, three customers, BioCARE, Inc. ("BioCare"), Reliance Life Sciences Pvt Limited ("Reliance") and Biolife Plasma Services, L.P. ("Biolife"), represented an aggregate of 82% of our consolidated revenues.

As of December 31, 2020, three customers, BioCare, Reliance and Priority Healthcare Distribution, Inc. ("Curascript"), represented a total of 92% of our consolidated accounts receivable.

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 existing regulatory approvals or a better understanding of the local regulatory process, allowing them to market their products more quickly. Moreover, plasma therapy generally faces competition from non-plasma products and other courses of treatments. For example, recombinant Factor VIII products compete with plasma-derived products in the treatment of Hemophilia A.

Intellectual Property

We rely on a combination of patents, patent applications, copyrights and trademarks, as well as contracts, such as confidentiality, material data transfer, license and invention assignment agreements, to protect our intellectual property rights. We also rely upon trade secret laws to protect unpatented know-how and advancing technological innovation.

We have intellectual property (patents, know-how, etc.) related to our immunotherapeutic compositions, manufacturing processes, immunotherapeutic treatment, and related methods and formulations.

Patents related to our immune globulin product ASCENIV include U.S. Patent No. 9,107,906, which covers compositions comprising pooled plasma, as well as immunoglobulin prepared therefrom, that contains a standardized, elevated titer of RSV neutralizing antibodies and elevated levels of antibodies specific for one or more other respiratory pathogens, as well as methods of making and using the compositions. U.S. Patent Nos. 9,714,283, 9,815,886, 9,969,793 and 10,683,343, encompassing immunotherapeutic compositions and immunotherapeutic methods proprietary to us, also relate to ASCENIV. Corresponding foreign patents and patent applications also pertain to this technology.

We also hold intellectual property, including patents and patent applications, related to immunotherapeutic compositions and immunotherapeutic methods for the treatment and prevention of *S. pneumonia* infection. U.S. Patent No. 10,259,856, issued in April 2019, pertains to various aspects of this technology. Additional U.S. and numerous corresponding foreign patent applications also relate to this technology.

We continue to prepare, file, and prosecute patent applications to provide broad and strong protection of our proprietary rights, including applications focused on existing and future products.

We 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-approved facility) of product in accordance with good manufacturing practices ("cGMP") to be used in the clinical trials and providing manufacturing information needed 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.

Prior to commencing the first clinical trial at a United States investigational site, we must submit manufacturing and analytical data, pre-clinical data from studies conducted in accordance with Good Laboratory Practices ("GLPs"), and clinical trial plans, 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. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance.

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, and must be conducted with product meeting cGMPs.

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. Before approving a marketing application, the FDA typically will inspect the facility or facilities where the product is manufactured, referred to as a Pre-Approval Inspection, as well as one or more clinical trial sites.

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 Complete Response Letter ("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. Even if the FDA approves a product, it may limit the approved indications or populations for use of the product, require that contraindications, warnings, or precautions be included in the product labeling, including a boxed warning, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may also not approve label statements that are necessary for successful commercialization and marketing. Products may be marketed only for the FDA-approved indications and in accordance with the FDA-approved label. The FDA 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, 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, list the manufactured products, 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. Recently, the information that must be submitted to FDA regarding manufactured products was expanded through the Coronavirus Aid, Relief, and Economic Security ("CARES)" Act to include the volume of drugs produced during the prior year. 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 and other agency regulations, guidance, and policies are often revised or reinterpreted in ways that may significantly affect our business and our product candidates. It is impossible, especially in light of the recent change to the U.S. administration, to predict whether further legislative or FDA regulation or other regulatory policy changes will be enacted or implemented and what the impact of such changes, if any, may be. It is possible that certain prior regulatory requirements may be postponed or frozen.

Regulation of ADMA BioCenters

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

Blood plasma collection and manufacturing centers are also subject to the Clinical Laboratory Improvement Amendments, 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 BioCenters facilities are currently in compliance with state and industry standards. Delays in obtaining, or failures to maintain, regulatory approvals for any facilities operated by ADMA BioCenters would harm our business. In addition, we cannot predict what adverse federal and state regulations and industry standards may arise in the future.

Foreign Regulation

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

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

Product Coverage, Pricing and Reimbursement

Significant 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, limitations on coverage, 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. By further example, on November 27, 2020, CMS issued an interim final rule implementing a Most Favored Nation payment model under which reimbursement for certain Medicare Part B drugs and biologicals will be based on a price that reflects the lowest per capita Gross Domestic Product-adjusted (GDP-adjusted) price of any non-U.S. member country of the Organisation for Economic Co-operation and Development (OECD) with a GDP per capita that is at least sixty percent of the U.S. GDP per capita. These and any additional healthcare reform measures could further constrain our business or limit the amounts that federal and state governments will pay for healthcare products and services, which could result in additional pricing pressures. 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.

Federal price reporting laws also require manufacturers to calculate and report complex pricing metrics used to determine prescription rebates, ceiling prices charged, and provider reimbursement under the Medicaid Drug Rebate Program, Medicare Parts B and D, the Veterans Healthcare Act programs, the 340B program, and the Tricare Retail Rebate program. Various state health care programs similarly obligate us to report drug pricing information that is used as the basis for their reimbursement of pharmacies and other health care providers and the negotiation of supplemental rebates. Payment for a manufacturer's drugs by these programs is conditioned on submission of this pricing information. Recently, the Part D Medicare coverage gap rebate manufacturer percentage increased to 70%. Rebates under these programs can also increase when commercial prices increase. Failure to comply with the rules for calculating and submitting pricing information or otherwise overcharging the government or its beneficiaries may result in criminal, civil, or administrative sanctions or enforcement actions, and expose us to U.S. False Claims Act, or the False Claims Act, liability.

Employees

As of December 31, 2020, we had a total of 407 employees, comprised of 406 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 BioCenters. ADMA BioManufacturing was formed in January 2017 to facilitate the acquisition of BTBU. ADMA BioCenters 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

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Form 10-K and our other filings with the SEC, before making an investment decision regarding our common stock.

- 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.
- Our auditor's report contains a going concern statement.
- We are currently not profitable and may never become profitable.
- The COVID-19 pandemic and efforts to reduce its spread has significantly affected worldwide economic conditions, and could have a material adverse impact on our business, liquidity, financial condition and results of operations, as well as a change to the overall market size and potential for our products.
- 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.

- The estimates of market opportunity and forecasts of market and revenue growth included in our filings 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.
- Both of our business segments and our facilities are subject to periodic inspections by the FDA, which, depending on the outcome of such inspection, could result in certain FDA actions, including the issuance of observations, notices, citations or warning letters.
- Business interruptions could adversely affect our business.
- 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.
- 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.
- 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.
- 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 and FDA could require clinical trials beyond what we may deem to be reasonable. Unless additional clinical trials are successfully conducted and the FDA approves a BLA or other required submission for review, we may not be authorized to market ASCENIV for any other indication.
- With the approval to market ASCENIV, BIVIGAM and Nabi-HB, 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.
- We depend on third-party researchers, developers and vendors to develop, manufacture, supply materials or test products and product candidates, and such parties are outside of our control.
- We may be unable to successfully expand our manufacturing processes to fulfill demand for our products or increase our production capabilities through the addition of new equipment, including if we do not obtain requisite approval from the FDA.
- 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.
- 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.
- 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.
- 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.
- 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 ADMA BioCenters 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.

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

- 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.

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

- 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.

- 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.

- We require additional funding and may be unable to raise capital in the future, which would force us to delay, curtail or eliminate one or more of our research and development programs or potentially modify our ongoing operations, commercialization efforts and expansion plans, as well as impact the overall business plan for the organization.

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

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.

Prior to the second half of 2019, we generated a substantial portion of our revenues from the sale of plasma by our plasma collection facilities. Following completion of the Biotest Transaction in June 2017, we began generating revenues from the sale of our plasma-derived immune globulins which include: BIVIGAM, ASCENIV, Nabi-HB, 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 we commenced commercial sales of this product 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. In addition, our end-to-end production cycle from procurement of raw materials to commercial release of finished product can take between seven and 12 months or potentially longer, requiring substantial investments in raw material plasma and other manufacturing materials.

We currently anticipate, based upon our projected revenue and expenditures, as well as the additional proceeds we expect to receive in connection with sales of our common stock pursuant to the Sale Agreement (as amended to date), that our current cash, cash equivalents and accounts receivable, will be sufficient to fund our operations into the fourth 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 anticipate that we will not be able to generate a sufficient amount of product revenue to achieve profitability until the beginning of 2024 and, as a result, we anticipate that we will need 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 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.

In addition, the auditor's report on our financial statements for the year ended December 31, 2020 includes a going concern paragraph. To date, our products have not generated significant revenue. As a result, we have suffered recurring losses and require significant additional cash resources to execute our business plan. These losses are expected to continue for an extended period of time. These factors raise substantial doubt about our ability to continue as a going concern beyond one year from the date of filing this Annual Report on Form 10-K. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern within one year after the date the financial statements are issued.

We recognize that we will need to raise additional capital in order to continue to execute our business plan in the future. Historically, the major source of our cash has been from proceeds from various public and private offerings of our common stock. The actual amount of cash that we will need is subject to many factors. There can be no assurances that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to us or that we will become profitable and generate positive operating cash flow. If we are unable to raise sufficient additional funds, we will have to scale back our operations.

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 flows into fiscal 2022, and we may never achieve or maintain profitability. For the years ended December 31, 2020 and 2019, we incurred net losses of $75.7 million and $48.3 million, respectively. From our inception in 2004 through December 31, 2020, we have incurred an accumulated deficit of $340.5 million. We expect that we will not be able to generate a sufficient amount of product revenue to achieve profitability until the beginning of 2024 and, as a result, we expect that we will need to continue 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. These factors raise substantial doubt about our ability to continue as a going concern. Our failure to achieve or maintain profitability could negatively impact the value of our securities.

The COVID-19 pandemic and efforts to reduce its spread has significantly affected worldwide economic conditions, and could have a material adverse impact on our business, liquidity, financial condition and results of operations

The COVID-19 pandemic has the potential to adversely impact several aspects of each of our business segments, our commercial manufacturing operations and plasma collection facilities, including but not limited to potential disruptions to our supply-chain operations, including procurement of raw materials and packaging materials, a portion of which are sourced internationally, and the testing of finished drug product that is required prior to its availability for commercial sale. Such testing has historically been performed by contract laboratories outside the United States. While we do not believe that the COVID-19 pandemic has significantly affected operations and immunoglobulin production at our Boca Facility or our ADMA BioCenters plasma collection operations at this time, we may experience adverse effects in the future, particularly in light of the recent increase in COVID-19 cases in the State of Florida. For example, our employees becoming ill, the imposition of additional mandatory remote working environments and federal, state and local responses to the pandemic could materially affect the efficiency and pace of our operations and manufacturing at our Boca Facility. Employee or donor illness, if not properly managed, could also impact the quality of our products and product candidates. In addition, travel and other restrictions that have been implemented in the United States could impact our commercial efforts with respect to any of our products, including BIVIGAM and ASCENIV, as trade shows, industry and medical conferences and other events we had been planning to utilize and exhibit and attend with our staff to increase awareness of our products by physicians and payers are subject to limitations, rescheduling or outright cancellation in response to the pandemic. Also, due to previous state and local "shelter-in-place" orders, as well as ongoing requirements around physical and social distancing, we have experienced, and may experience in the future, lower than expected donor collections at our FDA-licensed plasma collection centers. We were also subject to delays in shipments of source plasma from our contracted third-party suppliers, as well as delays in deliveries or price increases for personal protective equipment, reagents and other non-plasma raw materials and supplies used in the manufacture and distribution of our products. We have also experienced supply chain delays as a result of significant resources being diverted towards the rapid development and distribution of COVID-19 vaccines.

In the future we may continue to experience pandemic related challenges with respect to obtaining and manufacturing a sufficient amount of supplies, raw materials, and finished product to meet our need for commercial and clinical product supply. If we or any of our suppliers or manufacturers are adversely impacted by the pandemic or the restrictions resulting from the outbreak, if they or we cannot obtain the necessary supplies, or if third parties need to prioritize other products or customers over us, including under the Defense Production Act, we may experience future delays or disruptions in our supply chain, which could have a material and adverse impact on our business. Moreover, we, our suppliers, and any third-party manufacturers may also need to implement measures and changes, or deviate from typical requirements, because of the pandemic that may otherwise adversely impact our supply chains or the quality of the resulting products or supplies. Depending on the change, we may need to obtain FDA pre-approval or otherwise provide FDA with a notification of the change.

To the extent that we or our partners are conducting clinical trials, the pandemic could cause delays or disruptions in these or future development programs. By example, the pandemic may result in slower enrollment, the need to suspend enrollment into studies, patient withdrawals, postponement of planned clinical or preclinical studies, redirection of site resources from studies, study modification, suspension, or termination, the introduction of remote study procedures and modified informed consent procedures, study site changes, direct delivery of investigational products to patient homes requiring state licensing, study deviations or noncompliance, and changes or delays in site monitoring. The foregoing may require that we consult with relevant review and ethics committees, IRBs, and the FDA. The foregoing may also impact the integrity of our study data. The effects of the COVID-19 pandemic may also increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects. The pandemic could further impact our ability to interact with the FDA or other regulatory authorities and may result in delays in the conduct of inspections or review of pending applications or submissions. Due to the potential impact of the COVID-19 outbreak on clinical trials, drug development, and manufacturing, FDA issued a number of guidances specifically concerning COVID-19, including guidances with respect to blood and blood components. FDA's guidance is continually evolving.

Since the onset of the COVID-19 pandemic, there has been a noticeable decline in certain medical prescriptions attributed to lower incident rates for illnesses, fewer RSV, influenza and other respiratory viral pathogen-infected patients, hospital admissions and a reduction in doctor visits. In addition, physical and social distancing guidelines issued by public health authorities and the resulting global changes in human behavior have resulted in an observed reduction in infection transmission rates and spread of bacterial and viral infections, resulting in lower rates of infection across all patient populations, which, if continued, could potentially negatively impact the use of our IVIG products by patients.

The COVID-19 pandemic may also result in changes in laws and regulations. By example, in March 2020, the U.S. Congress passed the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which includes various provisions regarding FDA drug shortage reporting requirements, as well as provisions regarding supply chain security, such as risk management plan requirements, and the promotion of supply chain redundancy and domestic manufacturing. This and any future changes in law may require that we change our internal processes and procedures to ensure continued compliance.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, operations, or financial condition, or on healthcare systems or the global economy as a whole. Although the COVID-19 pandemic has not adversely affected our capital and financial resources to date, the pandemic's effects could have a material impact on our ability to access the capital markets as needed and on our operations and business, including those of the third parties on which we rely. Because we are unable to determine the ultimate severity or duration of the pandemic or its effects on, among other things, the global, national or local economies, the capital and credit markets, our workforce, our customers or our suppliers, at this time we are unable to predict whether COVID-19 will have a material adverse impact on our business, financial condition, liquidity and results of operations.

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 and results from operations.

Although we have built 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. In addition, our recently completed fill/finish suite has yet to be validated and approved by the FDA. 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;
- the COVID-19 pandemic could adversely affect our contracted fill/finishers' operations, supply chain or workforce;

- 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. These risks could also result in the delay in obtaining clinical supply, which would delay our development programs. 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, including the COVID-19 pandemic.

The estimates of market opportunity and forecasts of market and revenue growth included in our filings 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, including as a result of changing circumstances during the ongoing COVID-19 pandemic. 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 our filings 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.

Both of our business segments and our facilities, as well as our suppliers and contractors, are subject to periodic inspections by the FDA, which, depending on the outcome of such inspection, could result in certain FDA actions, including the issuance of observations, notices, citations or warning letters.

We and our suppliers and contractors may be unable to comply with our specifications, cGMP requirements and with other FDA, state, and foreign regulatory requirements for commercial and clinical supply. The FDA is authorized to perform inspections of our and our suppliers' facilities, including the Boca Facility. The FDA also must inspect and approve our and our third-parties' facilities before they may be used for commercial production. At the end of such an inspection, the FDA could issue a Form 483 Notice of Inspectional Observations, which could cause us to modify certain activities identified during the inspection and may not approve the use of the facility. Following such inspections, the FDA may issue an untitled letter as an initial correspondence that cites violations that do not meet the threshold of regulatory significance of a warning letter. FDA guidelines also provide for the issuance of warning letters for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. FDA also may issue warning letters and untitled letters in connection with events or circumstances unrelated to an FDA inspection.

We may not be able to timely resolve concerns raised by the FDA as a result of an inspection or without expending significant resources. 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 a 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.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our commercial manufacturing and any research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized internally and by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our commercial manufacturing, research and development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

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 or force majeure events, electric power loss, telecommunications failure, equipment failure and breakdown, human error, employee issues, global health occurrences such as the COVID-19 pandemic, 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 BLAs, or to repeat clinical trials. The evolving COVID-19 pandemic may directly or indirectly affect the pace of enrollment in clinical trials as patients may be restricted in traveling to and accessing healthcare facilities and physicians' offices. Additionally, such healthcare facilities and offices have their limited resources directed towards treating patients with COVID-19 symptoms. 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
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- temporary suspension resulting from the COVID-19 pandemic.

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 not permit us to commence a clinical trial, may require amendments to our clinical trial protocols, or may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA or IRB 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.

Other issues that may impact our clinical trials and that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, include:

- We may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our CROs;
- Regulators may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing, surveillance, or REMS requirements to maintain regulatory approval;
- Our third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- The cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by FDA upon the filing of a marketing application;
- The supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- We may not be able to achieve sufficient study enrollment, subjects may drop out or be withdrawn from out studies, we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- There may be flaws in our clinical trial design that are not discoverable until the clinical trial has progressed;
- The FDA or comparable foreign regulatory authorities may disagree with our intended indications or study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials, may find that a product candidate's benefits do not outweigh its safety risks, or may require that we conduct additional development or study work;
- The FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our contract manufacturer's manufacturing facility for clinical and future commercial supplies;
- We may need to make changes to our product candidates that require additional testing or that cause our product candidates to perform differently than expected;
- Global trade policies that may impact our or our manufacturers' ability to obtain raw materials and/or finished product for commercialization;
- FDA or comparable regulatory authorities may take longer than we anticipate to make decisions on our products or product candidates; and
- We may not be able to demonstrate that a product or product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

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. The approval process may also be delayed by changes in government regulation, future legislation, diversion of resources for FDA review during the ongoing COVID-19 pandemic 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 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 review, inspection and 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 and other governmental authorities strictly regulate and monitor 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. 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, among other consequences, 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.

Since receiving FDA approval for ASCENIV, we have been commercializing 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 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, including supply chain constraints directly or indirectly caused by the ongoing COVID-19 pandemic and government responses thereto, 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 or test products and product candidates, as well as for other pre-and-post approval services, 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 activities, 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 or the impact that the ongoing COVID-19 pandemic will have on such third parties. 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, our trials may be repeated, extended, delayed, or terminated, the approval of our FDA application(s), if any, and our introduction of new products, if any, will be delayed. We or they may also be subject to regulatory enforcement actions and we may not be able to meet commercial demand. 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.

We may be unable to successfully expand our manufacturing processes to fulfill demand for our products orincrease our production capabilities through the addition of new equipment, including if we do not obtain requisite approval from the FDA.

We currently anticipate expanding the manufacturing capacity of our Boca Facility by approximately 50% or more. We also anticipate expanding our production capabilities through the addition of our fill-finish machine at our Boca Facility. Following the expansion of any of our manufacturing processes or the addition of new equipment, such as our fill-finish machine, we will need to validate the expanded facility and equipment and have it inspected by the FDA. Given the significant delays that may result during the validation process, including due to any diverted FDA attention during the COVID-19 pandemic, we may experience a significant supply shortage of our products or our production capabilities may be limited until completion of and validation of our facility expansion and new manufacturing equipment.

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, discovery that the product is less effective than previously thought, 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;
- clinical holds or termination of clinical trials;
- requirements to conduct further post-marketing studies or clinical trials, implement risk mitigation strategies, or to issue corrective information;
- 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;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from healthcare programs, consent decrees, or corporate integrity agreements;
- product seizure or detention; 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, 2020, three customers, BioCare, Reliance and Biolife, represented an aggregate of 82% of our consolidated revenues. For the year ended December 31, 2019, three customers, BioCare, Biolife and Sanofi Pasteur S.A. ("Sanofi"), represented an aggregate of 70% of our consolidated revenues.

As of December 31, 2020, three customers, BioCare, Reliance Curascript, represented a total of 92% of our consolidated accounts receivable. At December 31, 2019, two customers, BioCare and McKesson Corporation ("McKesson"), represented 89% 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. Moreover, we anticipate deriving increased revenue from some of these customers 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;
- our ability to produce and deliver a sufficient quantity of our products in a timely manner to meet our customers' requirements; and
- the impact of the ongoing COVID-19 pandemic and government responses thereto on our customers and their businesses, operations and financial condition.

Additionally, an adverse change in the financial condition of any of our key customers could negatively affect revenue derived from such customer, which in turn could have a material adverse effect on our business and results of operations.

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

Our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our products and services and assuring the safety and efficacy of our products. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in 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 or 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, but not limited to:

- 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, as well as expanding our IP estate with patents issued for *S. Pneumoniae* hyperimmune IG. 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 successfully commercialize ASCENIV, as well as our ability to generate revenue from Nabi-HB, BIVIGAM, contract manufacturing, intermediate fractions and plasma attributable to the operations of ADMA BioCenters, to support our operations.

Our ADMA BioCenters 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, and will be amended by the California Privacy Rights Act, effective January 1, 2023. 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.

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, currently provides for a senior secured term loan facility in the principal amount of $100.0 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 issuance of a promissory note in favor of Perceptive on May 3, 2019 (the "Perceptive Tranche II Loan"), (iii) a term loan in the principal amount of $12.5 million evidenced by our issuance of a promissory note in favor of Perceptive on March 20, 2020, (the "Perceptive Tranche III Loan"); and (iv) a term loan in the principal amount of $15 million evidenced by our issuance of a promissory note in favor of Perceptive on December 8, 2020 (the "Perceptive Tranche IV Loan," and together with the Perceptive Tranche I Loan, the Perceptive Tranche II Loan and the Perceptive Tranche III Loan, the "Perceptive Loans"). The Perceptive Loans each have a maturity date of March 1, 2024, 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 patents, 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 or biosimilar 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, or 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. Our ability to accomplish each of these factors may be negatively impacted as a consequence of the COVID-19 pandemic. 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. Further, while many of our employees and certain suppliers with whom we do business operate in a remote working environment during the COVID-19 pandemic, the risk of cybersecurity attacks and data breaches, particularly through phishing attempts, may be increased as we and third-parties with whom we interact leverage our IT infrastructure in unanticipated ways during the ongoing COVID-19 pandemic. 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.

Our success depends in part on our ability to attract, motivate, and retain a sufficient number of qualified employees across various areas of our operations, such as research and development, manufacturing operations, and sales, who understand and appreciate our strategy and culture and are able to contribute to our mission. 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, finance and general and operational management. Qualified individuals of the requisite caliber and number needed to fill these positions may be in short supply in some areas. 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, particularly if the COVID-19 pandemic causes significant changes in the competitive market for such personnel or travel restrictions related to COVID-19 prevent qualified personnel from applying for employment. If we are unable to hire and retain personnel capable of consistently performing at a high level, our business and operations could be materially adversely affected. Additionally, any material increases in existing employee turnover rates or increases in labor costs could have a material adverse effect on our business, financial condition or operating results.

We currently collect human blood plasma at our ADMA BioCenters facilities, and if we cannot maintain FDA approval for these facilities 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 BioCenters collection facilities for the collection of human blood plasma and we may seek other governmental and regulatory approvals for these facilities. We also plan to grow through the building and licensing of additional ADMA BioCenters 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 and blood standards, 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 or untitled 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 sites.

We 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.

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. Even successful defense, however, could impair our results of operations. 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 civil and criminal Federal False Claims Act, the civil monetary penalty statute, requirements regarding the reporting and repayment of overpayments, other fraud and abuse laws 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 states, including the State of Florida with respect to the manufacture and marketing 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 recently promulgated a regulation that is effective in two phases. First, the regulation excludes from the definition of “remuneration” limited categories of (a) PBM rebates or other reductions in price to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization plan reflected in point-of sale reductions in price and (b) PBM service fees. Second, effective January 1, 2023, the regulation expressly provides that rebates to plan sponsors under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager will not be protected under the anti-kickback discount safe harbor.

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 of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to or at the request of covered recipients, such as, but limited to, physicians, physician assistants, nurse practitioners, clinical nurse specialists and certified registered nurse anesthetists and teaching hospitals, must be tracked and reported to CMS, and are publicly disclosed. Such "applicable manufacturers" are also required to report certain ownership interests held by physicians and their immediate family members. 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 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 regulatoryapproval 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, operations, facilities, suppliers and 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.

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 or product components 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. Product or component quality issues may also result in regulatory enforcement actions, liability, corrective actions and recalls, among other actions, as described elsewhere in this annual report.

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, such as COVID-19, 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 generally 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 current plasma collection facilities, an unsatisfactory inspection could prevent a new center from being licensed or risk the suspension or revocation of an existing license, among other enforcement actions. 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. Further, the COVID-19 pandemic has resulted in, and may continue to result in, significant constraints in raw material supply across various different industries, including the supply of plasma. It is possible that in the future, the COVID-19 pandemic and government responses thereto will have an adverse effect on our ability to source plasma from donors in quantity and quality sufficient for our manufacturing processes. 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 and other applicable regulatory requirements, 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 BioCenters plasma collection facilities. This strategy is dependent upon our ability to maintain a cGMP compliant environment at our plasma collection facilities and to expand production and attract donors to our facilities. There is no assurance that the FDA will inspect and license any of our current or future unlicensed plasma collection facilities 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 facilities to more efficient production levels may be affected by changes in the economic environment and population in selected regions where ADMA BioCenters operates its current or future plasma facilities, by the entry of competitive plasma centers into regions where ADMA BioCenters operates such centers, by misjudging the demographic potential of individual regions where ADMA BioCenters expects to expand production and attract new donors, by unexpected facility related challenges, or by unexpected management challenges at selected plasma 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. Moreover, in an effort to increase competition in the biologic product marketplace, Congress, the executive branch, and the FDA have taken certain legislative and regulatory steps. For example, in 2020 the FDA finalized a guidance to facilitate biologic product importation. The 2020 Further Consolidated Appropriations Act included provisions requiring that sponsors of approved biologic products provide samples of the approved products to persons developing biosimilar products within specified timeframes, in sufficient quantities, and on commercially reasonable market-based terms 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. This reform establishes significant cost-saving measures 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 was 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 also created 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 now equal to 70% 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 and there are ongoing legal challenges, including at the Supreme Court, which may contribute to the uncertainty of the ongoing implementation and impact of the law and also underscores the potential for additional reform going forward. We cannot assure that the law, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business. Certain provisions of enacted or proposed legislative changes may negatively impact coverage and reimbursement of, or rebates paid by manufacturers for, healthcare items and services. We will continue to evaluate the effect that the Healthcare Reform Law and any potential changes may have 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, 2020 and 2019, we had negative cash flows from operations of approximately $102.0 million and $76.2 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. In addition, our end-to-end production cycle from procurement of raw materials to commercial release of finished product can take between seven and 12 months or potentially longer, requiring substantial investments in raw material plasma and other manufacturing materials. We expect that we will not be able to generate a sufficient amount of product revenue to achieve profitability until the beginning of 2024 and, as a result, we expect that we will need to continue 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 expect to receive from the sale of common stock pursuant to the Sale Agreement (as amended to date), that our current cash, cash equivalents and accounts receivable will be sufficient to fund our operations, as currently conducted, into the fourth 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 fourth 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, including due to widespread liquidity constraints or significant market instability that could result from the COVID-19 pandemic, 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 $100.0 million, all of which has been drawn down and is currently outstanding. 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 of approximately $0.9 million, with all principal and unpaid interest due at maturity. The Perceptive Credit Facility has a maturity date of March 1, 2024, 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.

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, including as a result of the impact of the COVID-19 pandemic, 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.

Consequently, we have, and will continue to, incur increased costs related to our compliance with Section 404 of the Sarbanes-Oxley Act. Our Audit Committee has 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 ability to use our net operating loss carryforwards ("NOLs") may be limited.

We have incurred substantial losses during our history. As of December 31, 2020, we had federal and state NOLs of $239.8 million and $172.6 million, respectively. Federal and State NOLs of approximately $115.8 million and $90.0 million, respectively, will begin to expire at various dates beginning in 2027, if not limited by triggering events prior to such time. Under the provisions of the Internal Revenue Code 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.

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;
- uncertainties in the equity markets related to the effects of the COVID-19 pandemic;
- 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;
- overall market volatility;
- 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 16, 2021, most of our 121,275,357 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 December 31, 2020, Perceptive, our directors and executive officers and their affiliates beneficially owned approximately 22% of the outstanding 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;
- 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.

Our Board also recently adopted a short-term stockholder rights agreement with an expiration date of December 15, 2021 and an ownership trigger threshold of 10%. This stockholder rights agreement could render more difficult or discourage a merger, tender offer or assumption of control of the Company that is not approved by our Board. The rights agreement, however, should not interfere with any merger, tender or exchange offer or other business combination approved by our Board. In addition, the rights agreement does not prevent our Board from considering any offer that it considers to be in the best interest of the Company's stockholders.

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, 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.

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, 2020, there were 30,655,784 shares remaining available for issuance, after giving effect to 11,777,091 shares of our common stock that were subject to outstanding stock options, Restricted Stock Units and warrants as of December 31, 2020 that may be issued by us without stockholder approval, as well as an additional 2,664,237 shares reserved for the future issuance of awards under our equity compensation plans.

Item 1B. Unresolved Staff Comments

Not Applicable.

Item 2. Properties

The table below describes our principal facilities as of December 31, 2020:

Location	Principal Business Activity	Approximate Square Feet	Owned or expiration date of lease
Ramsey, NJ	Corporate Headquarters	4,200	September 30, 2021 *
Boca Raton, FL	Manufacturing and Administration	84,462	Owned
Boca Raton, FL	Laboratory and Administration	44,495	Owned
Kennesaw, GA	Plasma Collection Center	12,167	March 31, 2026
Roswell, GA	Administration	6,040	November 30, 2023
Knoxville, TN	Plasma Collection Center	11,657	November 30, 2030
Maryville, TN	Plasma Collection Center	10,800	January 31, 2031
Goose Creek, SC	Plasma Collection Center	14,968	March 31, 2031
Conyers, GA	Plasma Collection Center	11,996	February 28, 2032

* - Pursuant to a shared services agreement with Areth, LLC ("Areth") for office, warehouse space and related services. The agreement 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 of the Board of Directors, and Adam S. Grossman, our President and Chief Executive Officer.

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, 2020, 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, 2021, we estimate that there are more than 20,000 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 any cash dividends for the foreseeable future.

Stock Performance Graph

Not applicable.

Sale of Unregistered Securities

During the year ended December 31, 2020, 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, 2020.

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 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 and commenced commercial sales in August 2019; (ii) ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), 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. pneumoniae*. 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 these products at our 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 and our ongoing supply chain enhancement and capacity expansion initiatives, we believe this facility has the potential to produce quantities of our immune globulin ("IG") products of more than $250 million in annual revenue beginning in 2024 as well as achieving profitability during the first quarter of 2024, as we ramp-up production over the next three to five years.

Through our ADMA BioCenters subsidiary, we currently operate as an FDA-approved source plasma collection organization in the U.S. This business unit, which we refer to as our Plasma Collection Centers business segment, provides us with a portion of our blood plasma for the manufacture of our products and product candidates, and also allows us to sell certain quantities of source plasma to customers for further manufacturing. As a part of our planned supply chain robustness initiative, we opened two new plasma collection centers during 2020, and we now have seven plasma collection centers in various stages of approval and development, including three that are fully operational and collecting plasma. With respect to our fully operational plasma collection centers, two hold FDA licenses and the third has a Biologics License Application ("BLA") pending an FDA decision expected in the fourth quarter of 2021. In addition, one of our FDA-approved plasma collection centers also has approvals from the Korean Ministry of Food and Drug Safety ("MFDS"), as well as FDA approval to implement a Hepatitis B immunization program. After giving effect to the progress we made in 2020 with our plasma collection network expansion, we believe we remain on track to achieve our goal of having 10 or more plasma collection centers operating in the U.S. by 2024. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase and market conditions at the time of sale. Plasma collected from ADMA BioCenters' 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 sell plasma-derived intermediate fractions to certain customers, which are generated as part of our FDA-approved manufacturing process for IG and 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 and testing services for certain third-party clients.

We also provide laboratory contracting services to certain customers and anticipate providing contract filling, labeling and packing services upon FDA approval and implementation of our in-house fill-finish capabilities through our Vanrx SA25 Workcell aseptic filling machine.

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.

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 commence commercial sales of this product in the United States. We resumed production of BIVIGAM during the fourth quarter of 2017 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. We commenced commercial sales for this product 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 HHS License No. 2019 using a process known as fractionation. The Centers for Medicare and Medicaid Services ("CMS") has issued a permanent, product-specific-J-code for ASCENIV. Under the Healthcare Common Procedure Coding System ("HCPCS"), the J-code (J1554) will become effective April 1, 2021 and will replace the currently issued C-code for ASCENIV (C9072), which can continue to be utilized in the interim for reimbursement purposes. 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 antibody titers to respiratory syncytial virus ("RSV") using our proprietary microneutralization testing assay. We are able to identify the high titer or "hyperimmune" plasma that meets our internal and required specifications for ASCENIV with our patented testing methods and 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 Primary Immune Deficiency Disorder ("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 or potentially other respiratory viral pathogens. 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. The FDA approved Nabi-HB on March 24, 1999. 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 we continue to manufacture Nabi-HB under HHS License No. 2019.

IMPACT OF THE COVID-19 CRISIS

We continue to closely monitor ongoing developments in connection with the COVID-19 pandemic and its impacts to our commercial manufacturing operations and plasma collections facilities, including but not limited to potential disruptions to our supply chain operations, including collections of source plasma, procurement of raw materials and packaging materials, a portion of which are sourced internationally, and testing of finished drug product that is required prior to its availability for commercial sale. Such testing has historically been performed by contract laboratories outside the United States. In addition, travel and other restrictions that have been implemented in the United States have impacted our commercial engagement efforts with respect to some of our products, including BIVIGAM and ASCENIV, as trade shows, industry and medical conferences and other events we had been planning to utilize and exhibit and attend with our staff to increase awareness of our products by physicians and payers remain subject to reduction in scope, rescheduling or outright cancellation due to the pandemic.

We have experienced some delays with our third-party vendors and testing laboratories which perform final drug product GMP release testing. In response to these delays, we have added additional release testing laboratories to our FDA-approved consortium listed in our drug approval documents which we believe has adequately addressed this issue. In July 2020, we began receiving FDA lot releases with testing data from our new testing laboratory vendor. In addition, due to previous state and local "shelter-in-place" orders, as well as ongoing requirements around physical distancing, we have experienced, and may experience in the future, lower than normal donor collections at our FDA-approved plasma collection centers. We were also subject to delays in shipments of source plasma from our contracted third-party suppliers, as well as delays in deliveries for personal protective equipment, reagents and other non-plasma raw materials and supplies used in the manufacture and distribution of our products. We have also experienced supply chain delays as a result of certain of our suppliers diverting significant resources towards the rapid development and distribution of COVID-19 vaccines. In addition, we have experienced challenges with respect to our customer engagement initiatives, as our sales and medical affairs field forces face difficulties communicating directly with physicians and other healthcare professionals and the cancellation or postponement of a number of key scientific and medical conferences, further limiting our ability to communicate with potential customers. We have implemented a comprehensive suite of virtual engagement initiatives, though clinician engagement remains lower due to continuing COVID-19-related priorities at U.S. medical centers.

As of the date of this report, we do not believe that the operations and immunoglobulin and plasma products production at our Boca Facility, our contract fill/finishers or our plasma collection facilities have been significantly impacted by the COVID-19 pandemic. As a result, as of the date of this report, we have not experienced, and currently do not anticipate, any material impairments with respect to any of our long-lived assets, including our property and equipment, goodwill or intangible assets.

Although the COVID-19 pandemic has not, to date, materially adversely impacted our capital and financial resources, due to the economic uncertainty that has resulted from the pandemic, and the potential impact of such to our stakeholders, we are unable to predict with certainty any potential impacts to our business. Although we believe the effects of the COVID-19 pandemic on our business and our operations will be temporary, at the present time we are unable to determine the ultimate duration of the pandemic or its long-term effects on, among other things, the global, national or local economies, the capital and credit markets, our workforce, our customers or our suppliers. As a result, we are unable to predict whether the COVID-19 crisis will have a material adverse impact on our business, financial condition, liquidity and results of operations.

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 projecting future liquidity and capital requirements, 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, 2020 and 2019 are comprised of (i) revenues from the sale of our 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 and testing revenue from certain clients; 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. We extend credit to our customers based upon an evaluation of each customer's financial condition and credit history. Evaluations of the financial condition and associated credit risk of customers are performed on an ongoing basis. Based on these evaluations, we have concluded that our credit risk is minimal.

Cost of Product Revenue

Cost of product revenue includes costs associated with the manufacture of the Company's FDA approved products, intermediates and the sale of human source plasma, as well as expenses related to conformance batch production, process development and 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.

As a manufacturer of biological products, we are subject to the risks inherent in biological production, which could include normal course losses and failures inherent in the manufacturing process. As our biologics production levels increase there may be normal course inventory losses as we ensure product quality and compliance with FDA, state and local regulations, or due to testing results not meeting specifications. Such losses are charged to cost of product revenue in the period they are incurred.

Stock-Based Compensation

All equity-based payments, including grants of stock options and restricted stock units ("RSUs") are recognized at their estimated fair value at the date of grant, and compensation expense is recognized on a straight-line basis over the grantee's requisite vesting period. During the year ended December 31, 2020, we granted RSUs to members of our Board of Directors and certain members of our management and employees representing an aggregate of 361,000 shares of common stock. 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 1,468,412 and 1,508,000 shares of Common Stock during the years ended December 31, 2020 and 2019, respectively. To determine the risk-free interest rate, we utilize 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, testing and evaluation of new or alternative products or processes, including the testing and development of a new filling line at one of our third-party fill/finishers for a process that has not been approved by the FDA, studies for potentially extending a product's approved and labeled expiration dating and other potential label expansions, post-marketing commitment studies for BIVIGAM and ASCENIV, 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 prior to its approval by the FDA. All research and development costs are expensed as incurred.

Inventories

Raw materials inventory consists of various materials purchased from suppliers, including normal source plasma, that are used in the production of our products. Work-in-process and finished goods inventories reflect the cost of raw materials as well as costs for direct and indirect labor, primarily salaries, wages and benefits for applicable employees, as well as an allocation of overhead costs related to the Boca Facility including utilities, property taxes, general repairs and maintenance, consumable supplies and depreciation. The allocation of Boca Facility overhead to inventory is generally based upon the estimated square footage of the Boca Facility that is used in the production of our products relative to the total square footage of the facility.

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. Net realizable value is generally determined based upon the consideration we expect to receive when the inventory is sold, less costs to deliver the inventory to the recipient. The estimates for net realizable value of inventory are based on contractual terms or upon historical experience and certain other assumptions which we believe are reasonable. Inventory is periodically reviewed to ensure that its carrying value does not exceed its net realizable value, and adjustments are recorded to write down such inventory, with a corresponding charge to cost of product revenue, when the carrying value or historical cost exceeds its estimated net realizable value.

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, 2020 and 2019, 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, 2020 and 2019.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)* ("ASU 2016-13"), which requires financial assets to be presented at the net amount expected to be collected, with an allowance for credit losses to be deducted from the amortized cost basis of the financial asset such that the net carrying value of the asset is presented as the amount expected to be collected. Under ASU 2016-13, the entity's statement of operations is required to reflect the measurement of credit losses for newly recognized financial assets, as well as expected increases or decreases in expected credit losses that have taken place during the period. For public business entities, ASU 2016-13 is effective for fiscal years beginning after December 15, 2019. We adopted ASU No. 2016-13 on January 1, 2020, and the adoption of this update did not have a significant impact on our consolidated financial statements.

In July 2017, the FASB issued 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.

Year Ended December 31, 2020 Compared to December 31, 2019

The following table presents a summary of the changes in our results of operations for the year ended December 31, 2020 compared to the year ended December 31, 2019:

	Year Ended December 31,		
	2020	**2019**	**Increase (Decrease)**
Revenues	$ 42,219,783	$ 29,349,083	$ 12,870,700
Cost of product revenue (exclusive of amortization expense shown below)	61,291,426	39,504,238	21,787,188
Gross loss	(19,071,643)	(10,155,155)	(8,916,488)
Research and development expenses	5,907,013	2,343,848	3,563,165
Plasma center operating expenses	4,170,051	2,169,629	2,000,422
Amortization of intangibles	715,353	844,938	(129,585)
Selling, general and administrative expenses	35,050,817	25,910,757	9,140,060
Loss from operations	(64,914,877)	(41,424,327)	(23,490,550)
Interest expense	(11,985,066)	(8,993,379)	(2,991,687)
Gain (loss) on extinguishment of debt	991,797	(9,962,495)	10,954,292
Gain on transfer of plasma center assets	-	11,527,421	(11,527,421)
Other income, net	159,598	573,463	(413,865)
Net loss	$ (75,748,548)	$ (48,279,317)	$ (27,469,231)

Revenues

We recorded total revenues of $42.2 million during the year ended December 31, 2020, as compared to $29.3 million during the year ended December 31, 2019, an increase of $12.9 million, or approximately 44%. The increase is mainly due to increased sales of our immunoglobulin products generated by our Boca Facility manufacturing operations in 2020 totaling $14.5 million, partially offset by a $1.6 million decrease in plasma revenues generated by our plasma collection centers business segment.

Our revenues for the year ended December 31, 2020 were greater than the prior year as a result of our continued commercial scale-up for BIVIGAM and ASCENIV following these products' FDA approvals on May 9, 2019 and April 1, 2019, respectively, as well as from the manufacturing and supply agreement we entered into in January 2020 to produce and sell intermediate fractions to a certain customer.

Cost of Product Revenue

Cost of product revenue was $61.3 million for the year ended December 31, 2020, as compared to $39.5 million for the year ended December 31, 2019, an increase of $21.8 million. This increase reflects non-recurring production charges of $7.5 million for the manufacture of BIVIGAM conformance lots at an increased plasma pool production scale in connection with our planned capacity expansion and other production initiatives and investments at the Boca Facility. Cost of product revenue for the year ended December 31, 2020 also reflects increases in product revenue costs of approximately $22.5 million related to the increase in revenues, partially offset by a $7.4 million reduction in unabsorbed manufacturing expenses resulting from increased production throughput at the Boca Facility.

Research and Development Expenses

R&D expenses totaled $5.9 million for the year ended December 31, 2020, as compared to $2.3 million for the year ended December 31, 2019. The increase is primarily due to $1.4 million of costs incurred during 2020 for the testing and development of a new filling line at one of our third-party fill/finishers for a process that has not been approved by the FDA, a $1.0 million increase in expenses associated with clinical studies, mainly BIVIGAM post-marketing commitments, $0.4 million of costs incurred during 2020 for a study we commenced to potentially extend ASCENIV's approved and labeled expiration dating, $0.2 million of expenses in 2020 related to third-party assay development and a $0.2 million non-recurring expense for assistance with a third-party clinical research project.

Plasma Center Operating Expenses

Plasma center operating expenses were $4.2 million for the year ended December 31, 2020, as compared to $2.2 million for the year ended December 31, 2019. 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 increase in plasma center operating expenses is attributable to having additional plasma centers in operation in 2020, as well as higher employee compensation costs, donor fees, depreciation and rent expense, all related to plasma center expansion activities that took place in 2020. During the year ended December 31, 2019, we had one plasma collection facility in operation. During the year ended December 31, 2020, we opened two additional plasma collection centers and commenced construction and development activities on four additional plasma collection facilities. We expect additional increases in our plasma center operating expenses in 2021 as we continue our expansion activities in this business segment.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $35.1 million for the year ended December 31, 2020, an increase of $9.1 million from the year ended December 31, 2019. The increase was mainly due to higher employee compensation expenses of $5.1 million related to staffing increases in support of our commercialization efforts for BIVIGAM and ASCENIV as well as the overall growth in the size and scope of our operations. SG&A expenses were also impacted in 2020 by increased insurance expense of $1.6 million and marketing consulting fees incurred in connection with our ASCENIV commercialization efforts of $3.1 million, partially offset by lower travel expenses and information technology consulting fees. We expect our SG&A expenses to continue to increase in 2021 as we continue to execute on the various facets of our business plan (see Liquidity and Capital Resources).

Amortization of Intangibles

Amortization expense for intangible assets acquired in the Biotest Transaction was $0.7 million and $0.8 million for the years ended December 31, 2020 and 2019, respectively.

Loss from Operations

Our operating loss was $64.9 million for the year ended December 31, 2020, as compared to $41.4 million for the year ended December 31, 2019. The increase was mainly due to the increase in cost of product revenue and other operating expenses, partially offset by the increase in revenues.

Interest Expense

Interest expense was $12.0 million for the year ended December 31, 2020, as compared to $9.0 million for the year ended December 31, 2019. The increase reflects a higher average debt principal balance carried in 2020 as compared to 2019 due to the additional draws on our senior credit facility in May of 2019 and March of 2020 (see "Liquidity and Capital Resources"), which resulted in additional debt principal of $42.5 million.

Gain/Loss on Extinguishment of Debt

In December of 2020, we refinanced our subordinated note payable to Biotest with an additional draw on our senior credit facility. As a result of this transaction and the payoff of the Biotest note, we recorded a gain on the extinguishment of debt in the amount of $1.0 million (see Note 8 to the Consolidated Financial Statements). In connection with the refinancing of our senior credit facility in February of 2019, we incurred a loss on the extinguishment of 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

Our net loss was $75.7 million for the year ended December 31, 2020, as compared to $48.3 million for the year ended December 31, 2019. The increase in net loss of approximately $27.5 million was mainly due to the increase in operating loss and the higher interest expense.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2020, we had working capital of $133.8 million, including cash and cash equivalents of $55.9 million, and stockholders' equity of $88.2 million, as compared to working capital of $71.8 million, including cash and cash equivalents of $26.8 million, and stockholders' equity of $26.2 million as of December 31, 2019. We have incurred an accumulated deficit of $340.5 million since inception, had negative cash flows from operations of $102.0 million and $76.2 million for the years ended December 31, 2020 and 2019, respectively. We have funded our operations over the past few years primarily from the sale of our equity and debt securities.

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. In addition, our end-to-end production cycle from procurement of raw materials to commercial release of finished product can take between seven and 12 months or potentially longer, requiring substantial investments in raw material plasma and other manufacturing materials. We expect that we will not be able to generate a sufficient amount of product revenue to achieve profitability until the beginning of 2024 and, as a result, we expect that we will need to continue to finance our operations through additional equity or debt financings or through corporate collaboration and licensing arrangements. Based upon our current projected revenues, the remaining proceeds we expect to receive from the sale of common stock pursuant to the Sale Agreement (as amended to date) discussed below and our projected 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 will be sufficient to fund our operations, as currently conducted, into the fourth 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 fourth quarter of 2021. These estimates and timeframes may change based upon several factors, including 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. 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. The COVID-19 pandemic has negatively affected the global economy and created significant volatility and disruption to the financial markets. 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 the COVID-19 pandemic, FDA reviews, inspections and approvals related to our products, patient/payer acceptance of our products, ongoing compliance and maintenance 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 and are also subject to the effect of potential new government orders, policies and procedures that we must comply with which are outside of our control. As such, these factors raise substantial doubt about our ability to continue as a going concern.

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.

On August 5, 2020, we entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC, as agent ("Jefferies"), pursuant to which we could offer and sell, from time to time, at our option, through or to Jefferies, up to an aggregate of $50 million of shares of our common stock. On November 5, 2020, we and Jefferies entered into an amendment to the Sale Agreement (as amended, the "Amended Sale Agreement") to provide for an increase in the aggregate offering amount under the Sale Agreement, such that as of November 5, 2020, we may offer and sell shares having an additional aggregate offering price of up to $20 million. On February 3, 2021, we entered into an additional amendment to the Sale Agreement to provide for an additional increase in the aggregate offering amount under the Sale Agreement to allow us to sell shares having an aggregate offering price of up to $35.4 million.

For the year ended December 31, 2020, we sold 18,537,907 shares of our common stock under the Sale Agreement and received net proceeds in the amount of $42.5 million. Between January 1, 2021 and March 16, 2021, we sold an additional 16,311,084 shares of our common stock under the Sale Agreement and received net proceeds in the amount of $38.3 million, which leaves a remaining gross balance that can be raised under the Sale Agreement of $22.7 million. The net proceeds from this offering are being used for general corporate purposes, which may include (i) the procurement of raw materials for the manufacturing of BIVIGAM and ASCENIV; (ii) supporting the ongoing commercial sales of our IVIG products; (iii) expanding the manufacturing capacity of our Boca Facility, including supply chain functions, and enhancing the robustness of our supply chain oversight; (iv) expanding our plasma collection facility network; and (v) research and development and business development opportunities.

On February 11, 2019 (the "Perceptive Closing Date"), we and all of our 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 $100.0 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 $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, (iii) a term loan in the principal amount of $12.5 million evidenced by the Company's issuance of a promissory note (the "Perceptive Tranche III Note") in favor of Perceptive on March 20, 2020 (the "Perceptive Tranche III Loan"); and (iv) a term loan in the principal amount of $15 million evidenced by our issuance of a promissory note in favor of Perceptive on December 8, 2020 (the "Perceptive Tranche IV Loan", and together with the Perceptive Tranche I Loan, the Perceptive Tranche II Loan and the Perceptive Tranche III Loan, the "Perceptive Loans"). The Perceptive Tranche III Loan is the result of an amendment to the Perceptive Credit Agreement that the Company and Perceptive entered into on May 3, 2019 (the "First Perceptive Amendment"), and the Perceptive Tranche III Loan became available to the Company upon the approval of BIVIGAM on May 9, 2019. The Perceptive Tranche IV Loan is the result of an amendment to the Perceptive Credit Facility entered into on December 8, 2020 (the "Second Perceptive Amendment"), which also extended the maturity date of the Perceptive Credit Facility to March 1, 2024 (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, we 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"). We 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 us that was held in a debt service reserve account per the terms of the Marathon Credit Facility. In connection with the First Perceptive Amendment, we paid an additional facility fee to Perceptive in the amount of $0.1 million on May 3, 2019. In connection with the Second Perceptive Amendment, we paid a facility fee to Perceptive in the amount of $0.8 million. The proceeds from the Perceptive Tranche IV Loan were used to retire the $15.0 million subordinated note we had payable to Biotest, which had a maturity date of June 17, 2022.

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 of approximately $0.9 million per month 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, 2020 was 11.0%.

On the Maturity Date, we are required to pay Perceptive the entire outstanding principal amount underlying the Perceptive Loans and any accrued and unpaid interest thereon. There are no scheduled principal payments on the Perceptive Loans prior to the Maturity Date. 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 December 31, 2021, (ii) 2.0% of the prepaid principal amount, if prepaid after December 31, 2021 and on or prior to December 31, 2022, (iii) 4.0% of the prepaid principal amount, if prepaid after December 31, 2022 and on or prior to December 31, 2023, and (iv) 5.0% of the prepaid principal amount, if prepaid any time thereafter and prior to the Maturity 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 that of our 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 our or our subsidiaries' 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 ended 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 $31.2 million for the fiscal quarter ended March 31, 2021 to $55.0 million for the fiscal quarter ending December 31, 2021. At December 31, 2020, we were in compliance with all of the covenants contained in the Perceptive Credit Agreement.

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 $88.7 million. The proceeds from this offering were 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.

Cash Flows

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

	Year Ended December 31,	
	2020	**2019**
Net cash used in operating activities	$ (102,002,958)	$ (76,193,504)
Net cash used in investing activities	(12,724,680)	(3,811,838)
Net cash provided by financing activities	143,896,655	80,002,625
Net change in cash and cash equivalents	29,169,017	(2,717)
Cash and cash equivalents, including restricted cash - beginning of year	26,752,135	26,754,852
Cash and cash equivalents - end of year	$ 55,921,152	$ 26,752,135

Net Cash Used in Operating Activities

Cash used in operations for the year ended December 31, 2020 was $102.0 million, an increase of $25.8 million from the same period of a year ago, mainly due to the increase in net loss. The following table illustrates the primary components of our cash flows from operations:

	Year Ended December 31,	
	2020	**2019**
Net loss	$ (75,748,548)	$ (48,279,317)
Non-cash expenses, gains and losses	7,526,908	5,588,584
Changes in accounts receivable	(9,767,371)	(2,077,478)
Changes in inventories	(28,470,864)	(34,650,132)
Changes in prepaid expenses and other current assets	(512,873)	(773,174)
Changes in accounts payable and accrued expenses	5,300,930	4,080,553
Other	(331,140)	(82,540)
Cash used in operations	$ (102,002,958)	$ (76,193,504)

Net Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 was $12.7 million, which primarily consisted of $7.6 million for capital expenditures at the Boca Facility, which includes equipment purchases and implementation of our in-house fill/finish capabilities, and $5.1 million of capital expenditures for the construction and buildout of new plasma collection facilities. Cash used in investing activities of $3.8 million for the year ended December 31, 2019 was mainly attributable to capital expenditures at the Boca Facility. Although we have no specific material commitments for capital expenditures as of December 31, 2020, we expect our total capital expenditures will be between $12.0 million and $20.0 million for fiscal 2021.

Net Cash Provided by Financing Activities

Cash provided by financing activities of $143.9 million for the year ended December 31, 2020 mainly consisted of $88.7 million of net proceeds received from our underwritten public offering in February 2020, $42.5 million of proceeds received from the Sale Agreement during the second half of 2020 and $12.5 million of proceeds from the Perceptive Tranche III Loan received in March 2020. 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.

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, 2020 or 2019.

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, 2020. 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, 2020, 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

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 the 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, 2020. 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, 2020 based on those criteria.

As a Smaller Reporting Company, the Company is not required to include in this Annual Report on Form 10-K a report on the effectiveness of its internal control over financial reporting by the Company's independent registered public accounting firm.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2020 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 2021 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2020.

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 2021 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2020.

To the extent necessary, 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 2021 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2020.

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 2021 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2020.

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 2021 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2020.

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 2021 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2020.

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 2021 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2020.

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 2021 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2020.

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 25, 2021

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 25, 2021
/s/ Brian Lenz Brian Lenz	Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 25, 2021
/s/ Steven A. Elms Steven A. Elms	Chairman of the Board of Directors	March 25, 2021
/s/ Dr. Jerrold B. Grossman Dr. Jerrold B. Grossman	Vice Chairman of the Board of Directors	March 25, 2021
/s/ Martha J. Demski Martha J. Demski	Director	March 25, 2021
/s/ Bryant E. Fong Bryant E. Fong	Director	March 25, 2021
/s/ Lawrence P. Guiheen Lawrence P. Guiheen	Director	March 25, 2021

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders 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, 2020 and 2019, 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, 2020 and 2019, 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.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As further discussed in Note 1 to the accompanying consolidated financial statements, management believes that the Company will continue to incur net losses and negative net cash flows from operating activities through the drug commercialization process. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 Public Company Accounting Oversight Board (United States) ("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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Description of the matter

As of December 31, 2020, the Company's inventory totaled $81,535,599. As described in the notes to the consolidated financial statements, the valuation of inventory involves significant estimates relating to the capitalization of labor and overhead costs to the work in process and finished goods inventories as well as lower of cost or net realizable value considerations. Given the importance of inventory to the Company's operations, the various components, locations and complexity of the computations and the significance of the inventory value, auditing the inventory involved a relatively high degree of auditor judgement and high extent of our testing as well as the involvement of more senior members of the engagement team to design the appropriate responsive audit procedures and to supervise, execute and review the test results.

How we addressed the matter in our audit

We obtained an understanding of and tested the Company's process to estimate labor and overhead in the inventory to devise our responsive audit approach. We performed substantive test procedures relating to the inventory valuation which included verifying significant components of the valuation to supporting records, assessing the application of direct labor costs included in the valuation and assessing the appropriateness of the components of the indirect overhead pools as well as the application of such pool to the valuation. We verified the completeness and accuracy of the data used in management's valuation as well as the mathematical accuracy of the direct labor and overhead applications. To assess management's assertion that inventory is carried at the lower of cost or net realizable value, we tested subsequent net sales proceeds.

/s/ CohnReznick LLP

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

Holmdel, New Jersey

March 25, 2021

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2020 and 2019

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 55,921,152	$ 26,752,135
Accounts receivable, net	13,237,290	3,469,919
Inventories	81,535,599	53,064,734
Prepaid expenses and other current assets	3,046,466	2,533,593
Total current assets	153,740,507	85,820,381
Property and equipment, net	41,593,090	31,741,317
Intangible assets, net	2,444,121	3,159,474
Goodwill	3,529,509	3,529,509
Right to use assets	4,259,191	1,245,029
Deposits and other assets	2,106,976	1,595,015
TOTAL ASSETS	$ 207,673,394	$ 127,090,725
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,073,708	$ 9,174,591
Accrued expenses and other current liabilities	8,365,143	4,481,395
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	365,682	229,073
Total current liabilities	19,947,367	14,027,893
Senior notes payable, net of discount	92,968,866	68,291,163
Deferred revenue, net of current portion	2,118,698	2,261,532
Subordinated note payable, net of discount	-	14,908,053
Lease obligations, net of current portion	4,334,151	1,302,361
Other non-current liabilities	54,886	106,574
TOTAL LIABILITIES	119,423,968	100,897,576
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 shares authorized, 104,902,888 and 59,318,355 shares issued and outstanding	10,490	5,932
Additional paid-in capital	428,704,039	290,903,772
Accumulated deficit	(340,465,103)	(264,716,555)
TOTAL STOCKHOLDERS' EQUITY	88,249,426	26,193,149
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 207,673,394	$ 127,090,725

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, 2020 and 2019

	Years Ended December 31,	
	2020	**2019**
REVENUES:		
Product revenue	$ 42,076,949	$ 29,206,249
License revenue	142,834	142,834
Total revenues	42,219,783	29,349,083
OPERATING EXPENSES:		
Cost of product revenue (exclusive of amortization expense shown below)	61,291,426	39,504,238
Research and development	5,907,013	2,343,848
Plasma center operating expenses	4,170,051	2,169,629
Amortization of intangible assets	715,353	844,938
Selling, general and administrative	35,050,817	25,910,757
Total operating expenses	107,134,660	70,773,410
LOSS FROM OPERATIONS	(64,914,877)	(41,424,327)
OTHER INCOME (EXPENSE):		
Interest income	288,126	800,785
Interest expense	(11,985,066)	(8,993,379)
Gain (loss) on extinguishment of debt	991,797	(9,962,495)
Gain on transfer of plasma center assets	-	11,527,421
Other expense	(128,528)	(227,322)
Other expense, net	(10,833,671)	(6,854,990)
NET LOSS	$ (75,748,548)	$ (48,279,317)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.88)	$ (0.89)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic and Diluted	86,145,052	54,348,136

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, 2020 and 2019

	Common Stock Voting		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
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
Stock-based compensation	-	-	2,855,122	-	2,855,122
Warrants issued in connection with note payable	-	-	3,740,980	-	3,740,980
Vesting of Restricted Stock Units	15,000	2	(2)	-	-
Issuance of common stock, net of offering expenses	45,562,907	4,555	131,190,736	-	131,195,291
Stock options exercised	6,626	1	13,431	-	13,432
Net loss	-	-	-	(75,748,548)	(75,748,548)
Balance at December 31, 2020	104,902,888	$ 10,490	$ 428,704,039	$ (340,465,103)	$ 88,249,426

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, 2020 and 2019

	Years Ended December 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (75,748,548)	$ (48,279,317)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,942,292	3,258,148
Loss on disposal of fixed assets	81,697	207,071
Stock-based compensation	2,855,122	2,650,777
Amortization of debt discount	1,782,428	1,180,348
(Gain) loss on extinguishment of debt	(991,797)	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	(9,767,371)	(2,077,478)
Inventories	(28,470,864)	(34,650,132)
Prepaid expenses and other current assets	(512,873)	(773,174)
Deposits and other assets	(196,749)	107,974
Accounts payable	1,899,115	3,274,200
Accrued expenses	3,401,815	806,353
Other current and non-current liabilities	(134,391)	(190,514)
Net cash used in operating activities	(102,002,958)	(76,193,504)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(12,726,680)	(3,811,838)
Proceeds from the sale of property and equipment	2,000	-
Net cash used in investing activities	(12,724,680)	(3,811,838)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	(13,950,000)	(30,000,000)
Payment of end of end of term fee	-	(2,760,000)
Proceeds from issuance of common stock, net of offering expenses	131,195,291	48,397,088
Proceeds from the exercise of stock options	13,432	75,048
Payment of debt refinancing fees	(830,000)	(6,499,867)
Proceeds from issuance of note payable	27,500,000	72,500,000
Payment of debt issuance costs	-	(1,679,661)
Payments on finance lease obligations	(32,068)	(29,983)
Net cash provided by financing activities	143,896,655	80,002,625
Net increase (decrease) in cash and cash equivalents	29,169,017	(2,717)
Cash and cash equivalents, including restricted cash - beginning of year	26,752,135	26,754,852
Cash and cash equivalents - end of year	$ 55,921,152	$ 26,752,135

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 BioCenters Georgia Inc. ("ADMA BioCenters"). ADMA BioManufacturing was formed in January 2017 to facilitate the acquisition of the Biotest Therapy Business Unit ("BTBU") from BPC Plasma, Inc. (formerly Biotest Pharmaceuticals Corporation) ("BPC" and, together with Biotest AG, "Biotest") on June 6, 2017. The acquisition included 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"). BTBU had previously been the Company's third-party contract manufacturer. ADMA BioCenters is the Company's source plasma collection business with three plasma collection facilities located in the U.S., two of which hold an approved license with the U.S. Food and Drug Administration (the "FDA") while the other facility's Biologics License Application ("BLA") is pending FDA approval.

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 the Company received FDA approval on May 9, 2019 and commenced commercial sales in August 2019; (ii) ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), an IVIG product indicated for the treatment of PI, for which the Company 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. In addition to its commercially available immunoglobulin products, the Company provides contract manufacturing and laboratory services for certain clients and generates revenues from the sale of intermediate by-products that result from the immunoglobulin production process. 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.

As of December 31, 2020, the Company had working capital of $133.8 million, including $55.9 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 accessing the available funds under the open market sale agreement for sales of the Company's common stock as discussed below, the Company's management currently believes that its cash, cash equivalents, projected revenue and accounts receivable will be sufficient to fund ADMA's operations, as currently conducted, into the fourth quarter of 2021. In order to have sufficient cash to fund its operations thereafter, the Company anticipates it will need to raise additional capital before the end of the fourth quarter of 2021. These estimates may change based upon several factors, including the success of the Company's commercial sales of its products, manufacturing ramp-up activities, the acceptability of ADMA's immune globulin products by physicians, patients or payers and the various financing options that may be available to the Company. In addition, the Company's end-to-end production cycle from procurement of raw materials to commercial release of finished product can take between seven and 12 months or potentially longer, requiring substantial investments in raw material plasma and other manufacturing materials. 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.

Due to numerous risks and uncertainties associated with FDA review, inspections and approvals related to the Company's products or the labeled indications of such products, ongoing compliance requirements and capacity expansion efforts at the Company's Boca Facility and future commercialization of the Company's products, including the Company's ability to obtain adequate quantities of FDA-approved plasma with proper specifications on acceptable terms for use in the Company's manufacturing process, as well as the additional uncertainties surrounding the COVID-19 pandemic (see Note 11), the Company is unable to estimate with certainty the amounts of increased capital outlays and operating expenditures required to fund its commercial and development activities. The Company's current estimates may be subject to change as circumstances regarding its business requirements evolve. Failure to secure any necessary financing in a timely manner and on commercially reasonable terms could have a material adverse effect on the Company's business plan and financial performance and it could be forced to delay or discontinue its commercialization, product development or clinical activities or delay or discontinue the approval efforts for any of the Company's products, processes or product candidates. The Company has reported cumulative losses since inception in June 2004 through December 31, 2020 of $340.5 million. As such, these factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments related to the recoverability and classification of asset carrying amounts and the classification of liabilities that might be necessary from the outcome of this uncertainty.

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.

On August 5, 2020, the Company entered into an open market sale agreement (the "Sale Agreement") with Jefferies LLC ("Jefferies"), pursuant to which the Company could offer and sell, from time to time, at its option, through or to Jefferies, up to an aggregate of $50 million of shares of the Company's common stock. The Company and Jefferies have since entered into amendments to the Sale Agreement to provide for increases in the aggregate offering amount under the Sale Agreement such that, as of February 3, 2021, the Company may sell shares having an additional aggregate offering price of up to $55.4 million under the Sale Agreement (see Notes 9 and 18). Through December 31, 2020, the Company received net proceeds from the sale of its common stock under the Sale Agreement of $42.5 million.

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, 2020 and 2019, comprehensive loss was equal to the net loss amounts presented for the respective periods in the accompanying consolidated statements of operations. In addition, certain prior year balances have been reclassified to conform to the current presentation. Specifically, the Company's right-to-use assets related to its operating and finance leases are now disclosed separately in the Company's consolidated balance sheets. Previously, these assets were reflected within Deposits and other assets.

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 projecting future liquidity and capital requirements, 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 its 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.

During the year ended December 31, 2019, $4.0 million of cash that was held in a reserve account as required by the Company's then-senior lending agreement and previously classified as restricted cash in the Company's consolidated balance sheet was returned to the Company upon the retirement of the debt underlying that agreement (see Note 8).

Accounts receivable

Accounts receivable is reported at realizable value, net of allowances for contractual credits and doubtful accounts, which are recognized in the period the related revenue is recorded. The Company extends credit to its customers based upon an evaluation of each customer's financial condition and credit history. Evaluations of the financial condition and associated credit risk of customers are performed on an ongoing basis. Based on these evaluations, the Company has concluded that its credit risk is minimal (see Note 17).

Inventories

Raw materials inventory consists of various materials purchased from suppliers, including normal source plasma, used in the production of the Company's products. Work-in-process and finished goods inventories (see Note 3) reflect the cost of raw materials as well as costs for direct and indirect labor, primarily salaries, wages and benefits for applicable employees, as well as an allocation of overhead costs related to the Boca Facility including utilities, property taxes, general repairs and maintenance, consumable supplies and depreciation. The allocation of Boca Facility overhead to inventory is generally based upon the estimated square footage of the Boca Facility that is used in the production of the Company's products relative to the total square footage of the facility.

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. Net realizable value is generally determined based upon the consideration the Company expects to receive when the inventory is sold, less costs to deliver the inventory to the recipient. The estimates for net realizable value of inventory are based on contractual terms or upon historical experience and certain other assumptions, and the Company believes that such assumptions are reasonable. Inventory is periodically reviewed to ensure that its carrying value does not exceed its net realizable value, and adjustments are recorded to write down such inventory, with a corresponding charge to cost of product revenue, when the carrying value or historical cost exceeds its estimated net realizable value. 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 during the period the product was produced. In addition, costs associated with the production of conformance or engineering lots that would not qualify as immediately available for commercial sale are charged to cost of product revenue and not capitalized into inventory.

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, 2020 and 2019 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, 2020 and 2019.

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, 2020 and 2019 did not result in any impairment charges related to goodwill for the years ended December 31, 2020 and 2019.

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, 2020 and 2019, the Company determined that there was no impairment of its long-lived assets.

Revenue recognition

Revenues for the years ended December 31, 2020 and 2019 are comprised of (i) revenues from the sale of the Company's immunoglobulin products, BIVIGAM, ASCENIV and Nabi-HB, (ii) product revenues from the sale of human plasma collected by the Company's Plasma Collection Centers business segment, (iii) contract manufacturing and laboratory services 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 costs associated with the manufacture of the Company's FDA approved products, intermediates and the sale of human source plasma, as well as expenses related to conformance batch production, process development and 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.

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 and ASCENIV, 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 $1.1 million and $1.0 million for the years ended December 31, 2020 and 2019, 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 basis 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 12). The Company is subject to income tax examinations by major taxing authorities for all tax years since 2016 and for previous periods as it relates to the Company's net operating loss carryforwards.

Loss Per Share

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted 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 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, 2020 and 2019, 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,	
	2020	**2019**
Stock options	6,922,931	5,630,351
Restricted stock units	326,000	-
Warrants	4,528,160	2,138,160
	11,777,091	7,768,511

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 8) approximates fair value due to the variable interest rate on this debt.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2016-13,*Financial Instruments – Credit Losses (Topic 326)* ("ASU 2016-13"), which requires financial assets to be presented at the net amount expected to be collected, with an allowance for credit losses to be deducted from the amortized cost basis of the financial asset such that the net carrying value of the asset is presented as the amount expected to be collected. Under ASU 2016-13, the entity's statement of operations is required to reflect the measurement of credit losses for newly recognized financial assets, as well as expected increases or decreases in expected credit losses that have taken place during the period. For public business entities, ASU 2016-13 is effective for fiscal years beginning after December 15, 2019. The Company adopted ASU No. 2016-13 on January 1, 2020, and the adoption of this update did not have a significant impact on the Company's consolidated financial statements.

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 13). 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 10.

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. 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, 2020	December 31, 2019
Raw materials	$ 32,044,393	$ 33,381,806
Work-in-process	30,293,288	14,455,665
Finished goods	19,197,918	5,227,263
Total inventories	$ 81,535,599	$ 53,064,734

Raw materials includes plasma and other materials expected to be used in the production of BIVIGAM, ASCENIV and Nabi-HB, as there are alternative uses for these materials that provide a probable future benefit or will be consumed in the production of goods expected to be available for sale. 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, 2020 and 2019 is summarized as follows:

	December 31, 2020	December 31, 2019
Manufacturing and laboratory equipment	$ 14,468,874	$ 8,831,817
Office equipment and computer software	3,253,528	1,690,248
Furniture and fixtures	2,389,585	582,088
Construction in process	3,336,557	4,285,915
Leasehold improvements	5,272,490	1,673,084
Land	4,339,441	4,339,441
Buildings and building improvements	17,396,557	16,063,680
	50,457,032	37,466,273
Less: Accumulated depreciation	(8,863,942)	(5,724,956)
Total property, plant and equipment, net	$ 41,593,090	$ 31,741,317

The Company recorded depreciation expense on property and equipment of $3.2 million and $2.4 million for the years ended December 31, 2020 and 2019, respectively.

6. INTANGIBLE ASSETS

Intangible assets at December 31, 2020 and 2019 consist of the following:

	December 31, 2020			December 31, 2019		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Trademark and other intangible rights related to Nabi-HB	$ 4,100,046	$ 2,098,833	$ 2,001,213	$ 4,100,046	$ 1,513,112	$ 2,586,934
Rights to intermediates	907,421	464,513	442,908	907,421	334,881	572,540
Customer contract	1,076,557	1,076,557	-	1,076,557	1,076,557	-
	$ 6,084,024	$ 3,639,903	$ 2,444,121	$ 6,084,024	$ 2,924,550	$ 3,159,474

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 are 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, the 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, and the Company had 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, 2020 and 2019 was $0.7 million and $0.8 million, respectively. Estimated aggregate future aggregate amortization expense is expected to be as follows:

2021	$ 715,352
2022	715,352
2023	715,352
2024	298,065

7. ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other current liabilities at December 31, 2020 and 2019 are as follows:

	December 31, 2020	December 31, 2019
Accrued incentives	$ 3,210,884	$ 1,899,769
Accrued rebates	2,604,245	978,786
Accrued payroll	734,972	347,091
Accrued distribution fees	828,120	549,356
Accrued testing	779,660	69,415
Other	207,262	636,978
Total accrued expenses and other current liabilities	$ 8,365,143	$ 4,481,395

8. NOTES PAYABLE

Senior Notes Payable

A summary of outstanding senior notes payable is as follows:

	December 31, 2020	December 31, 2019
Notes payable	$ 100,000,000	$ 72,500,000
Less:		
Debt discount	(7,031,134)	(4,208,837)
Senior notes payable	$ 92,968,866	$ 68,291,163

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 $100.0 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 $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, (iii) a term loan in the principal amount of $12.5 million evidenced by the Company's issuance of a promissory note (the "Perceptive Tranche III Note") in favor of Perceptive on March 20, 2020 (the "Perceptive Tranche III Loan"); and (iv) a term loan in the principal amount of $15 million evidenced by our issuance of a promissory note in favor of Perceptive on December 8, 2020 (the "Perceptive Tranche IV Loan", and together with the Perceptive Tranche I Loan, the Perceptive Tranche II Loan and the Perceptive Tranche III Loan, the "Perceptive Loans"). The Perceptive Tranche III Loan is the result of an amendment to the Perceptive Credit Agreement that the Company and Perceptive entered into on May 3, 2019 (the "First Perceptive Amendment"), and the Perceptive Tranche III Loan became available to the Company upon the approval of BIVIGAM on May 9, 2019. The Perceptive Tranche IV Loan is the result of an amendment to the Perceptive Credit Facility entered into on December 8, 2020 (the "Second Perceptive Amendment"), which also extended the maturity date of the Perceptive Credit Facility to March 1, 2024 (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. In connection with the First Perceptive Amendment, the Company paid an additional facility fee to Perceptive in the amount of $0.1 million on May 3, 2019. In connection with the Second Perceptive Amendment, the Company paid a facility fee to Perceptive in the amount of $0.8 million.

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 for the year ended December 31, 2019 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, 2020 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. There are no scheduled principal payments on the Perceptive Loans prior to the Maturity Date. 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 December 31, 2021, (ii) 2.0% of the prepaid principal amount, if prepaid after December 31, 2021 and on or prior to December 31, 2022, (iii) 4.0% of the prepaid principal amount, if prepaid after December 31, 2022 and on or prior to December 31, 2023, and (iv) 5.0% of the prepaid principal amount, if prepaid any time thereafter and prior to the Maturity 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 its 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 ended 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 ended June 30, 2019 to $55.0 million for the fiscal quarter ending December 31, 2021. At December 31, 2020, 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 purchase1,360,000 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 is 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 ofFebruary 11, 2029. In connection with the First Perceptive Amendment, the Company issued an additional warrant (the "Perceptive Tranche III Warrant") 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. As consideration for the Second Perceptive Amendment, the Company issued an additional warrant (the "Perceptive Tranche IV Warrant" and, together with the Perceptive Warrant and the Perceptive Tranche III Warrant, the "Perceptive Warrants") to purchase 2,390,000 shares of the Company's common stock to Perceptive with an exercise price of $1.94 per share, which is equal to the trailing 10-day VWAP of the Company's common stock on the business day immediately prior to the date of the Perceptive Second Amendment. The Perceptive Tranche IV Warrant was valued by the Company at $3.7 million and has an expiration date of December 8, 2030. Perceptive has represented to the Company, among other things, that it was 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 Loans in the amount of $7.1 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 December 8, 2020 was approximately 13.7%.

Subordinated Note Payable

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

	December 31, 2020	December 31, 2019
Subordinated note payable to Biotest	$ -	$ 15,000,000
Less:		
Debt discount	-	(91,947)
Subordinated note payable	$ -	$ 14,908,053

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 carried an interest at a rate of 6.0% per annum payable semi-annually and was to mature on June 6, 2022. 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. On December 8, 2020, the Company retired the subordinated note with the proceeds from the Perceptive Tranche IV Loan. As part of this transaction, the lender agreed to a 7% discount from the principal, and the obligation under the note was satisfied by a payment by the Company of approximately $14.0 million. As a result, the Company recorded a gain on the extinguishment of the note of approximately $1.0 million.

9. 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, 2020 and 2019.

Common Stock

As of December 31, 2020 and 2019, the Company was authorized to issue 150,000,000 shares of its common stock, $0.0001 par value per share, and 104,902,888 and 59,318,355 shares of common stock were outstanding as of December 31, 2020 and 2019, 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 for awards issued under the Company's equity incentive plans, 30,655,784 shares of common stock were available for issuance as of December 31, 2020.

On August 5, 2020, the Company entered into the Sale Agreement with Jefferies, pursuant to which the Company could offer and sell, from time to time, at its option, through or to Jefferies, up to an aggregate of $50 million of shares of the Company's common stock. On November 5, 2020, the Company and Jefferies amended the Sale Agreement to provide for an increase in the aggregate offering amount under the Sale Agreement such that, as of November 5, 2020, the Company could sell shares having an additional aggregate offering price of up to $20 million. For the year ended December 31, 2020, the Company sold18,537,907 shares of common under the Sale Agreement and received net proceeds of $42.5 million.

On February 11, 2020, the Company completed an underwritten public offering of23,500,000 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 $88.7 million.

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 years ended December 31, 2020 and 2019, the Company issued6,626 and 27,787 shares, respectively, of common stock in connection with the exercise of stock options that had been granted to employees.

Warrants

On December 8, 2020, the Company issued the Perceptive Tranche IV Warrant, whereby Perceptive may purchase an aggregate of2,390,000 shares of common stock at an exercise price $1.94 per share (see Note 8). The warrant was valued at $3.7 million, using the Black-Scholes option-pricing model assuming an expected term of10 years, a volatility of 69.3%, a dividend yield of0% and a risk-free interest rate of0.92%.

On the Perceptive Closing Date, the Company issued the Perceptive Warrant, whereby Perceptive may purchase an aggregate of1,360,000 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 of0% and a risk-free interest rate of2.65%.

On May 3, 2019, the Company issued the Perceptive Tranche III Warrant, whereby Perceptive may purchase an aggregate of250,000 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 of0% and a risk-free interest rate of2.54%.

At December 31, 2020, the Company had outstanding warrants to purchase an aggregate of4,528,160 shares of common stock, with a weighted average exercise price of $2.82 per share and expiration dates ranging between June 2022 and December 2030. 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.

Equity Incentive Plans

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, 2020, an aggregate of 2,664,237 shares were available for issuance under the 2007 Plan and the 2014 Plan. In accordance with the foregoing, on January 1, 2021 the aggregate number of shares available for issuance increased to 6,860,353.

During the years ended December 31, 2020 and 2019, the Company recorded stock-based compensation expense to employees of $2.9 million and $2.7 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, 2020 and 2019, 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, 2020 and 2019 were determined using the Black-Scholes option-pricing model with the following assumptions:

	Years Ended	
	December 31, 2020	December 31, 2019
Expected term	5.5-6.3 years	5.8-6.3 years
Volatility	62-70%	54-63%
Dividend yield	0.0	0.0
Risk-free interest rate	0.33-1.68%	1.36-2.92%

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, 2020 and 2019:

	Shares	Weighted Average Exercise Price
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
Forfeited	(141,724)	$ 3.81
Expired	(27,482)	$ 4.26
Granted	1,468,412	$ 2.93
Exercised	(6,626)	$ 2.03
Options outstanding, vested and expected to vest at December 31, 2020	6,922,931	$ 4.40
Options exercisable	4,544,902	$ 5.01

The weighted average remaining contractual term of stock options outstanding and expected to vest at December 31, 2020 is 6.5 years. The weighted average remaining contractual term of stock options exercisable at December 31, 2020 is 5.4 years. The following table summarizes additional information regarding outstanding and exercisable options under the stock option plans at December 31, 2020:

	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
$2.04 - $3.20	1,328,220	9.2	$ 2.80	$ -	140,474	8.3	$ 2.95	$ -
$3.22 - $4.83	3,925,951	6.9	$ 3.62	-	2,787,632	6.6	$ 3.64	-
$4.84 - $7.26	520,607	5.5	$ 5.51	-	468,643	5.2	$ 5.48	-
$7.56 - $10.80	1,148,153	2.2	$ 8.39	-	1,148,153	2.2	$ 8.39	-
	6,922,931	6.5	$ 4.40	$ -	4,544,902	5.4	$ 5.00	$ -

During the year ended December 31, 2020, the Company granted Restricted Stock Units ("RSUs") to members of the Company's Board of Directors and to certain management employees of the Company. The total RSUs granted during the year represent an aggregate of 361,000 shares of the Company's common stock. The RSUs vest semi-annually over a period of one year for directors and annually over a period of four years for employees. Total compensation expense related to unvested RSUs for the year ended December 31, 2020 was $0.3 million. A summary of the Company's unvested RSU activity and related information is as follows:

	Shares	Weighted Average Grant Date Fair Value
Balance at December 31, 2019	-	$ -
Granted	361,000	$ 2.82
Vested	(15,000)	$ 2.92
Forfeited	(20,000)	$ 2.83
Balance at December 31, 2020	326,000	$ 2.81

Aggregate stock-based compensation expense for the years ended December 31, 2020 and 2019 was as follows:

	2020	2019
Research and development	$ 471,146	$ 360,569
Plasma center operating expenses	33,464	51,340
Selling, general and administrative	2,107,577	2,047,025
Cost of product revenue	242,935	191,843
Total stock-based compensation expense	$ 2,855,122	$ 2,650,777

As of December 31, 2020, the total unrecognized compensation expense related to unvested options was $4.0 million, which is expected to be recognized over a weighted-average period of 2.3 years. As of December 31, 2020, the Company had $0.7 million of unrecognized compensation expense related to unvested RSUs granted under the Company's equity incentive plans, which is expected to be recognized over a weighted-average period of 3.2 years.

10. 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. The Company did not provide such written notice to Areth as of July 31, 2020. Rent expense for the years ended December 31, 2020 and 2019 amounted to $0.1 million. 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, warehousing 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, 2020 and 2019.

During the year ended December 31, 2020, the Company purchased certain specialized medical equipment and services related to the Company's plasma collection centers, as well as personal protective equipment, from GenesisBPS and its affiliates ("Genesis") in the amount of $0.1 million. Genesis is owned by Dr. Grossman and Adam Grossman. Purchases from Genesis for the year ended December 31, 2019 were not material to the Company's consolidated financial statements.

See Note 8 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.

11. 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.

COVID-19 Pandemic

The Company continues to monitor the ongoing developments related to the COVID-19 pandemic and its impacts to the Company's supply-chain operations, including procurement of raw materials and packaging materials, a portion of which are sourced internationally, and the testing of finished drug product that is required prior to its availability for commercial sale. A substantial portion of such testing has historically been performed by contract laboratories outside the United States.

The Company has experienced some delays with final drug product release testing by third-party vendors. In response to these delays, the Company added additional release testing laboratories to its FDA-approved consortium listed in its drug approval documents which the Company believes has adequately addressed this issue. In addition, due to previous state and local "shelter-in-place" orders, the Company has experienced lower than normal donor collections at its FDA approved plasma collection centers. The Company was also subject to delays in shipments of source plasma from its contracted third-party suppliers, as well as delays in deliveries for personal protective equipment, reagents and other non-plasma raw materials and supplies used in the manufacture of its products. The COVID-19 pandemic has also impacted, to a certain degree, the Company's customer engagement initiatives, whereby ADMA's sales and medical affairs field personnel have faced difficulties communicating directly with physicians and other healthcare professionals, as well as the cancellation or postponement of a number of key scientific and medical meetings, further limiting the Company's ability to communicate with potential customers. The Company has implemented a comprehensive suite of virtual engagement initiatives, however, clinician engagement has been reduced due to rapidly evolving COVID-19 priorities at U.S. medical centers.

Notwithstanding the foregoing, the COVID-19 pandemic to date has not had a material impact on the Company's financial condition or results of operations, and the Company does not believe that its production operations at the Boca Facility, the Company's contract fill/finishers or its plasma collection facilities have been significantly impacted by the COVID-19 pandemic. As a result, the Company does not anticipate and has not experienced any material impairments with respect to any of its long-lived assets, including the Company's property and equipment, goodwill or intangible assets.

Although the COVID-19 pandemic has not, to date, materially adversely impacted the Company's capital and financial resources, because the Company is unable to determine the ultimate severity or duration of the pandemic or its long-term effects on, among other things, the global, national or local economies, the capital and credit markets or the Company's workforce, customers or our suppliers, at this time the Company is unable to predict whether COVID-19 will have a material adverse impact on the Company's business, financial condition, liquidity and results of operations.

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 (see Note 17). 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 ("NSP") 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 agreed 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 NSP 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 NSP 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. 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 June of 2023.

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, 2020. The Company does not anticipate recognizing any significant losses relating to these arrangements.

12. 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,	
	2020	2019
Benefit at U.S. federal statutory rate	$ (15,907,195)	$ (10,138,657)
State taxes - deferred	(3,797,393)	(2,010,517)
Increase in valuation allowance	19,535,265	11,790,031
Research and development credits	(246,989)	(115,086)
Other	416,312	474,229
Benefit for income taxes	$ -	$ -

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

	Year Ended December 31,	
	2020	2019
Federal and state net operating loss carryforwards	$ 59,114,928	$ 42,496,374
Federal and state research credits	921,577	630,516
Interest expense limitation carryforwards	2,911,508	-
Transaction costs	1,080,041	1,174,733
Deferred revenue	563,956	603,535
Accrued expenses and other	2,397,513	2,433,142
Total gross deferred tax assets	66,989,523	47,338,300
Less: valuation allowance for deferred tax assets	(66,989,523)	(47,338,300)
Net deferred tax assets	$ -	$ -

As of December 31, 2020, the Company had federal and state (post-apportioned basis) net operating losses ("NOLs") of $239.8 million and $172.6 million, respectively, as well as federal research and development tax credit carryforwards of approximately $0.9 million. Approximately $115.8 million and $90.0 million of the foregoing federal and state NOLs, respectively, will expire at various dates from 2027 through 2040, 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, 2020, the Company performed a preliminary analysis of limitations imposed by Section 382 of the Internal Revenue Code and determined no ownership changes occurred in the current year which would cause additional limitation on the use of the NOLs.

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

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, 2020 and 2019, and does not anticipate a significant change in unrecognized tax benefits during the next 12 months.

13. LEASE OBLIGATIONS

The Company leases certain properties and equipment for its ADMA BioCenters 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 2031. 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 lease expense and cash paid for the Company's operating leases for the year ended December 31, 2020 was $0.7 million and $0.5 million, respectively. For the year ended December 31, 2019 aggregate lease expense and cash paid on these leases was $0.6 million.

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. Including a finance lease the Company entered into in June 2018, the Company has aggregate lease liabilities of $4.7 million and $1.5 million as of December 31, 2020 and 2019, respectively, which are comprised primarily of the leases for the Company's plasma collection centers. The Company's operating leases have a weighted average remaining term of 8.7 years. Scheduled payments under the Company's lease obligations are as follows:

Year ended December 31, 2021	$ 954,133
2022	1,031,213
2023	1,009,159
2024	871,532
2025	866,475
Thereafter	3,168,953
Total payments	7,901,465
Less: imputed interest	(3,201,632)
Current portion	(365,682)
Balance at December 31, 2020	$ 4,334,151

During the year ended December 31, 2020, the Company entered into an additional property lease where the Company intends to construct a new plasma collection facility. As of December 31, 2020, the Company had not taken possession of the property pertaining to this lease, which has a lease commencement date of February 1, 2021. With the exception of an advance deposit and an initial months' rent totaling approximately $34,000, no payments were made under this lease during the year ended December 31, 2020. The initial term of the first lease is for 133 months, with monthly rental payments varying between approximately $13,000 and $17,000, including common area maintenance charges.

14. 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 three plasma collection facilities, two of which hold an approved license with the FDA (and of which one facility has received approvals from the Korean Ministry of Food and Drug Safety as well as FDA approval to implement a Hepatitis B immunization program) and a third for which FDA approval is pending as of December 31, 2020, and one FDA-licensed source plasma collection facility for the year ended December 31, 2019. 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, 2020

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 36,673,287	$ 5,403,662	$ 142,834	$ 42,219,783
Cost of product revenue	55,908,696	5,382,730	-	61,291,426
Loss from operations	(46,904,634)	(4,410,890)	(13,599,353)	(64,914,877)
Interest and other expense, net	(984,017)	(7,388)	(10,834,063)	(11,825,468)
Gain on extinguishment of debt	-	-	991,797	991,797
Net loss	(47,888,651)	(4,418,278)	(23,441,619)	(75,748,548)
Capital expenditures	7,579,437	5,147,243	-	12,726,680
Depreciation and amortization expense	3,341,506	591,593	9,193	3,942,292
Total assets	140,908,957	13,102,008	53,662,429	207,673,394

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

15. 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 $0.9 million and $0.7 million of related compensation expense for the years ended December 31, 2020 and 2019, respectively.

16. SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Supplemental cash flow information for the years ended December 31, 2020 and 2019 is as follows:

	2020	2019
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 10,267,632	$ 8,112,231
Noncash Financing and Investing Activities:		
Equipment acquired reflected in accounts payable and accrued liabilities	$ 973,958	$ 514,904
Right-to-use assets in exchange for lease obligations	$ 3,329,374	$ 1,421,669
Warrants issued in connection with notes payable	$ 3,740,980	$ 3,579,115

17. 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, 2020, three customers accounted for approximately 92% of the Company's consolidated accounts receivable. At December 31, 2019, two customers accounted for89% of the Company's total accounts receivable.

For the year ended December 31, 2020, three customers represented an aggregate of82% of the Company's consolidated revenues. For the year ended December 31, 2019, three customers totaled 70% of the Company's consolidated revenues.

The Company purchases substantially all of its raw material plasma from Grifols. For the year ended December 31, 2020, plasma purchases from Grifols were approximately $25.0 million, or 68% of the Company's total inventory purchases. 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.

18. SUBSEQUENT EVENTS

Issuance of Common Stock

On February 3, 2021, the Company amended the Sale Agreement with Jefferies (see Note 1) to increase the aggregate offering amount under the Sale Agreement to allow the Company to sell shares having an additional aggregate offering price of up to $35.4 million.

Between January 1, 2021 and March 16, 2021, the Company sold an additional16,311,084 shares of its common stock under the Sale Agreement and received net proceeds in the amount of $38.3 million, which leaves a remaining gross balance that can be raised under the Sale Agreement of $22.7 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).
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock of ADMA Biologics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on December 16, 2020).
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	Warrant to Purchase Stock, dated May 3, 2019, issued by the Company to Perceptive Credit Holdings II, LP (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on May 3, 2019).
4.7*	Warrant to Purchase Stock, dated December 8, 2020, issued by the Company to Perceptive Credit Holdings II, LP.
4.8	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).
4.9	Note, dated May 3, 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 May 3, 2019).
4.10	Note, dated December 8, 2020, issued by the Company to Perceptive Credit Holdings II, L.P. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on December 9, 2020).
4.11*	Description of Securities Registered under Section 12 of the Securities Exchange Act of 1934.
4.12	Rights Agreement, dated as of December 16, 2020, by and between ADMA Biologics, Inc. and Continental Stock Transfer and Trust Company, as rights agent (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on December 16, 2020).
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).
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).
10.9.1	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. (incorporated herein by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed on March 12, 2020).
10.10	Lease, effective as of February 17, 2017, by and between Home Center Properties, LLC and ADMA BioCenters 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 BioCenters 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).
10.15	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 BioCenters 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	Amendment No. 1 to Credit Agreement and Guaranty, dated as of May 3, 2019, by and among the Company, ADMA Plasma Biologics, Inc., ADMA BioCenters Georgia Inc., ADMA BioManufacturing, LLC and Perceptive Credit Holdings II, LP (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 3, 2019).
10.18	Amendment No. 2 to the Credit Agreement and Guaranty, dated December 8, 2020, by and among the Company, ADMA Plasma Biologics, Inc., ADMA BioCenters Georgia Inc., ADMA BioManufacturing, LLC and Perceptive Credit Holdings II, LP. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 9, 2020).
10.19	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).
10.20+	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).
10.20.1	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).
10.21+	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).
10.21.1+	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).

10.21.2+	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).
10.22	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).
10.23+	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).
10.23.1++	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).
10.24+	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).
10.25	Share Transfer, Amendment and Release Agreement, dated as of May 14, 2018, by and among the Company, ADMA BioManufacturing, LLC, ADMA BioCenters 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).
10.26	Open Market Sale Agreement℠, dated August 5, 2020, by and between ADMA Biologics, Inc. and Jefferies LLC (incorporated by reference to Exhibit 1.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 5, 2020).
10.26.1	Amendment to Open Market Sale Agreement℠, dated November 5, 2020, by and between ADMA Biologics, Inc. and Jefferies LLC (incorporated by reference to Exhibit 1.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 5, 2020).
10.26.2	Amendment No. 2 to the Open Market Sale Agreement℠ by and between ADMA Biologics, Inc., and Jefferies LLC (incorporated by reference to Exhibit 1.1. to the Company's Current Report on Form 8-K filed on February 3, 2021).
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, 2020, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at December 31, 2020 and December 31, 2019, (ii) Consolidated Statements of Operations for the years ended December 31, 2020 and 2019, (iii) Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2020 and 2019, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2020 and 2019; and (v) Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

+ 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.

EXHIBIT 31.1

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

I, Adam S. Grossman, certify that:

1. I have reviewed this Annual Report on Form 10-K of ADMA Biologics, Inc. for the year ended December 31, 2020;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 25, 2021

/s/ Adam S. Grossman
Name: Adam S. Grossman
Title: President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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

I, Brian Lenz, certify that:

1. I have reviewed this Annual Report on Form 10-K of ADMA Biologics, Inc. for the year ended December 31, 2020;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 25, 2021

/s/ Brian Lenz
Name: Brian Lenz
Title: Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

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

In connection with the annual report of ADMA Biologics, Inc., a Delaware corporation (the "Company"), on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Adam S. Grossman, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 25, 2021

/s/ Adam S. Grossman
Name: Adam S. Grossman
Title: President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

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

In connection with the annual report of ADMA Biologics, Inc., a Delaware corporation (the "Company"), on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian Lenz, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 25, 2021

/s/ Brian Lenz
Name: Brian Lenz
Title: Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2020, ADMA Biologics, Inc. (the "Company," "we," or "our") had two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock, $0.0001 par value per share (the "Common Stock") and our preferred share purchase rights.

The Company is authorized to issue 160,000,000 shares of capital stock, divided into two classes consisting of (i) 150,000,000 shares of Common Stock, and (ii) 10,000,000 shares of preferred stock, $0.0001 par value per share ("Preferred Stock").

DESCRIPTION OF COMMON STOCK

The following description of our Common Stock is a summary, does not purport to be complete and is subject to the provisions of our Second Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") and our Amended and Restated Bylaws (the "Bylaws"). For the complete terms of our Common Stock, please refer to our Certificate of Incorporation and our Bylaws.

General

The Common Stock is not redeemable, and has no subscription or conversion rights. The Common Stock does not have any sinking fund provisions. Holders of Common Stock do not have cumulative or preemptive rights.

Voting

Holders of Common Stock are entitled to one vote per share on all matters on which stockholders are generally entitled to vote. Holders of a majority of the outstanding shares of Common Stock constitute a quorum at a meeting of stockholders for the transaction of any business. Directors are elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Any other action is authorized by a majority of the votes cast, except where the Delaware General Corporation Law ("DGCL") prescribes a different percentage of votes or a different exercise of voting power.

Dividends

Holders of our Common Stock are entitled to receive ratably such dividends, if any, as may be declared by our Board of Directors out of funds legally available therefor, subject to any preferential dividend rights for our outstanding Preferred Stock.

Distributions upon Dissolution, Liquidation or Winding Up

Upon a liquidation, dissolution or windup of the Company, subject to the rights, if any, of holders of any outstanding series of Preferred Stock that may be issued, holders of Common Stock shall be entitled to receive the assets of the Company available for distribution to its stockholders ratably in proportion to the number of shares of Common Stock held by them.

Delaware Anti-Takeover Law

The Company is subject to the provisions of Section 203 of the DGCL. Section 203 prohibits publicly held Delaware corporations from engaging in a "business combination" with an "interested stockholder" 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. A "business combination" includes mergers, asset sales and other transactions resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation's voting stock. These provisions could have the effect of delaying, deferring or preventing a change of control of the Company or reducing the price that certain investors might be willing to pay in the future for shares of the Company's stock.

Staggered Board; Removal of Directors; Certificate of Incorporation

The Company's Certificate of Incorporation divides the Company's Board into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of the Company's stockholders, with the other classes continuing for the remainder of their respective three year terms. Except as the DGCL may otherwise require, any newly created directorships or vacancies on the Board may be filled only by the Board, but subject to the rights of holders of any series of Preferred Stock.

The Company's Certificate of Incorporation provides that (i) all stockholder actions must be effected at a duly called meeting of the stockholders and (ii) stockholders may not adopt actions by written consent without a meeting.

The combination of these provisions will make it more difficult for the Company's existing stockholders to replace the Board as well as for another party to obtain control of the Company by replacing members of the Board. Since the Board has the power to retain and discharge the officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated Preferred Stock makes it possible for the Board to issue Preferred Stock with voting or other rights or preferences that could impede any attempt to effect a change of control of the Company.

Registration Rights

In connection with our acquisition of certain assets of Biotest Pharmaceuticals Corporation ("BPC") in 2017 (the "Biotest Transaction"), we entered into a registration rights agreement with BPC pursuant to which BPC, or its transferee, or its affiliate(s) have, among other things, certain registration rights under the Securities Act of 1933, as amended, with respect to its shares of our Common Stock, subject to certain transfer restrictions. In July 2018, BPC agreed to transfer its remaining shares of Common Stock to The Biotest Divestiture Trust (the "Biotest Trust"). In connection with the transfer of shares, the Biotest Trust has agreed to be bound by all obligations of, and will have all of the remaining rights of BPC under the aforementioned registration rights agreement.

Transfer Agent

Continental Stock Transfer & Trust Company, 1 State Street 30th Floor, New York, New York, serves as the transfer agent and registrar for the Company's stock.

Stock Exchange Listing

Our Common Stock is traded on the Nasdaq Stock Market under the symbol "ADMA."

DESCRIPTION OF PREFERRED SHARE PURCHASE RIGHTS

On December 16, 2020, the Board of Directors (the "Board") of the Company, approved and adopted a Rights Agreement, dated as of December 16, 2020 (the "Rights Agreement"), by and between the Company and Continental Stock Transfer and Trust Company, as rights agent. Pursuant to the Rights Agreement, the Board declared a dividend of one preferred share purchase right (each, a "Right") for each outstanding share of Common Stock (each share, a "Common Share"). The Rights are distributable to stockholders of record as of the close of business on December 30, 2020 (the "Record Date"). One Right also will be issued together with each Common Share issued by the Company after December 30, 2020, but before the Distribution Date (as defined below) (or the earlier redemption or expiration of the Rights) and, in certain circumstances, after the Distribution Date.

Generally, the Rights Agreement works by causing substantial dilution to any person or group that acquires beneficial ownership of ten percent (10%) or more of the Common Shares without the approval of the Board. As a result, the overall effect of the Rights Agreement and the issuance of the Rights may be to render more difficult or discourage a merger, tender or exchange offer or other business combination involving the Company that is not approved by the Board. The Rights Agreement is not intended to interfere with any merger, tender or exchange offer or other business combination approved by the Board. The Rights Agreement also does not prevent the Board from considering any offer that it considers to be in the best interest of its stockholders.

The following is a summary description of the Rights and material terms and conditions of the Rights Agreement. This summary is intended to provide a general description only, does not purport to be complete and is qualified in its entirety by reference to the complete text of the Rights Agreement, a copy of which is filed as Exhibit 4.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on December 16, 2020. All capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Rights Agreement.

The Rights

Subject to the terms, provisions and conditions of the Rights Agreement, if the Rights become exercisable, each Right would initially represent the right to purchase from the Company one one-thousandth of a share of a newly-designated series of preferred stock, Series A Junior Participating Preferred Stock, par value $0.0001 per share, of the Company (each, a "Series A Preferred Share" and, collectively, the "Series A Preferred Shares"), at an exercise price of $12.50 per one one-thousandth of a Series A Preferred Share, subject to adjustment (the "Exercise Price"). If issued, each one one-thousandth of a Series A Preferred Share would give the stockholder approximately the same dividend, voting and liquidation rights as does one Common Share. However, prior to exercise, a Right does not give its holder any rights as a stockholder of the Company, including, without limitation, any dividend, voting or liquidation rights. A copy of the Certificate of Designation of Series A Junior Participating Preferred Stock (the "Series A Certificate of Designation") that the Company intends to file with the Secretary of State of the State of Delaware on December 16, 2020 to designate the Series A Preferred Shares is filed as Exhibit 3.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Initial Exercisability

Initially, the Rights will not be exercisable, certificates will not be sent to stockholders and the Rights will automatically trade with the Common Shares. Until the Rights separate from the Common Shares and become exercisable (or the earlier redemption or expiration of the Rights), the Rights will be evidenced by Common Share certificates, Rights relating to any uncertificated Common Shares that are registered in book entry form will be represented by a notation in book entry on the records of the Company, and the surrender for transfer of any Common Shares will also constitute the transfer of the associated Rights.

Subject to certain exceptions specified in the Rights Agreement, the Rights will separate from the Common Shares and become exercisable following the earlier to occur of the tenth (10th) business day (or such later date as may be determined by the Board) after (i) the day on which a public announcement or filing with the Securities and Exchange Commission (the "SEC") is made indicating that a person has become an Acquiring Person (as defined below) or that discloses information that reveals the existence of an Acquiring Person (the "Shares Acquisition Date"), or (ii) the commencement by any person (other than certain exempted persons) of, or the first public announcement of the intent of any person (other than certain exempted persons) to commence, a tender or exchange offer by or on behalf of a person, the successful consummation of which would result in any person (other than certain exempted persons) becoming an Acquiring Person, irrespective of whether any shares are actually purchased or exchanged pursuant to such offer (the earlier of these dates is called the "Distribution Date").

After the Distribution Date, separate rights certificates will be issued and the Rights may be transferred other than in connection with the transfer of the underlying Common Shares unless and until the Board has determined to effect an exchange pursuant to the Rights Agreement (as described below).

Acquiring Person

Under the Rights Agreement, an Acquiring Person is any person who or that, together with all Affiliates and Associates (as defined in the Rights Agreement) of such person, from and after the first public announcement by the Company of the adoption of the Rights Agreement, is or becomes the beneficial owner of ten percent (10%) or more of the Common Shares outstanding, subject to various exceptions. For purposes of the Rights Agreement, beneficial ownership is defined to include the ownership of derivative securities.

The Rights Agreement provides that an Acquiring Person does not include the Company, any subsidiary of the Company, any employee benefit plan of the Company or any subsidiary of the Company, or any person organized, appointed, or established to hold Common Shares pursuant to any employee benefit plan of the Company or for the purpose of funding any such plan.

The Rights Agreement also provides that the following persons shall not be deemed an Acquiring Person thereunder: (i) any person who becomes the beneficial owner of ten percent (10%) or more of the shares of Common Stock of the Company then outstanding solely as a result of the initial grant or vesting of any options, warrants, rights or similar interests (including restricted shares and restricted stock units) by the Company to its directors, officers and employees pursuant to any employee benefit or stock ownership plan of the Company, or the acquisition of shares of Common Stock of the Company upon the exercise or conversion of any such securities so granted; (ii) any person who as the result of an acquisition of shares of Common Stock by the Company (or any subsidiary of the Company, or any person organized, appointed, established or holding shares of Common Stock of the Company for or pursuant to the terms of any such plan) that, by reducing the number of shares of Common Stock of the Company outstanding, increases the proportionate number of shares of Common Stock of the Company beneficially owned by such person to ten percent (10%) or more of the Common Shares then outstanding; (iii) any person who or that became the beneficial owner of ten percent (10%) or more of the Common Shares then outstanding as a result of the acquisition of Common Shares directly from the Company; or (iv) any person who or that would otherwise be an Acquiring Person who or that the Board determines had become such inadvertently (including, without limitation, because (A) such person was unaware that it beneficially owned a percentage of the Common Shares that would otherwise cause such person to be an "Acquiring Person," or (B) such person was aware of the extent of its beneficial ownership of Common Shares but had no actual knowledge of the consequences of such beneficial ownership under the Rights Agreement), and who or that thereafter within five (5) business days of being requested by the Company, reduces such person's beneficial ownership to less than ten percent (10%) of the Common Shares then outstanding.

"Grandfathering" of Existing Holders

The Rights Agreement also provides that any person who beneficially owned ten percent (10%) or more of the Common Shares immediately prior to the first public announcement by the Company of the adoption of the Rights Agreement (each a "Grandfathered Person"), shall not be deemed to be an "Acquiring Person" for purposes of the Rights Agreement unless and until a Grandfathered Person becomes the beneficial owner of one or more additional Common Shares after the first public announcement by the Company of the adoption of the Rights Agreement (other than pursuant to a dividend or distribution paid or made by the Company on the outstanding Common Shares, pursuant to a split, reclassification or subdivision of the outstanding Common Shares or pursuant to the acquisition of beneficial ownership of Common Shares upon the vesting or exercise of any option, warrants or other rights, or upon the initial grant or vesting of restricted stock, granted or issued by the Company to its directors, officers and employees, pursuant to a compensation or benefits plan or arrangement adopted by the Board). However, if upon acquiring beneficial ownership of one or more additional Common Shares at any time after the first public announcement by the Company of the adoption of the Rights Agreement, the Grandfathered Person does not, at such time, beneficially own ten percent (10%) or more of the Common Shares then outstanding, the Grandfathered Person will not be treated as an "Acquiring Person" for purposes of the Rights Agreement.

Flip-In Trigger

If a person becomes an Acquiring Person, then, following the occurrence of the Distribution Date and subject to the terms, provisions and conditions of the Rights Agreement, each Right will entitle the holder thereof to purchase from the Company, upon payment of the Exercise Price, in lieu of a number of one one-thousandths of a Series A Preferred Share, a number of Common Shares (or, in certain circumstances, cash, property or other securities of the Company) having a then-current market value of twice the Exercise Price. However, the Rights are not exercisable until such time as the Rights are no longer redeemable by the Company, as further described below.

Following the occurrence of an event set forth in the preceding paragraph, all Rights that are or, under certain circumstances specified in the Rights Agreement, were beneficially owned by an Acquiring Person or certain of its transferees will become null and void and nontransferable.

Flip-Over Trigger

If, after an Acquiring Person obtains beneficial ownership of ten percent (10%) or more of the Common Shares, (i) the Company merges into another entity, (ii) an acquiring entity merges into the Company, or (iii) the Company sells or transfers more than fifty percent (50%) of its assets, cash flow or earning power, then each Right (except for Rights that have previously been voided as set forth above) will entitle the holder thereof to purchase, upon payment of the Exercise Price, in accordance with the terms of the Rights Agreement, a number of shares of common stock of the person engaging in the transaction having a then-current market value of twice the Exercise Price.

Redemption of the Rights

At any time until the close of business on the tenth (10th) business day after the Shares Acquisition Date (or, if the tenth (10th) business day after the Shares Acquisition Date occurs before the Record Date, the close of business on the Record Date), or thereafter under certain circumstances, the Company may redeem the Rights in whole, but not in part, at a price of $0.001 per Right (the "Redemption Price"). The Redemption Price may be paid in cash, Common Shares or other forms of consideration, as determined by the Board, in the exercise of its sole discretion. The redemption of the Rights may be made effective at such time, on such basis and subject to such conditions as the Board in its sole discretion may establish. Immediately upon any redemption of the Rights, the right to exercise the Rights will terminate and the only right of the holders of Rights will be to receive the Redemption Price without any interest thereon.

Exchange of the Rights

At any time after any person (other than certain exempted persons and Grandfathered Persons) becomes an Acquiring Person, and prior to the acquisition by any person of beneficial ownership of fifty percent (50%) or more of the Common Shares, the Board may, at its option, cause the Company to exchange all or part of the then outstanding and exercisable Rights (other than Rights held by the Acquiring Person or any Affiliate or Associate thereof, which would have become null and void and nontransferable in accordance with the terms of the Rights Agreement), in whole or in part, for Common Shares at an exchange ratio (subject to adjustment) of one Common Share for each Right.

In any exchange of the Rights pursuant to the Rights Agreement, the Company, at its option, may, and to the extent there are an insufficient number of authorized Common Shares not reserved for any other purpose to exchange for all of the outstanding Rights, shall, substitute preferred stock or other securities of the Company for some or all of the Common Shares exchangeable for Rights such that the aggregate value received by a holder of Rights in exchange for each Right is substantially the same value as one Common Share. The exchange of the Rights by the Board may be made effective at such time, on such basis, and subject to such conditions as the Board in its sole discretion may establish. Immediately upon the action of the Board authorizing the exchange of the Rights, the right to exercise the Rights will terminate, and the only right of the holders of Rights will be to receive the Common Shares or other consideration issuable in connection with the exchange.

Expiration of the Rights

The Rights and the Rights Agreement will expire upon the earliest to occur of (i) the date on which all of the Rights are redeemed, (ii) the date on which the Rights are exchanged, and (iii) the close of business on December 15, 2021.

Amendment of Rights Agreement

Except as otherwise provided in the Rights Agreement, the Company, by action of the Board, may from time to time, in its sole and absolute discretion, supplement or amend any provision of the Rights Agreement in any respect without the approval of any holders of Rights, including, without limitation, in order to (i) cure any ambiguity in the Rights Agreement, (ii) correct or supplement any provision contained in the Rights Agreement that may be defective or inconsistent with any other provisions contained therein, (iii) shorten or lengthen any time period in the Rights Agreement, or (iv) otherwise change, amend, or supplement any provisions in the Rights Agreement in any manner that the Company may deem necessary or desirable; *provided, however*, that from and after such time as any person becomes an Acquiring Person, the Rights Agreement may not be supplemented or amended in any manner that would adversely affect the interests of the holders of Rights (other than Rights that have become null and void pursuant to the Rights Agreement) as such or cause the Rights Agreement to become amendable other than in accordance with the terms of the Rights Agreement. Without limiting the foregoing, the Company, by action of the Board, may at any time before any person becomes an Acquiring Person amend the Rights Agreement to make the provisions of the Rights Agreement inapplicable to a particular transaction by which a person might otherwise become an Acquiring Person or to otherwise alter the terms and conditions of the Rights Agreement as they may apply with respect to any such transaction.

Rights of Holders

Until a Right is exercised, a Right does not give its holder any rights as a stockholder of the Company, including, without limitation, any dividend, voting or liquidation rights.

Anti-Dilution Provisions

The Board may adjust the Exercise Price, the number of Series A Preferred Shares issuable and the number of outstanding Rights to prevent dilution that may occur from a stock dividend, a stock split or a reclassification of the Series A Preferred Shares or Common Shares.

With certain exceptions, no adjustments to the Exercise Price will be made until the cumulative adjustments amount to at least one percent (1%) of the Exercise Price. No fractional Series A Preferred Shares will be issued other than fractions that are integral multiples of one one-thousandth of a share and, in lieu thereof, an adjustment in cash will be made based on the current market price of the Series A Preferred Shares.

Tax Consequences

The adoption of the Rights Agreement and the subsequent distribution of the Rights to stockholders should not be a taxable event for the Company or its stockholders under presently existing U.S. federal income tax laws. However, if the Rights become exercisable or if the Rights are redeemed, stockholders may recognize taxable income, depending on the circumstances then existing.

Accounting Treatment

The distribution of the Rights as a dividend to the Company's stockholders is not expected to have any financial accounting or reporting impact. The fair value of the Rights is expected to be zero when they are distributed because the Rights will be "out of the money" when distributed and no value should be attributable to them. Additionally, the Rights do not meet the definition of a liability under generally accepted accounting principles in the United States and are therefore not accounted for as a long-term obligation.

Authority of the Board

When evaluating decisions relating to the redemption of the Rights or any amendment to the Rights Agreement to delay or prevent the Rights from detaching and becoming exercisable as a result of a particular transaction, pursuant to the Rights Agreement, the Board, or any future board of directors, would not be subject to restrictions such as those commonly known as "dead-hand," "slow-hand," "no-hand," or similar provisions.

Certain Anti-Takeover Effects

The Rights are not intended to prevent a takeover of the Company and should not interfere with any merger or other business combination approved by the Board. However, the Rights may cause substantial dilution to a person or group that acquires beneficial ownership of ten percent (10%) or more of the issued and outstanding Common Shares (which includes for this purpose stock referenced in derivative transactions and securities) without the approval of the Board.

SEC Registration

Since the Rights are not exercisable immediately, registration with the SEC of the Series A Preferred Shares issuable upon exercise of the Rights is not required until the Rights become exercisable.

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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.

Adam S. Grossman, Founder, Director

Martha J. Demski, Director
Former SVP, CFO Ajinomoto Althea

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

Lawrence P. Guiheen, Director
CEO Wellmond LLC

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 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-Documents" section of the ADMA Biologics, Inc. website at www.admabiologics.com.

CORPORATE HEADQUARTERS

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Phone: (201) 478-5552
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www.admabiologics.com

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 10 a.m. ET on May 27, 2021 via webcast through the link: www.virtualshareholdermeeting.com/ADMA2021.

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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14 Sylvan Way, 3rd Floor
Parsippany, NJ 07054
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 American 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: BIVIGAM® (immune globulin intravenous, human) for the treatment of primary humoral immunodeficiency (PI); ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) for the treatment of PI; and NABI-HB® (hepatitis B immune globulin, human) to provide enhanced immunity against the hepatitis B virus. ADMA manufactures its immune globulin products at its FDA-licensed 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. 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. For more information, please visit www.admabiologics.com.

Cautionary Statement Regarding Forward-Looking Information

These statements include statements about our ability to continue as a going concern; our ability to manufacture BIVIGAM and ASCENIV on a commercial scale and commercialize these products as a result of their approval by the U.S. Food and Drug Administration (the "FDA") in 2019; our plans to develop, manufacture, market, launch and expand our commercial infrastructure 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 our third-party customers and vendors and their compliance with applicable regulatory requirements; our belief that we have addressed the delays experienced with final drug product GMP release testing by our third-party vendors by adding additional release testing laboratories to our FDA-approved consortium listed in our drug approval documents; our ability to obtain adequate quantities of FDA-approved plasma with proper specifications; our plans to increase our supplies of source plasma, which include plasma collection center expansion, our ability to obtain and maintain regulatory compliance and receive FDA approvals of new plasma collection centers and reliance on 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 BIVIGAM, ASCENIV and Nabi-HB, 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 and timing by 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 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 and efficiencies of our manufacturing capacity, yield improvements, supply-chain robustness, in-house fill-finish capabilities, 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; effects of the coronavirus COVID-19 pandemic on our business, financial condition, liquidity and results of operations, and our ability to continue operations in the same manner as previously conducted prior to the macroeconomic effects of the COVID-19 pandemic; 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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