

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, 2023

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

(State or Other Jurisdiction of Incorporation or Organization)

56-2590442

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

465 State Route 17, Ramsey, New Jersey

(Address of Principal Executive Offices)

07446

(Zip Code)

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

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

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common stock, par value \$0.0001 per share	ADMA	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	<input checked="" type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-accelerated Filer	<input type="checkbox"/>	Smaller Reporting Company	<input checked="" type="checkbox"/>
		Emerging Growth Company	<input type="checkbox"/>

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b).

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 \$793,963,197 as of June 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter), based on a total of 215,166,178 shares of common stock held by non-affiliates and a closing price of \$3.69 as reported on the Nasdaq Global Market on June 30, 2023.

As of February 23, 2024, there were 228,220,236 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.

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Explanatory Note

Based on the value of the non-affiliate float for our common stock as of June 30, 2023, we have transitioned from a “Non-Accelerated Filer” and “Smaller Reporting Company” for 2023 to a “Large Accelerated Filer” for 2024. As this Annual Report on Form 10-K is our first filing following our transition from being a Smaller Reporting Company to a Large Accelerated Filer, we are permitted to continue to provide scaled disclosures under Regulations S-K and S-X for this Annual Report on Form 10-K and in our definitive proxy statement on Schedule 14A for our 2024 Annual Meeting of Stockholders. We have elected to make such scaled disclosures in this Annual Report on Form 10-K and in our definitive proxy statement on Schedule 14A for our 2024 Annual Meeting of Stockholders. Commencing with our Quarterly Report on Form 10-Q for the quarter ending March 31, 2024, we will no longer be permitted to report under the Smaller Reporting Company scaled disclosure regime for our periodic reports. Additionally, immediately upon filing this Annual Report on Form 10-K, we will become a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

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 that 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 manufacture ASCENIV and BIVIGAM on a commercial scale and further 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 current Good Manufacturing Practices (“cGMP”) 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, our ability to obtain and maintain regulatory compliance 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 ASCENIV, BIVIGAM 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 (“IG”) 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 Humoral Immunodeficiency (“PI”), also known as Primary Immunodeficiency Disease (“PIDD”) or Inborn Errors of Immunity, 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 ability to develop, manufacture, receive regulatory approval and commercialize our potential pipeline of any new hyperimmune globulins;
- 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 positive cash flows and the potential 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;
- pandemics, or a resurgence of a pandemic, may adversely affect our business, financial condition, liquidity or results of operations; and
- future domestic and global economic conditions including, but not limited to, supply chain constraints, inflationary pressures or performance or geopolitical conditions, including the continuing conflict in Europe or the evolving conflict in the Middle East and surrounding areas.

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 “ASCENIVTM”, “BIVIGAM[®]” and “Nabi-HB[®]”, which are protected under applicable intellectual property laws and are the property of ADMA Biologics, Inc., or its subsidiaries. Solely for convenience, trademarks, trade names and service marks referred to in this Annual Report may appear without the [®] or TM 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 subsidiaries, ADMA BioManufacturing, LLC, a Delaware limited liability company (“ADMA BioManufacturing”), ADMA BioCenters Georgia Inc., a Delaware corporation (“ADMA BioCenters”) and ADMA Plasma Biologics, Inc., a Delaware corporation (“ADMA Plasma Biologics”).

Overview

We are an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty 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”) or Inborn Errors of Immunity, and for which we received FDA approval on May 9, 2019 and commenced commercial sales in August 2019; (ii) ASCENIV (Immune Globulin Intravenous, Human – sIra 10% Liquid), an IVIG product indicated for the treatment of PI in adults and adolescents, 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, plasma fractionation and purification facility located in Boca Raton, Florida with a peak annual processing capability of up to 600,000 liters (the “Boca Facility”). Based on current production yields, our completed and ongoing supply chain enhancements and capacity expansion initiatives, we believe this facility has the potential to produce sufficient quantities of our immune globulin (“IG”) products representing annual revenues of approximately \$330 million in 2024 and potentially \$380 million in 2025. At these revenue levels, we forecast achieving consolidated gross margins in the range of 40-50% and net income margins in the range of 20-30%. These assumptions translate to potential fiscal year 2024 and 2025 net income of \$65 million and \$115 million or more and adjusted EBITDA of \$90 million and \$140 million or more, respectively.

For the year ended December 31, 2023 we had a net loss of loss of \$28.2 million and achieved adjusted net income of \$0.7 million which, as further described under “Non-GAAP Financial Measures”, excludes charges related to the refinancing of our senior debt of \$26.2 million and an IT systems disruption of \$2.7 million (see Management’s Discussion and Analysis of Financial Condition and Results of Operations). We also generated positive cash flow from operations for the year ended December 31, 2023 for the first time in the Company’s history, primarily as a result of our significant revenue growth and continued physician, patient and payer acceptance of ASCENIV and BIVIGAM that we have experienced over the past several years.

Through our ADMA BioCenters subsidiary, we currently operate ten source plasma collection facilities in the U.S., all of which hold FDA licenses. This business unit, which we refer to as our Plasma Collection Centers business segment, provides us with the blood plasma required for the manufacture of our products, and also allows us to sell certain quantities of source and hyperimmune plasma to third-party customers for further manufacturing. In addition, three of our FDA-approved plasma collection centers also have approvals from the Korean Ministry of Food and Drug Safety (“MFDS”), as well as FDA approval to operate a Hepatitis B immunization program. 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 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, through a five-year manufacturing and supply agreement we entered into in January 2020. These intermediate by-products are used as the starting raw material to produce other plasma-derived biologics. In addition, from time to time we provide contract manufacturing services for certain third-party clients. We also provide laboratory contracting services to certain customers and anticipate providing contract filling, labeling and packing services utilizing our FDA-approved in-house fill-finish capabilities.

Our Products

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) became effective April 1, 2021. 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 PIDD or PI, 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 ("SBI") 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 patients diagnosed with PIDD better positions ADMA to potentially further evaluate ASCENIV in immune-compromised patients infected with or at-risk for RSV infection or potentially other respiratory viral pathogens at an appropriate time. Due to the COVID-19 pandemic, our plans have been delayed. In the future, however, we may elect to work with the FDA and the immunology and infectious disease community to potentially design an appropriate clinical trial to evaluate the use of ASCENIV in this patient population. Commercial sales of ASCENIV commenced in October of 2019 and in 2023, ADMA commenced manufacturing ASCENIV at the 4,400 Liter production scale for the first time in the Company's history. We expect that this expansion should meaningfully improve the product's margin profile and increase plant production capacity as fewer batches will be needed to support our revenue goals. ASCENIV's prescriber and patient base continued to expand during 2023, which drove record utilization and pull-through for this product. These elevated demand trends have sustained into 2024, and ADMA currently expects that this product's rapid growth will continue throughout 2024 and beyond.

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 (known as fractionation), thereby enabling us to re-launch and commercialize this product in the U.S. 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. The commercial re-launch and first commercial sales for this product commenced in August of 2019.

On April 28, 2021, we announced that the FDA granted approval for our expanded plasma pool production scale process, allowing for a 4,400-liter plasma pool for the manufacture of our BIVIGAM IVIG product. This increased IVIG plasma pool scale, which allows us to produce BIVIGAM at an expanded capacity utilizing the same equipment, release testing assays and labor force, has had a favorable impact on our gross margins, manufacturing efficiencies and operating results.

On December 12, 2023, we announced that the FDA approved the expansion of BIVIGAM’s label in the U.S. to now include the pediatric setting for those two years of age and older.

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, which is a major global health problem. The Hepatitis B virus can cause chronic infection and places 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.

Evaluation of ASCENIV in PIDD Patients

PIDD or PI, also known as Inborn Errors of Immunity, is 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 by *The Plasma Proteins Market In The United States*, the U.S. sales of immune and hyperimmune globulin products for all its uses were reported to be approximately \$10.5 billion in 2022 and are expected to exceed \$20 billion by 2030.

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 SBI 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 Biologics License Application (“BLA”), exceed the requirement specified by FDA guidance of ≤ 1 serious infection 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 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 over the past several years.

Based on these results, we may elect to evaluate ASCENIV for the treatment of RSV or other respiratory viral pathogens in immunocompromised patients or other appropriate patient populations. Due to the COVID-19 pandemic, our plans to commence such evaluation have been delayed. In the future however, we may work with the FDA and the immunology and infectious disease community to design an appropriate clinical trial to evaluate the use of ASCENIV in this patient population.

Plasma Collection Operations

ADMA BioCenters operates a total of ten U.S.-based plasma collection facilities, all of which hold FDA licenses and are actively collecting source and high-titer RSV plasma. Currently, three facilities have also received approvals from MFDS as well as FDA approval to implement a Hepatitis B immunization program. Source plasma that is collected from our FDA-licensed facilities provides us with the blood plasma for the manufacture of our products. 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.

Our Strategy

Our goal is to be a leader in manufacturing, marketing and developing specialty biologics 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 ASCENIV and BIVIGAM for the treatment of patients with PI.** We continue to enhance our recruiting initiatives and expand our existing specialty commercial sales force and commercial-facing organization to market ASCENIV and BIVIGAM to appropriate sites of care including 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, quality control, inventory management, regulatory affairs, manufacturing, scientific affairs and third-party reimbursement. We currently use and may continue to partner with a network of national distributors to fulfill orders for ASCENIV and BIVIGAM.
- **Increase marketing efforts around Nabi-HB.** We plan to increase our marketing efforts and attend relevant virtual or in-person medical conferences during 2024, raising awareness of the risks associated with Hepatitis B and the benefits and efficacy of Nabi-HB in its indicated populations. We have published and may continue to publish scientific data supporting the use of Nabi-HB in at-risk and appropriate patient populations.
- **Expand ASCENIV's FDA-approved uses.** Having received approval by the FDA for ASCENIV as a treatment for PIDD, we may elect to evaluate the clinical and regulatory paths to grow the ASCENIV franchise through expanded FDA-approved uses. We believe that there may be other patient populations beyond PIDD that could potentially 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, as well as in other patient populations we may believe are appropriate.
- **Improve the Boca Facility's and ADMA BioCenters' operating efficiencies, yields and gross margins.** During 2024, we plan to advance our biologic production yield enhancement initiative to capture additional IG production yields from our manufacturing process with the same quantities of starting raw material. These initiatives are subject to further evaluation, validation of commercial-scale production and requisite regulatory review. During 2021, we received FDA approvals for our 4,400L expanded IVIG production scale, as well as our in-house fill-finish and related operations production line using our aseptic filling machine. In 2023, ADMA commenced manufacturing ASCENIV at the 4,400 Liter production scale for the first time in the Company's history. We expect that this expansion should meaningfully improve the product's margin profile and increase plant production capacity as fewer batches will be needed to support revenue goals. Our successful experience in ramping up BIVIGAM to this production scale over the last two years lends confidence to its ability to leverage these same processes for ASCENIV. We began to realize these benefits in the fourth quarter of 2023.

- **Broadly Implement Innovative AI Program, ADMalytics, to improve efficiencies across our supply chain and production operations.** In February 2024, we announced the successful initial use of our Artificial Intelligence (AI) program, named ADMalytics. ADMalytics combines AI and machine learning to improve and predict outcomes for production and operational processes. Recently, we successfully produced our first batch of ASCENIV utilizing this innovative ADMalytics software to prospectively automate and realize efficiency improvements to plasma pooling during commercial manufacturing. We expect broad implementation of the new ADMalytics capabilities will provide for rapid realization of efficiencies across our supply chain and production operations.
- **Label expansion.** Upon regulatory approval, the ongoing post-marketing clinical study of ASCENIV, which has successfully completed enrollment, may provide a label expansion opportunity to include pediatric-aged PI patients as well as additional publications supporting product safety.
- **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. As part of expanding our product pipeline, we are looking to develop an S. pneumonia hyperimmune globulin. S. pneumonia is the predominant cause of community-acquired pneumonia in the U.S., ranking as the ninth leading cause of overall mortality. We believe the strategic importance and unmet need are evident in both the prophylactic and therapeutic settings where documented anti-infective resistance is on the rise. Annually, approximately one million U.S. adults contract pneumococcal pneumonia, resulting in 400,000 hospitalizations and a 5-7% mortality rate, of which approximately 7,000 deaths annually are attributable to anti-infective resistance. Despite vaccine availabilities, vaccine-naïve and immune-compromised patient populations remain at risk and could potentially benefit from the immediately available neutralizing antibodies conferred with a hyperimmune globulin in both the in-patient and out-patient treatment settings. We estimate that an S. pneumonia hyperimmune globulin, if approved, has the potential to generate peak revenue of \$300-500 million.
- **Secure new supply contracts for potential contract manufacturing organization (“CMO”) opportunities.** We are exploring new potential CMO, contract testing and business development opportunities, which include fill-finish capabilities, with our multi-faceted revenue generation platform, while continuing to fulfill our 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. As reported by *The Plasma Proteins Market In The United States 2022* and *Marketing Research Bureau Inc., October 2022*, the U.S. market for IG in 2022 was \$10.5 billion and is expected to exceed \$20 billion by 2030.

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 in 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-authorized, automated device with a sterile, self-contained collection kit. The plasma that is collected is known as “normal source plasma.” There are over 1,000 plasma donation centers in the U.S. As noted in a variety of plasma industry trade reports and related conferences, approximately 39 million liters of source plasma were collected in the U.S. in 2021. 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 by *The Plasma Proteins Market In The United States 2022* and *Marketing Research Bureau Inc., October 2022*, the U.S. sales of immune and hyperimmune globulin products for all its uses were reported to be approximately \$10.5 billion in 2022 and are expected to exceed \$20 billion in 2030. 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 ten years. Source plasma is collected at any one of over 1,000 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 certain diseases, such as antibodies to human immunodeficiency virus types 1 and 2 (HIV-1/2), HbsAg and 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. 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 or through our own in-house fill-finish process, which was approved by the FDA in the second half of 2021. Labeling and packaging operations must further comply with regulatory requirements and products must be labeled in accordance with their regulatory approval and Drug Supply Chain Security Act (“DSCSA”) serialization requirements. The end-to-end production cycle can take approximately seven to 12 months for a batch of FDA released drug product. Since 2020, we have successfully implemented several manufacturing and supply chain enhancements, including the purchase and installation of a new 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 BioCenters has a total of ten source plasma collection facilities in its network, all of which are FDA-licensed, and should allow the Company to be essentially self-sufficient for its raw material source plasma supply to produce its commercial IG product portfolio. Three of our ADMA BioCenters plasma collection facilities also have approvals from the South Korean MFDS and licensure from the FDA for the collection and sale of Hepatitis B hyperimmune plasma obtained from immunized donors. At the present time, we do not plan to build additional plasma collection facilities beyond the existing ten, but we continue to have third-party supply contracts in place to augment our vertically integrated plasma collections.

Pursuant to the terms of a plasma purchase agreement dated as of November 17, 2011 (the “2011 Plasma Purchase Agreement”), we agreed to purchase from our former contract manufacturer 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 the counterparty, and under the original 2011 Plasma Purchase Agreement we were permitted to 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 to (i) allow us to collect our raw material RSV high-titer plasma from any number of wholly-owned ADMA plasma collection facilities and (ii) allow us to purchase our raw material RSV high-titer plasma from other third-party collection organizations, in each case, provided that the annual minimum volumes from our former contract manufacturer were met, thus allowing us to expand our reach for raw material supply as we execute our 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. On December 10, 2018, our former contract manufacturer 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 June 6, 2017, we entered into a Plasma Supply Agreement with our former contract manufacturer, pursuant to which the counterparty 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 ten-year term. On July 19, 2018, the Plasma Supply Agreement was amended to provide, among other things, that in the event the counterparty 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 the counterparty, then the counterparty shall reimburse ADMA BioManufacturing for the difference in price ADMA BioManufacturing incurs. On December 10, 2018, our former contract manufacturer assigned its rights and obligations under the Plasma Supply Agreement to Grifols, effective January 1, 2019.

Sales and Commercialization of Our Products

Currently, ASCENIV, BIVIGAM 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. Our management and Board of Directors (“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.

Efforts to generate increased market awareness for Nabi-HB include attending and presenting scientific information at medical conferences, as well as sponsoring medical education symposiums. We have also hired a specialty sales force consisting of account managers, medical science liaisons and other customary scientific, medical and detail representatives to market BIVIGAM and ASCENIV to hospitals, physician offices/clinics, and other specialty treatment organizations as applicable. In addition, we have expanded staffing efforts 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 December 31, 2012, we granted to Biotest AG (“Biotest”) an exclusive license to market and sell ASCENIV 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 Biotest’s plasma samples using our proprietary RSV assay, and to reference (but not access) our proprietary information for the purpose of Biotest seeking regulatory approval for ASCENIV in the Territory. As consideration for the license, Biotest provided us with certain in-kind services and also compensated us with cash payments upon the completion of certain milestones. Biotest is also obligated to pay us an adjustable royalty based on a percentage of revenues from the sale of ASCENIV in the Territory for 20 years from the date of first commercial sale.

Major Customers

For the year ended December 31, 2023, two customers, BioCARE, Inc. (“BioCare”) and Priority Healthcare Distribution, Inc. (“Curascript”), represented an aggregate of 72% of our consolidated revenues.

Competition

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

These competitors may include but are not limited to: CSL Behring, Grifols, Takeda, Octapharma and Permira. There are four producers of plasma-derived products in the U.S. consisting of: CSL Behring, Grifols, Takeda and ADMA Biologics. In addition to competition from other large worldwide plasma product 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.

New technologies are being developed by biotech and pharmaceutical companies which may impact physician prescription and patient usage of IVIG. One such 2021 approved FDA therapy is an anti-FcRn inhibitor (neonatal Fc receptor, IgG receptor) which is a protein in humans responsible for maintaining IgG levels. This FDA approved anti-FcRn is for the treatment of generalized Myasthenia Gravis that may impact a subset of overall general IVIG usage. Other such FcRn potential targeted indications in development that may disrupt general IVIG usage may include but are not limited to: Chronic Inflammatory Demyelinating Polyradiculoneuropathy (“CIDP”), a rare type of autoimmune disorder, Immune Thrombocytopenic Purpura (“ITP”), a blood disorder characterized by a decrease in the number of platelets in the blood and Pemphigus Vulgaris (“PV”), a rare type of autoimmune disorder.

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, 10,683,343, 11,339,206 and 11,780,906, 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 Nos. 10,259,865 and 11,084,870, each with a term through 2037, pertain 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 patents 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 currently hold multiple trademarks, including but not limited to ASCENIV, BIVIGAM, Nabi-HB and Advantage Ig. We have spent considerable resources registering these 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), quality control, research and development, approval and post-approval monitoring and reporting, manufacturing, labeling, storage, recordkeeping, advertising, promotion, import, export, marketing, sales and distribution of our products and product candidates. If we do not comply with applicable requirements, we may be subject to civil penalties, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, fined, the government may refuse to approve our marketing applications, supplemental applications or allow us to manufacture or market our products, we may be criminally prosecuted and we may be debarred or excluded from participation in government healthcare programs. These requirements are continually evolving. We and our manufacturers may also be subject to regulations under other federal, state and local laws.

U.S. Government Regulation

Our current and anticipated future product candidates are considered “biologics” under the FDA regulatory framework. 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. In the U.S., the FDA regulates biologic products under the Federal Food, Drug and Cosmetic Act (the “FDCA”), the Public Health Service (“PHS”) Act and related federal regulations under Title 21 of the Code of Federal Regulations (“CFR”). The FDA also issues nonbinding guidance documents on a continuous basis, which provide the agency’s interpretation of its laws and regulations, as well as the FDA’s approach to scientific issues and questions. Biologics are also regulated under other federal, state, and local statutes and regulations by other regulatory authorities. 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, nonclinical and formulation studies performed in accordance with the FDA's Good Laboratory Practice ("GLP") regulations and other applicable laws and regulations;
- submission to the FDA of an Investigational New Drug ("IND") application which must become effective before clinical trials may begin;
- obtaining approval by an Institutional Review Board ("IRB") at each clinical site before a clinical trial may be initiated at that site;
- performance of adequate and well-controlled clinical trials meeting FDA requirements, commonly referred to as Good Clinical Practices ("GCP"), and other additional requirements for the protection of human research subjects and 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 the FDA's current 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 for marketing approval that includes substantial evidence of safety, purity and potency from results of clinical trials; the results of preclinical testing; detailed information about the Chemistry, Manufacturing, and Controls ("CMC") and proposed labeling and packaging for the product candidate;
- 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;
- satisfactory completion of potential FDA inspections of the preclinical study and clinical trial sites that generate the data in support of the BLA; and
- FDA review and approval of a BLA prior to any commercial marketing, sale or shipment of the product, including agreement on post-marketing commitments, and compliance with any post approval commitments, such as Risk Evaluation and Mitigation Strategies ("REMS") and post approval studies required by the FDA.

The testing, review and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our product candidates. In addition, the FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of our products. FDA may also conduct inspections, including remote regulatory assessments, of our facilities or the facilities of our contractors, both during product development and following approval. Any findings from those inspections could materially impact our business.

Pre-Clinical Studies

Prior to commencing the first clinical trial at a United States investigational site, we must submit manufacturing and analytical data, pre-clinical or nonclinical data from studies conducted in accordance with GLP 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 allowing us 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. Special clinical trial ethical considerations also must be taken into account if a study involves children. 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 GCP requirements and regulations for informed consent and must be conducted with product meeting cGMPs. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, which reviews data and makes recommendations to the sponsor regarding the trial.

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 larger but 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.
- Phase III trials are conducted to establish the overall risk/benefit profile of the product. Certain Phase III clinical trials are referred to as pivotal trials. Phase III clinical trials aim to provide substantial evidence of reproducibility of clinical efficacy and safety results for approval 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 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 (“iPSP”) within 60 days of an end-of-Phase II 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 iPSP. Congress also passed legislation that will require that sponsors submit to the FDA a diversity action plan for Phase III or other pivotal studies, unless such requirement is waived by the FDA.

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, which are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for: serious and unexpected adverse events; any findings from other studies, tests in laboratory animals or in vitro testing and other sources that suggest a significant risk for human subjects; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase I, Phase II and Phase III clinical trials might not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients. Information about clinical trials, including results, must be submitted within specific timeframes for listing on the ClinicalTrials.gov website.

In limited circumstances, the FDA also permits the administration of investigational biological products to patients under its expanded access program. Under this program, provided certain qualifying criteria are met, patients who are not able to participate in a clinical trial may be eligible for accessing investigational products, including through individual compassionate or emergency use in concert with their requesting physician. Sponsors or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access.

Concurrent with clinical trials, companies usually complete additional preclinical studies, animal studies, develop additional information about the physical characteristics of the biological product candidate and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

The manufacture of Investigational biologics for the conduct of human clinical trials is subject to cGMP requirements. Investigational biologics and active ingredients and therapeutic substances imported into the United States are also subject to regulation by the FDA. Further, the export of investigational products outside the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

Biologics License Applications

The results of product candidate development, preclinical and nonclinical 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. Under the Prescription Drug User Fee Act ("PDUFA"), the fees payable to the FDA for reviewing an original BLA, as well as annual program fees for approved products can be substantial, subject to certain limited deferrals, waivers and reductions that may be available. The FDA has agreed to specified performance goals in the review of BLAs under the PDUFA.

Following submission, the FDA has 60 days to review all BLAs to determine if they are substantially complete before it accepts them for filing. The FDA may refuse to file a BLA that it deems incomplete or not reviewable at the time of submission, in which case the BLA will have to be updated and resubmitted. The FDA may also request additional information to be submitted in a very short time frame before accepting a BLA for filing.

If the FDA accepts the application for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure, and potent for its intended use, and whether the product is being manufactured in compliance with cGMP. During its review of a BLA, the FDA may refer the application for novel product candidates or products that present difficult questions 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's PDUFA review goal is to review 90% of priority BLAs within six months of filing and 90% of standard applications within ten months of filing, but the FDA can and frequently does extend this review timeline to consider certain later-submitted information or information intended to clarify or supplement an initial submission. The FDA may not complete its review or approve a BLA within these established goal review times.

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. The FDA will not approve a product candidate unless cGMP compliance is satisfactory.

After the FDA conducts its in-depth review of the application and after the inspection of the manufacturing facilities and clinical trial sites, the FDA issues either an approval letter or a Complete Response Letter ("CRL"). A CRL generally outlines the deficiencies in the submission and 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 12 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 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. CBER also includes specific goals for review of manufacturing and labeling supplements, though 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. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing 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 for 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 many 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 any changes 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.

Post-Approval Regulatory Requirements

After regulatory approval is obtained, biological drug products are subject to extensive and continuing regulation by the FDA, which may impose a number of post-approval requirements as a condition of approval of an application. For example, as a condition of approval of a BLA, the FDA may require post-marketing testing and surveillance to monitor the product's safety or efficacy. In addition, holders of an approved BLA are required to keep extensive records (including certain electronic records and signature requirements), submit annual reports, report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for their products. 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. 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 refusal to approve pending applications, license suspension or revocation, withdrawal of approval of a BLA, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, suspension of manufacturing, sales or use, product seizures or recalls, import restrictions, 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.

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. 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. Certain manufacturing deviations and unexpected manufacturing events must be investigated, corrected, and reported to the FDA.

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 to the FDA, and are subject to periodic unannounced inspections or remote regulatory assessments 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. 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 subject to lot release, for each product lot the applicant must submit materials related to that lot to the FDA prior to that lot being 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 towards production and quality control to maintain cGMP compliance.

The commercial distribution of prescription drugs (including biological drug products) is subject to the 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 certain transaction-related information in an electronic, and, as of November 2023, an interoperable form. Further, the DSCSA limits the distribution of prescription pharmaceutical products and imposes requirements to ensure overall accountability and security in the drug supply chain, including requirements related to the detection and investigation of suspect and illegitimate products. The distribution of product samples continues to be regulated under the PDMA.

FDA post-approval requirements are continually evolving. For example, in March 2020, the U.S. Congress passed the CARES Act, which includes various provisions regarding FDA drug shortage and manufacturing volume 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. As part of the CARES Act implementation, the FDA issued a guidance on the reporting of the volume of drugs produced, which reporting will require additional administrative efforts by drug manufacturers. Executive orders have also been issued to encourage domestic manufacturing.

Advertising and Promotion

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 product cannot be promoted before it is approved. After approval, product promotion can include only those claims related to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for “off-label” uses— that is, uses not approved by the FDA and not described in the product’s labeling because the FDA does not regulate the practice of medicine. However, FDA regulations impose restrictions on manufacturers’ communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label use. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil penalties, criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug.

Companies are required to supply sufficient information that balances the risks of a product in its marketing and promotional materials. In 2023, the FDA implemented several measures in the advertising and promotional areas. These included the issuance of a final rule and a guidance on the disclosure of risks and effectiveness in direct-to-consumer advertising, as well as a guidance on the dissemination of off-label scientific data about approved products. 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. It is impossible 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 and registered with the FDA. In order to achieve licensure, the organization must submit a BLA and obtain BLA approval prior to distribution of any product. The approval of the BLA requires passage of an FDA inspection. ADMA BioCenters has completed these requirements and holds an FDA license for all ten of its plasma collection facilities for source plasma. In order to maintain an FDA license, under FDA guidance each such facility operated by ADMA BioCenters will be inspected within the first year of operations and then at least every two years and must meet certain regulatory requirements. ADMA BioCenters is also required to submit annual reports to the FDA, as well as reports of fatalities related to blood and blood component collection or transfusion. Establishments must also comply with the FDA’s regulatory standards which include a variety of requirements related to, among other areas, cGMPs, deviation investigation and reporting, donor screening and product testing, as well as product labeling. Facilities must further ensure that all tests and equipment that are used are appropriate for their intended use, which may include FDA clearance and/or approval of the applicable test or equipment.

Blood plasma collection and manufacturing centers are also subject to the Clinical Laboratory Improvement Amendments (“CLIA”), 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. State requirements may differ significantly from federal requirements, which may complicate compliance efforts. 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 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, decentralized or national 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 decentralized procedure provides for approval by one or more “concerned” member states based on an assessment of an application performed by one member state, known as the “reference” member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state’s assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states. In addition to the centralized procedure and the decentralized procedure, it may also be possible to obtain a marketing authorization for one single member state through a national procedure. 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.

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 and disabled 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) became effective April 1, 2021.

Significant uncertainties exist as to the coverage and reimbursement status of our current products as well as any products for which we may obtain regulatory approval. In the U.S., sales of BIVIGAM, ASCENIV and Nabi-HB, as well as 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. No uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. 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 our current products and 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 current products 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, increased rebates, 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. We have addressed additional reforms related to government pricing programs that could be relevant to our products below. 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 our current products and 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, the 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.

Government Price Reporting

Manufacturers participate in, and have certain price reporting obligations under, the Medicaid Drug Rebate Program, state Medicaid supplemental rebate program(s), and other governmental pricing programs. For calendar quarters beginning January 1, 2022, manufacturers will be required to report the average sales price for certain drugs under the Medicare program regardless of whether the manufacturer participates in the Medicaid Drug Rebate Program. Previously, this reporting obligation extended only to manufacturers participating in the Medicaid Drug Rebate Program. Under this Program, manufacturers are required to pay a rebate to each state Medicaid program for covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available for their drugs under Medicaid and Part B of the Medicare program.

Medicaid rebates are based on pricing data reported by manufacturers on a monthly and quarterly basis to the CMS, the federal agency that administers the Medicaid and Medicare programs. This data includes the average manufacturer price and, in the case of innovator products, the best price for each drug, which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts, and other price concessions. The amount of the rebate is adjusted upward if the average manufacturer price increases more than inflation (measured by reference to the Consumer Price Index— Urban). Currently, the rebate is capped at 100% of the average manufacturer price, but, effective January 1, 2024, this cap on the rebate will be removed, and our rebate liability could increase accordingly.

If a manufacturer becomes aware that its reporting for a prior quarter was incorrect or has changed as a result of recalculating the pricing data, the manufacturer is obligated to resubmit the corrected data for up to three years after it was originally due, which revisions could affect rebate liability for prior quarters. The ACA made significant changes to the Medicaid Drug Rebate Program, and CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate Program under the ACA. On December 21, 2020, CMS issued a final rule that modified the Medicaid Drug Rebate Program regulations to permit reporting multiple best price figures with regard to value-based purchasing arrangements (beginning in 2022); provided definitions for “line extension”, “new formulation,” and related terms with the practical effect of expanding the scope of drugs considered to be line extensions (beginning in 2022); and revised best price and average manufacturer price exclusions of manufacturer-sponsored patient benefit programs, particularly regarding potential inapplicability of such exclusions in the context of pharmacy benefit manager “accumulator” programs (beginning in 2023).

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over or that are disabled as well as those with certain health conditions. Medicare Part B generally covers drugs that must be administered by physicians or other health care practitioners, among others. Medicare Part B generally pays for such drugs under a payment methodology based on the average sales price of the drugs. Manufacturers are required to report average sales price information to CMS on a quarterly basis. The manufacturer-submitted information is used by CMS to calculate Medicare payment rates.

Congress could enact additional changes that affect our overall rebate liability and the information manufacturers report to the government as part of price reporting calculations. For example, Congress is considering a Medicare Part B inflation rebate, under which manufacturers would owe additional rebates if the average sales price of a drug were to increase faster than the pace of inflation.

Civil monetary penalties can be applied if a manufacturer is (1) found to have knowingly submitted any false pricing or other information to the government, (2) found to have made a misrepresentation in the reporting of our average sales price, or (3) fails to submit the required data on a timely basis. Such conduct also could be grounds for CMS to terminate a Medicaid Drug Rebate Program agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for the manufacturer’s covered outpatient drugs.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service’s 340B drug pricing program (the “340B program”) in order for federal funds to be available for the manufacturer’s drugs under Medicaid and Medicare Part B. The 340B program, which is administered by the Health Resources and Services Administration (“HRSA”), requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. Covered entities include hospitals that serve a disproportionate share of financially needy patients, community health clinics, and other entities that receive certain types of grants under the Public Health Service Act. The ACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals, but exempts “orphan drugs” from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and Medicaid rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement.

The final regulation issued by HRSA regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities has affected manufacturer obligations and potential liability under the 340B program. Any charge by HRSA that a manufacturer has violated the requirements of the regulation could result in civil monetary penalties. Moreover, under a final regulation effective January 13, 2021, HRSA established a new Administrative Dispute Resolution (“ADR”) process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that can be appealed to a federal court. An ADR proceeding could subject a manufacturer to onerous procedural requirements and could result in additional liability. HRSA also implemented a price reporting system under which manufacturers are required to report 340B ceiling prices on a quarterly basis to HRSA, which then publishes those prices to 340B covered entities. In addition, legislation could be passed, that would further expand the 340B program to additional covered entities, or participating manufacturers could be required to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

In order to be eligible to have their products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies (U.S. Department of Veterans Affairs (“VA”), Department of Defense (“DoD”), Coast Guard, and Public Health Service (“PHS”)) and grantees, manufacturers must participate in the VA Federal Supply Schedule (“FSS”) pricing program. Prices for innovator drugs purchased by the VA, DoD, Coast Guard, and PHS are subject to a cap (known as the “Federal Ceiling Price”) equal to 76% of the annual Non-Federal Average Manufacturer price “non-FAMP”) minus, if applicable, an additional discount. The additional discount applies if non-FAMP increases more than inflation (measured by reference to the Consumer Price Index – Urban (“CPIU”)). In addition, in the second and subsequent year, the price also is capped at prior year FSS contract plus CPIU. Manufacturers must also participate in the Tricare Retail Pharmacy Program, under which they pay quarterly rebates to DoD for prescriptions of innovator drugs dispensed to Tricare beneficiaries through Tricare Retail network pharmacies. The governing statute provides for civil monetary penalties for failure to provide information timely or for knowing submission of false information to the government.

Medicare Part D generally provides coverage to enrolled Medicare patients for self-administered drugs (*i.e.*, drugs that are not administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and subject to detailed program rules and government oversight. Each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time to time. The prescription drug plans negotiate pricing with manufacturers and pharmacies and may condition formulary placement on the availability of manufacturer rebates. In addition, manufacturers are required to provide to CMS a 70% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design. If a manufacturer fails to provide these discounts, civil monetary penalties can be applied in the amount of 125% of the discount that was due. Congress could enact legislation that sunsets this discount program and replaces it with a new manufacturer discount program. Congress further could enact a Medicare Part D inflation rebate, under which manufacturers would owe additional rebates if the average manufacturer price of a drug were to increase faster than the pace of inflation.

Congress also could enact a drug price negotiation program under which the prices for certain high Medicare spend single source drugs would be capped by reference to the non-FAMP price. This or any other legislative change could impact the market conditions for our products. We further expect continued scrutiny on government price reporting from Congress, federal agencies, and other bodies.

Group health plans, health insurance issuers, health maintenance organizations, other healthcare payors, and pharmacy benefit managers in the United States are adopting more aggressive utilization management techniques and are increasingly requiring significant discounts and rebates from manufacturers as a condition to including products on formulary with favorable coverage and cost-sharing. These payors may not cover or adequately reimburse for use of our products or may do so at levels that disadvantage them relative to competitive products. Outside the United States, within the EU, our products are paid for by a variety of payors, with governments being the primary source of payment. Government health authorities in the EU determine or influence reimbursement of products and set prices or otherwise regulate pricing. Negotiating prices with governmental authorities can delay commercialization of our products. Governments may use a variety of cost-containment measures to control the cost of products, including price cuts, mandatory rebates, value-based pricing and reference pricing (*i.e.*, referencing prices in other countries or prices of competitive products and using those reference prices to set a price). Budgetary pressures in many EU countries are continuing to cause governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates and expanded generic substitution and patient cost-sharing. Recently, several states also have enacted or are considering legislation intended to make drug prices more transparent and deter significant price increases that impose reporting requirements on biopharmaceutical companies. These laws may affect our future sales, marketing, and other promotional activities by imposing administrative and compliance burdens. Such laws also typically impose significant civil monetary penalties for each instance of reporting noncompliance that can quickly aggregate into millions of dollars.

U.S. Healthcare Reform

The containment of healthcare costs has become a priority of Federal and state governments, and the prices of drugs have been a focus in this effort. Changes in government legislation or regulation and changes in private third-party payors' policies toward reimbursement for our products, if successfully developed and approved, may reduce reimbursement of our products' costs to physicians, pharmacies, patients and distributors. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, payment of rebates, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results for products, if any, we commercialize in the future.

The pricing and reimbursement environment for our products may change in the future and become more challenging due to state and federal healthcare reform measures. The American Recovery and Reinvestment Act of 2009 ("ARRA"), for example, allocated new federal funding to compare the effectiveness of different treatments for the same condition. The plan for the research was published in 2012 by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although ARRA does not mandate the use of the results of comparative effectiveness studies for reimbursement purposes, it is not clear what effect, if any, the research will have on the sales of any products for which we receive marketing approval or on the reimbursement policies of public and private payors. It is possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of any product for which we receive marketing approval. For example, if third-party payors find our products not to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The ACA is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges, and the expansion of the Medicaid program. This law has substantially changed the way healthcare is financed by both governmental and private insurers and has significantly impacted the pharmaceutical industry. Changes that may affect our business include those governing enrollment in Federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate Program, expansion of the Public Health Service Act's 340B drug pricing program, or 340B program, and fraud and abuse enforcement. These changes have impacted previously existing government healthcare programs and have resulted in the development of new programs, including Medicare payment for performance initiatives and improvements to the Medicare physician quality reporting system and feedback program.

One of the goals of ACA was to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA increased minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program and extended manufacturers' Medicaid rebate liability to drugs dispensed to individuals who are enrolled in Medicaid managed care organizations. The ACA also requires 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 report annually to CMS information related to certain direct or indirect payments and other transfers of value to U.S.-licensed physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives and to U.S. teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of \$1,000 to \$10,000 for each payment or ownership interest that is not timely, accurately, or completely reported (annual maximum of \$150,000), and \$10,000 to \$100,000 for each knowing failure to report (annual maximum of \$1 million) (for an aggregate annual maximum of \$1,150,000).

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the ACA. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact sales of our products that are approved and that we successfully commercialize, and our business and financial condition. Where Medicaid patients receive insurance coverage under any of the new options made available through the ACA, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues.

Certain provisions of the ACA have been subject to judicial challenges as well as efforts to modify them or to alter their interpretation or implementation. For example, Congress eliminated, starting January 1, 2019, the tax penalty for not complying with the ACA's individual mandate to carry health insurance. Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drugs plans, commonly known as the "donut hole," by raising the required manufacturer point-of-sale discount from 50% to 70% off the negotiated price effective as of January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the ACA remain possible, but the nature and extent of such potential changes or challenges are uncertain at this time. It is unclear how the ACA and its implementation, as well as efforts to modify or invalidate the ACA, or portions thereof, or its implementation, will affect our business, financial condition and results of operations. It is possible that the ACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our products or product candidates for which we receive regulatory approval or to successfully commercialize our products and product candidates.

Other legislative changes related to reimbursement have been adopted in the U.S. since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2031 (with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, due to the COVID-19 pandemic). The law provides for 1% Medicare sequestration in the second quarter of 2022 and allows the full 2% sequestration thereafter until 2031. As long as these cuts remain in effect, they could adversely impact payment for any products we may commercialize in the future. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

Additional legislative changes, regulatory changes, or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates. For example, there has been increasing legislative, regulatory, and enforcement interest in the United States with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient assistance and support programs, potentially permit government negotiation of Medicare pricing with manufacturers relative to certain international prices paid, and reform government healthcare program reimbursement methodologies for drug products. If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for any approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

It is possible that the ACA, as currently enacted or may be amended in the future, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria and new payment methodologies and in additional downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. We cannot be sure whether additional legislative changes will be enacted in the U.S. or outside the U.S., or whether regulatory changes, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

Anti-Fraud and Abuse Laws

We are also subject to numerous fraud and abuse laws and regulations globally. In the U.S., there are a variety of Federal and state laws restricting certain marketing practices in the pharmaceutical industry pertaining to healthcare fraud and abuse, including anti-kickback laws and false claims laws. Our sales, marketing, patient support and medical activities may be subject to scrutiny under these laws. The U.S. Federal healthcare program Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving anything of value (“remuneration”) to induce (or in return for) the referral of business, including the purchase, recommendation or prescription of a particular drug reimbursable under Medicare, Medicaid or other federally financed healthcare programs. The statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and patients, prescribers, purchasers and formulary managers on the other. The Beneficiary Inducement Civil Monetary Penalties Law imposes similar restrictions on interactions between pharmaceutical manufacturers and federal healthcare program beneficiaries. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution and administrative sanction, the exceptions and safe harbors are drawn narrowly and are subject to regulatory revision or changes in interpretation by the U.S. Department of Justice (“DOJ”), and the Office of Inspector General of the U.S. Department of Health and Human Services (“OIG”). Recent regulations eliminate the discount safe harbor protection for manufacturer rebates paid directly, or indirectly through a Pharmacy Benefit Manager (“PBM”) to Medicare Part D or Medicare Advantage plans. Recent legislation and a final rule promulgated on December 29, 2023 delayed implementation of this portion of the 2020 final rule until January 1, 2032. Practices or arrangements that involve remuneration may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances.

Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce or reward referrals of federal healthcare program business, including purchases of products paid by federal healthcare programs, the statute has been violated. Violations of the federal Anti-Kickback Statute may be established without providing specific intent to violate the statute, and may be punishable by civil, criminal, and administrative fines and penalties, damages, imprisonment, and/or exclusion from participation in federal healthcare programs.

The Federal civil False Claims Act (“FCA”) prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false statement to get a false claim paid, or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. The FCA has been used to assert liability on the basis of improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses not expressly approved by the FDA in a product’s label, and allegations as to misrepresentations with respect to products, contractual requirements, and services rendered. In addition, private payers have been filing follow-on lawsuits alleging fraudulent misrepresentation, although establishing liability and damages in these cases is more difficult than under the FCA. Intent to deceive or actual knowledge of falsity is not required to establish liability under the FCA. Rather, a claim may be false for deliberate ignorance of the truth or falsity of the information provided or for acts in reckless disregard of the truth or falsity of that information. A claim resulting from a violation of the federal Anti-Kickback Statute constitutes a per se false or fraudulent claim. The False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of themselves and the federal government alleging violations of the statute and to share in any monetary recovery. Violations of the False Claims Act may result in significant financial penalties (including mandatory penalties on a per claim or statement basis), treble damages and exclusion from participation in federal health care programs. For these reasons, since 2004, False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, as much as \$3.0 billion, regarding certain sales practices and promoting off label uses.

The government may further prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the FCA, requires proof of intent to submit a false claim.

Pharmaceutical companies are subject to other federal false claim and statements laws, some of which extend to non-government health benefit programs. For example, the healthcare fraud provisions under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, or HIPAA, impose criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third party payors, or falsifying or covering up a material fact or making any materially false or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Violations of HIPAA fraud provisions may result in criminal, civil and administrative fines, penalties and damages, including exclusion from participation in federal healthcare programs.

The majority of states have adopted analogous laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers. Other states have adopted laws and regulations that, among other things, require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines with respect to interactions with healthcare professionals and the relevant compliance program guidance promulgated by the U.S. Federal government that otherwise restrict payments that may be made to healthcare professionals and other potential referral sources, and that require drug manufacturers to file reports related to pricing and marketing information, which requires tracking price increases and gifts and other remuneration and items of value provided to healthcare professionals and entities. In addition, some jurisdictions have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co-pay assistance that pharmaceutical companies can offer to patients.

The Federal Physician Payment Sunshine Act requires tracking of certain payments and transfers of value to U.S.-licensed physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives and to U.S. teaching hospitals, and ownership interests held by physicians and their families, and reporting to the federal government and public disclosure by the federal government of this data.

Data Protection and Privacy

Throughout the clinical trial process, we may obtain the private health information of our trial subjects. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. The Healthcare Information Portability and Accountability Act of 1996 ("HIPAA") imposes privacy, security, breach reporting obligations, and mandatory contractual terms on covered entity health care providers, health plans, and health care clearinghouses, as well as their "business associates" – certain persons or covered entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. We could potentially be subject to civil and criminal penalties if we, our affiliates, or our agents use or disclose protected health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Even when HIPAA does not apply, according to the Federal Trade Commission ("FTC") failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individuals about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act ("FTC Act"). 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. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to, but less prescriptive than, what is required by the HIPAA Security Rule. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

All states have laws requiring notification of affected individuals and state regulators (breach notification laws) in the event of a breach of personal information. Some state laws impose significant data security requirements, such as encryption, to ensure ongoing protection of personal information. Additionally, in California, the California Consumer Privacy Act (“CCPA”) establishes certain requirements for data use and sharing transparency and creates new data privacy rights for California residents. The CCPA and its implementing regulations have already been amended multiple times since their enactment. In November 2020, California voters approved the California Privacy Rights Act (“CPRA”) ballot initiative, which introduced significant amendments to the CCPA and established a dedicated California privacy regulator, the California Privacy Protection Agency (“CPPA”). The amendments introduced by the CPRA became effective on January 1, 2023. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of security incidents. These claims may result in significant liability and damages. Virginia, Colorado, Connecticut and Utah have also enacted privacy laws that became effective in 2023 and are similar in many respects to the CCPA.

Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. For example, the European Union’s General Data Protection Regulation (“GDPR”), which imposes fines of up to EUR 20 million or 4% of the annual global revenue of a noncompliant company, whichever is greater, and other data protection, privacy and similar national, state/provincial and local laws may also restrict the access, use and disclosure of patient health information abroad. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers, or to alleviate problems caused by such breaches. Compliance with these laws is difficult, constantly evolving, time consuming, and requires a flexible privacy framework and substantial resources. Compliance efforts will likely be an increasing and substantial cost in the future.

Environmental, Social and Governance (“ESG”)

Our Code of Ethics and Business Conduct states that employees should strive to conserve resources and reduce water consumption and emissions through recycling and other energy conservation measures. Employees are responsible for promptly reporting any known or suspected violations of environmental laws or any events that may result in a discharge or emissions of hazardous materials. We manufacture, market and develop specialty biologics for the prevention and treatment of infectious diseases in the immune compromised and other patients at risk for infection, and, as such, we consider our environmental impact to be low. These activities do not include either industrial production or distribution, and therefore do not use raw materials that would result in significant releases into the environment or greenhouse gas emissions from our manufacturing emissions. Further, our activities do not produce any particular noise nuisance for staff or neighboring tenants or residents as well as wildlife surrounding our facilities and offices. Annual electricity and water consumption are monitored and factored into our sustainable resource practices.

Waste Management Policy

The objective of our waste management policy is to identify and mitigate risks and hazards with the aim of achieving zero incidents, zero injuries, and zero spills or environmental harm. We are dedicated to the safe handling and management of all non-hazardous and hazardous materials, and all employees are responsible for appropriate waste management.

We are dedicated to high environmental standards and expect all employees to be familiar with and comply with the contents of this policy. We are committed to providing a safe and healthy work environment. We comply with all applicable laws, regulations, and requirements associated with our environmental obligations and impact. We strive for the continual improvement of all environmental impacts associated with our operations. We are committed to the prevention of pollution in all aspects of our business activities, as well as a sustainable approach to the development and provision of our products and services.

Social

We actively sponsor and participate in industry-related charitable events on a local and national level and encourage our employees to actively participate and volunteer their time and participation. We actively support and fund initiatives designed to improve the communities in which we operate and where our employees and stakeholders reside.

Governance

We pursue fair employment practices in every aspect of our business. We strive to ensure and are extremely proud that our Board and our employee base is diverse and consists of individuals of varying gender, origin, sexual orientation and backgrounds with various and relevant career experience, relevant technical skills, education, industry knowledge and experience and possess local or community ties.

Employees

As of December 31, 2023, we had a total of 624 employees, all of whom are full-time. Over the course of the next year, we anticipate hiring additional full-time employees devoted to compliance, production, quality assurance, quality control, plasma collection and processing, sales and marketing, medical and scientific affairs and administration, as well as hiring additional staff for our plasma collection centers as appropriate. We use Clinical Research Organizations (“CROs”), third parties and consultants to perform our post-marketing commitment clinical studies and other process and/or analytical development projects to augment our in-house capabilities and staff.

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 BioManufacturing, ADMA BioCenters and ADMA Plasma Biologics. ADMA BioManufacturing was formed in January 2017 to facilitate the acquisition of certain assets held by the Company’s then-third-party contract manufacturer. ADMA BioCenters is the Company’s source plasma collection business which operates in the U.S. Each of ADMA’s ten operational plasma collection centers 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.

- We have a history of losses and we may, in the future, need to raise additional capital to operate our business, which may not be available on favorable terms, if at all.
- Although we achieved net income on a non-GAAP basis and generated positive cash flows for the year ended December 31, 2023 for the first time, we may not be able to achieve profitability and generate positive cashflows in the future.
- 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 inspections, could result in certain FDA actions, including the issuance of observations, notices, citations, warning letters or other enforcement actions.
- Business interruptions could adversely affect our business.
- 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 further 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 for or test our 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.
- Our senior secured credit facility with Ares Capital Corporation and certain of its affiliates (“Ares”) is subject to acceleration in specified circumstances, which may result in Ares 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 the manufacturing processes we have in place to counter 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.
- 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 a history of losses and have historically needed to raise, and in the future may be required to raise, additional capital to operate our business.

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, continue to build out our 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, that our current cash, cash equivalents and accounts receivable, along with our projected future operating cash flow, will be sufficient to fund our operations, as currently conducted, through the end of the first quarter of fiscal 2025. However, our current outlook on cash flows and profitability may change based upon how quickly we are able to execute on our commercialization efforts and operational initiatives and whether or not the assumptions underlying our projected revenues and expenses are correct. Although we achieved net income on a non-GAAP basis (see “Non-GAAP Financial Measures” within Management’s Discussion and Analysis of Financial Condition and Results of Operations) and positive cash flow from operations for the first time in our history for the year ended December 31, 2023, at present we cannot be certain that we will be able to generate a sufficient amount of product revenue to maintain profitability through 2024 and beyond. If we are unable to generate sufficient positive cash flow throughout 2024 and cannot raise additional capital if needed, we may have to delay, curtail or eliminate our commercialization efforts and product development activities. Even if we are able to raise additional capital, such equity or debt 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.

Historically, the major source of our cash has been from proceeds from various public offerings of our common stock and debt transactions. The actual amount of additional cash that we may need, if any, is subject to many factors. There can be no assurances that additional financing will be available if needed or that management will be able to obtain financing on terms acceptable to us or that we will continue to be profitable and generate positive operating cash flow.

We may not be able to achieve profitability in 2024 and beyond.

We have a history of losses through December 31, 2023, and we may not be able to achieve profitability. For the years ended December 31, 2023, 2022 and 2021, we incurred net losses of \$28.2 million, \$65.9 million and \$71.6 million, respectively. From our inception in 2004 through December 31, 2023, we have incurred an accumulated deficit of \$506.3 million. We may not be able to generate a sufficient amount of product revenue to achieve profitability throughout 2024, and if we are unable to continue to generate positive cash flow we may 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 as our business continues to grow our operating expenses will increase accordingly as we:

- expand commercialization and marketing efforts;
- implement additional internal systems, controls and infrastructure;
- hire additional personnel; and
- expand production capacity at the Boca Facility.

As a result, we will need to generate significant revenues in order to maintain profitability. We may not be able to generate these revenues or maintain profitability in the future.

Pandemics, or a resurgence of a pandemic, may adversely affect our business, financial condition, liquidity or results of operations.

The COVID-19 pandemic negatively impacted certain aspects of our business and operations. The resurgence of the COVID-19 pandemic, or a future pandemic or health epidemic, could adversely affect our business, financial condition, liquidity or results of operations. These adverse effects include, but are not limited to, the potential adverse effects on the global economy, our manufacturing processes, including our supply chain, our submissions or applications to the FDA and our employees. The ultimate impact will depend on the severity and duration of the pandemic and actions taken by governmental authorities and other third parties in response, each of which is uncertain and difficult to predict.

We contract with third parties for a portion of the filling, packaging, testing and labeling of the drug substance we manufacture, and also obtain plasma from certain third parties. This reliance on third parties carries the risk that the services upon which we rely may not be performed in a timely manner, in sufficient quantities 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 parties may not perform as agreed or in accordance with FDA requirements. Any significant problem that our third-party 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 services and products meeting the necessary quality standards or at all could have a material and adverse effect on our products, business, financial condition and results from operations.

Although we are utilizing our FDA-approved fill/finish suite that we built at the Boca Facility for a portion of our finished drug product and although we receive our raw material plasma from our ADMA BioCenters plasma collection facilities, we also intend to continue to utilize third parties to supplement our fill/finish process for final drug product and to supply raw material source and high-titer RSV plasma. Any failure by us, our contract fill/finishers, or other third parties involved in the process for producing our products or product candidates to comply with the applicable manufacturing and regulatory requirements, including quality requirements, could place us and them at risk of regulatory enforcement actions, recalls and other adverse consequences, could adversely impact our products, and could adversely impact patients receiving our products, which may negatively impact our business and our ability to produce and supply products to meet commercial and clinical needs.

Our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify contractors 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;
- a pandemic, or the resurgence of a pandemic such as 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, 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 contractors might be unable to timely provide finished drug product or raw material plasma in sufficient quantity to meet our commercial needs;
- contractors may not be able to execute our inspection procedures and required tests appropriately;
- contractors 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;
- contractors may fail to comply with applicable regulatory requirements, placing them and us at risk of regulatory enforcement actions, recalls and other adverse consequences, and which place our patients at risk, which may negatively impact our business and their ability to supply products to meet our development, clinical and commercial needs;
- our third parties 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 us or the FDA, which could result in higher costs or adversely impact our revenues. These risks could also result in the delay in obtaining clinical supplies, 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, international conflicts, trade and sanction requirements and limits, other acts of God or force majeure events or global health occurrences and emergencies.

The estimates of market opportunity and forecasts of market and revenue growth included in 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. In particular, the size and growth of the overall U.S. IVIG and source plasma markets and the potential market opportunity for an *S. pneumonia* hyperimmune globulin 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 collection 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.

Geopolitical conditions, war, terrorism or other military actions may have a material adverse effect on our business.

Geopolitical conflicts, war or other military action or international acts of terrorism may cause significant disruption to commerce throughout the world. To the extent that such disruptions result in disruptions to our supply chain, delays or cancellations of customer orders, a general decrease in consumer spending, our inability to effectively market and distribute our products and/or our inability to access the capital markets, our business and results of operations could be materially and adversely affected. For example, in response to the ongoing conflict between Russia and Ukraine, the United States has imposed and may further impose, and other countries may additionally impose, broad sanctions or other restrictive actions against governmental and other entities in Russia. Additionally, further escalation of geopolitical tensions, such as ongoing conflicts in the Middle East and the surrounding areas could have a broader impact that extends into other markets where we do business. We are unable to predict geopolitical conditions, whether acts of international terrorism or the involvement in a war or other military actions will result in any long-term commercial disruptions or if such involvement or responses will have any long-term material adverse effect on our business, results of operations, or financial condition.

Both of our business segments and our facilities, as well as our suppliers and contractors, are subject to periodic inspections by the FDA and other regulatory authorities, which, depending on the outcome of such inspections, could result in certain regulatory 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 and other regulatory authorities are authorized to perform inspections and remote regulatory assessments of our and our suppliers' facilities, including the Boca Facility. The FDA and other regulatory authorities also may inspect and approve our and our third-parties' facilities before they may be used for commercial production. If we or our suppliers are not able to comply with the applicable regulatory requirements, we or they may be subject to regulatory enforcement actions, which can materially impact our business. For instance, at the end of such an inspection, the FDA could issue a Form 483 Notice of Inspectional Observations, which could cause the FDA to not approve the use of the facility and cause us to modify certain activities identified during the inspection. 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. Depending on the seriousness of any findings, we or our suppliers may be subject to additional significant enforcement actions which could have a material impact on our business.

In the event of any enforcement actions, we and our third-party contractors would need to implement remedial actions which may be time-intensive or costly. We may not be able to timely resolve concerns raised by the applicable regulator as a result of an inspection or without expending significant resources. We are unable to control the timing of inspections, communications and actions, and will be required to respond to the regulator and make certain submissions within certain timeframes. We also do not know whether or not the regulator will change its requirements, guidance or expectations. If the regulator 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. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption to 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 and service providers 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, cyberattacks on our operations and information technology systems and breakdown, human error, employee issues, global health occurrences such as the COVID-19 pandemic, global and economic uncertainty, war, geopolitical conditions 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 commencement and completion of clinical trials or ultimate product approval for any current or future development product candidate may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of safety or effectiveness, or other adverse study results during clinical trials;
- slower than expected rates of patient recruitment or noncompliance with clinical trial requirements;

- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

We cannot be certain as to what type and how many clinical trials the FDA, or equivalent foreign regulatory agencies, will require us to conduct before we may successfully gain approval to market any of our product candidates that still require FDA approval. Prior to approving a new drug or biologic, the FDA generally requires that the effectiveness of the product candidate (which is not typically fully investigated until Phase III) be demonstrated in two adequate and well-controlled clinical trials. However, if the FDA or an equivalent foreign regulatory authority determines that our Phase III 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 III 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 could be adversely affected.

In addition, the FDA or an IRB 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. Regulatory authorities may also not accept data from clinical trials if the trials are not conducted in accordance with the applicable regulatory requirements. Failure to comply with the applicable regulatory requirements may also result in enforcement actions. 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:

- Delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our CROs;
- Regulators requiring us to perform additional or unanticipated clinical trials to obtain approval or becoming subject to additional post-marketing testing, surveillance, or REMS requirements to maintain regulatory approval;
- Failure by our third-party contractors 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 our being required to engage in additional clinical trial site monitoring;

- The cost of clinical trials of our product candidates being greater than we anticipate or our having insufficient funds for a clinical trial or to pay the substantial user fees required by FDA upon the filing of a marketing application;
- Insufficient supply or inadequate quality of our product candidates or other materials necessary to conduct clinical trials;
- Inability to achieve sufficient study enrollment, subjects dropping out or withdrawing from our studies, delays in adding new investigators or clinical trial sites or a withdrawal of clinical trial sites;
- Flaws in our clinical trial design that are not discoverable until the clinical trial has progressed;
- Disagreement by the FDA or comparable foreign regulatory authorities with our intended indications or study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials, finding that a product candidate's benefits do not outweigh its safety risks or requiring that we conduct additional development or study work;
- The 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 ability to obtain raw materials and/or finished product for commercialization;
- FDA or comparable regulatory authorities taking longer than we anticipate to make decisions on our products or product candidates; and
- Potential inability 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 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 new contract manufacturing arrangements with 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 or that we will be able to maintain our current approvals. 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 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 candidates;
- 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 and the 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 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, require payment of 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 further developing and expanding commercial operations, collecting and procuring an adequate supply of high-titer antibody RSV plasma 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 related 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, 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. As a result, we may experience an insufficient supply of this plasma.

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' performance is, to some extent, outside of our control.

We depend on independent investigators and collaborators, such as universities and medical institutions, contract laboratories, CROs, contract manufacturers, contract fill/finishers, third-party plasma centers 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. These third parties 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 products and/or development programs, or if their performance is substandard or does not comply with the applicable regulatory standards, 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, and we may not be able to maintain existing approvals or meet our regulatory requirements. We or they may also be subject to regulatory enforcement actions, may need to take corrective actions, including initiating recalls, 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 and maintain approval for our product candidates.

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.

We currently anticipate expanding the manufacturing capacity and product output capability of 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, make the necessary submissions to FDA, obtain any FDA-required approvals and have it inspected by the FDA. Given the significant delays that may result during the validation process, we may experience a 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 and 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 related 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 application supplement to allow for the commercial relaunch of BIVIGAM, as well as the FDA's approval of our BLA for ASCENIV, require us to conduct specified post-marketing studies, including pediatric and safety studies. If, during the post-marketing period (after marketing approval) previously unknown adverse events emerge, there is the 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 programs, refusal of orders under existing government contracts, exclusion from participation in federal healthcare programs, consent decrees, deferred or non-prosecution agreements or corporate integrity agreements;
- product seizure or detention; or
- injunctions or the imposition of civil penalties or criminal fines.

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, 2023, two customers, BioCARE, Inc. ("BioCare") and Priority Healthcare Distribution, Inc. d/b/a CuraScript SD Specialty Distribution ("Curascript"), represented an aggregate of 72% of our consolidated revenues. For the year ended December 31, 2022, BioCare and Curascript represented an aggregate of 74% of our consolidated revenues.

As of December 31, 2023, five customers, BioCare, Healix Infusion Therapy, LLC (“Healix”), Curascript, AmerisourceBergen Corporation and Reliance Life Sciences Pvt. Ltd., represented an aggregate of approximately 98% of our consolidated accounts receivable. As of December 31, 2022, BioCare and Healix represented an aggregate of 92% 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;
- the impact of a pandemic, or the resurgence of a pandemic, and government responses thereto on our customers and their businesses, operations and financial condition; and
- widespread economic conditions or geopolitical conditions, including the exacerbated conflicts in Europe, the Middle East and the surrounding areas.

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, patient injury, 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.

In addition, 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 or write-downs as we ensure product quality and compliance with cGMP, FDA, state and local regulations, or due to testing results not meeting specifications. As a result, our operating results are subject to potentially significant variability from one reporting period to the next should such normal course losses occur in any given period. However, because our products and product candidates are plasma-based products, not only are we subject to the FDA’s drug and biologic cGMP requirements, but we are also subject to special requirements for the collection, testing, handling, storage, and use of blood products. This adds an extra level of compliance and complexity to our operations, which we may not be able to successfully meet. Failure to meet any regulatory quality standards could have an adverse impact on our business.

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 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. If we are not successful in developing or acquiring additional products and product candidates, we will have to depend on our ability to continue to generate revenues from ASCENIV, BIVIGAM, Nabi-HB, 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 requirements with respect to safeguarding the privacy, security and transmission of protected health information (“PHI”) held by covered entities and business associates. HIPAA “covered entities” include health plans/insurers, healthcare providers engaging in HIPAA standard electronic transactions and healthcare clearinghouses. A “business associate” provides services to covered entities (directly or as subcontractors to other business associates) involving arranging, creating, receiving, maintaining, or transmitting 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 that receives PHI on behalf of the entity.

While we are not a covered entity or business associate subject to HIPAA, personal information that we obtain pursuant to a clinical trial may be subject to U.S. Federal Trade Commission (the “FTC”) privacy regulation. Failing to take appropriate steps to keep consumers’ personal information secure may constitute an unfair act or practice violating 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, but less prescriptive than, 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. For example, the CCPA was amended by the CPRA, effective January 1, 2023. The CCPA, among other things, imposes 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. We could be subject to enforcement action and litigation exposure if we fail to adhere to these data privacy and security laws. Virginia, Colorado, Connecticut and Utah have also enacted privacy laws that became effective in 2023 and are similar in many respects to the CCPA. Several other states have also enacted privacy laws similar to the CCPA that will become effective in the coming years, adding to potential privacy compliance obligations.

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

On December 18, 2023 (the “Ares Closing Date”), we entered into a new senior secured credit facility with Ares (the “Ares Credit Agreement”) (see “Liquidity and Capital Resources”). The Ares Credit Agreement provides for a total of \$135 million in senior secured credit facilities (the “Ares Credit Facility”) consisting of (i) a term loan in the aggregate principal amount of \$62.5 million and (ii) a revolving credit facility in the aggregate principal amount of \$72.5 million (collectively, the “Ares Loans”), both of which were fully drawn on the Ares Closing Date. The Ares Credit Facility has a maturity date of December 20, 2027 (the “Ares Maturity Date”). The Ares 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. If there is an event of default, we would incur an increase in the rate of interest on the Ares Loans of 2% per annum. The occurrence of an event of default could result in, among other things, the termination of commitments under the Ares Credit Facility, the declaration that all outstanding loans are immediately due and payable in whole or in part, and Ares taking immediate possession of, and selling, any collateral securing the Ares 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 continue to discover novel technologies related to our products and we may draft patent applications directed to these technologies. 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, the U.S. Patent and Trademark Office or foreign patent offices. 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, 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 raw material 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 operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business could be harmed.

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

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

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

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is important to our operations and reputation. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate our proprietary and confidential information including e-mails and other electronic communications. Further, while many of our employees and certain suppliers with whom we do business operate in a remote working environment, 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. 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, such as the IT disruption described elsewhere in this report, 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, finance, general and operational management and plasma collections. In particular, over the next 12-24 months, we expect to hire several new employees devoted to our plasma collection centers, commercialization, sales, marketing, medical and scientific affairs, regulatory affairs, quality control, information technology, 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. 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 licensure for these facilities or obtain FDA licensure for additional facilities that we may construct 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 licensure of our current and future ADMA BioCenters collection facilities for the collection of human blood plasma and we may seek other governmental and regulatory approvals for these facilities. Collection facilities are subject to FDA and potentially other governmental and regulatory inspections and extensive regulation, including compliance with current cGMP and blood standards and FDA licensure and other governmental approvals, as applicable. Failure to comply with applicable governmental regulations or to receive applicable approvals for our current or 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 material adverse effect on our ability to manufacture our products or offer for sale plasma collected at the affected sites. Failure to comply with applicable governmental regulations may also impact the ultimate quality and compliance of our finished biologic products, which may have a material adverse effect on our business.

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. There is also no guarantee that we will be able to fulfill our contractual requirements to our customers. Moreover, to the extent that we use third-party vendors to fulfill our regulatory or contractual requirements, these 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. If we are not able to maintain manufacturing compliance at our facilities or our vendors' facilities for our products and product candidates, we may not be able to successfully develop and commercialize our products and product candidates and we may face potential contractual or regulatory actions, which would have an adverse impact on our business.

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. Product liability claims may also result in recalls and/or regulatory enforcement actions. 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, state and local levels by criminal, civil and administrative sanctions. 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, 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 significant criminal and/or civil sanctions, including jail sentences, fines or exclusion from participation in or debarment from federal and state healthcare or government procurement programs, pursuant to enforcement actions by DOJ, Medicare, Medicaid, OIG and other regulatory authorities. 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 significant criminal and/or civil sanctions, including jail sentences, fines or exclusion from participation in applicable state healthcare 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 to induce or reward patient referrals, or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease, or ordering of any item 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 participation in the Medicare and Medicaid programs. Arrangements with referral sources such as purchasers, group purchasing organizations, healthcare 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 paid by a manufacturer to a PBM. 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 Statute discounts safe harbor. Recent legislation and a final rule promulgated on December 29, 2023 delayed implementation of this portion of the rule until January 1, 2032.

Also, certain business practices, such as payments of consulting fees to healthcare professionals, sponsorship of educational or research grants, charitable donations, interactions with healthcare professionals who 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 professionals to prescribe or purchase particular products or as a reward for past prescribing. Under 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, U.S.-licensed physicians, physician assistants, nurse practitioners, clinical nurse specialists and certified registered nurse anesthetists and U.S. 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 sanctions against manufacturers have resulted in substantial fines, penalties and damages. Many manufacturers have been required to enter into consent decrees or orders that prescribe allowable corporate conduct and/or Corporate Integrity Agreements that impose ongoing compliance requirements on a manufacturer.

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 been brought against companies accused of promoting off-label uses of drugs, because such promotion induces unapproved 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 federal Anti-Kickback Statute that applies to government healthcare programs, and other healthcare fraud provisions, leading to the possibility of greatly increased lawsuits by whistleblowers 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 criminal and/or civil liability under the federal False Claims Act, the federal Anti-Kickback Statute and various other laws, rules and regulations.

We have established systems for collecting and reporting this data accurately to CMS and have instituted 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. Most 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 voluntary industry guidelines 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 and localities 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 and local laws, rules, regulations and permits. Failure to appropriately comply with such state and local requirements could result in temporary or long-term cessation of our manufacturing operations, as well as fines and other sanctions. Any such penalties may have a material adverse effect on our business and results of operations.

We are subject to extensive and rigorous governmental regulation, including the requirement of FDA and other federal, state and local business regulatory approvals 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 CROs 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 and nonclinical 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, CRLs, 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 approvals. Any failure to receive the marketing approvals necessary to commercialize our products 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 to accept the payment of user fees, as well as 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 few 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 the 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 certain amounts of raw materials and work-in-process inventory 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 or losses 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 our manufacturing processes are inadequate to inactivate or remove an infectious agent, our ability to manufacture and distribute our products would be impaired. If a new infectious disease were to emerge in the human population or if there were a reemergence of an infectious disease, the regulatory and public health authorities could impose precautions to limit the transmission of the disease that would impair our ability to procure plasma, manufacture our products or both. Such precautionary measures could be taken before there is conclusive medical or scientific evidence that a disease poses a risk for plasma-derived products. In recent years, new testing and viral inactivation methods have been developed that more effectively detect and inactivate infectious viruses in collected plasma. There can be no assurance, however, that such new testing and inactivation methods will adequately screen for, and inactivate, infectious agents in the plasma used in the production of our products.

We could become supply-constrained and our financial performance would suffer if we cannot obtain adequate quantities of FDA-approved source and high-titer 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. Additionally, although we achieved plasma supply self-sufficiency with the approval of our tenth plasma collection center in November 2023, we remain reliant on the purchase of plasma from third parties and the collection of plasma from our FDA-licensed plasma collection centers to manufacture our products. We can give no assurances that appropriate plasma will be available to us through our own plasma collection facilities or on commercially reasonable terms, or at all, to manufacture our products. Further, the COVID-19 pandemic resulted in significant constraints in raw material supply across various different industries, including the supply of plasma. It is possible that in the future, pandemics 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.

Additionally, our supply contract with Grifols for the purchase of normal source plasma ("NSP") expired on December 31, 2022 and was not renewed. Although we have executed additional agreements with other third-party suppliers of NSP, we anticipate that the NSP used in IG production in 2024 and beyond will be sourced from our ADMA BioCenters plasma collection facilities. There can be no assurances that we will be able to obtain an adequate supply of NSP from other third-party suppliers or be able to collect NSP in the same quantities, or at all, through our ADMA BioCenters plasma collection facilities at a cost that is not higher than the price we paid to Grifols for NSP. If our costs to obtain NSP through collections at our ADMA BioCenters plasma collection facilities or from other third-party suppliers are higher than what we paid to Grifols under our supply contract, our liquidity and results of operations could be adversely impacted.

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 insurance 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 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, plus the inflation penalty if applicable. 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, plus the inflation penalty if applicable. 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, and the Bipartisan Budget Act of 2015 established a new inflation penalty for these drugs. In 2010, the Healthcare Reform Law also newly extended the Medicaid drug 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, and recent regulations have established a civil monetary penalty for failure to refund these overcharges.

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 legal challenges and attempts by Congress to repeal or change the Healthcare Reform Law and the possibility of future challenges or legislative changes 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.

Corporate responsibility, specifically related to Environmental, Social and Governance ("ESG") matters, may impose additional costs and expose us to new risks.

Public ESG and sustainability reporting is becoming more broadly expected by investors, stockholders and other third parties. Certain organizations that provide corporate governance and other corporate risk information to investors and stockholders have developed, and others may in the future develop, scores and ratings to evaluate companies and investment funds based upon ESG or "sustainability" metrics. Many investment funds focus on positive ESG business practices and sustainability scores when making investments and may consider a company's ESG or sustainability scores as a reputational or other factor in making an investment decision. In addition, investors, particularly institutional investors, use these scores to benchmark companies against their peers and if a company is perceived as lagging, these investors may engage with such company to improve ESG disclosure or performance and may also make voting decisions, or take other actions, to hold these companies and their boards of directors accountable. Board diversity is an ESG topic that is, in particular, receiving heightened attention by investors, stockholders, lawmakers and listing exchanges. Certain states have passed laws requiring companies to meet certain gender and ethnic diversity requirements on their boards of directors. We may face reputational damage in the event our corporate responsibility initiatives or objectives, including with respect to board diversity, do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party ratingservices. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks.

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

If we are unable to continue to generate positive cashflows and net income, we may require additional funding and may be unable to raise capital when needed, which would adversely affect our operations and could force us to delay, curtail or eliminate some of our commercialization efforts or one or more of our research and development programs.

Although we generated positive cash flow from operations for the year ended December 31, 2023, our operations have consumed substantial amounts of cash since inception. While we generated positive cash flow of \$8.8 million for the year ended December 31, 2023, for the years ended December 31, 2022 and 2021, we had negative cash flows from operations of \$59.5 million and \$112.4 million, respectively. We expect to continue to spend substantial amounts for collecting plasma at our plasma collection centers, maintaining our plasma collection centers, procurement of raw material plasma and other raw materials necessary to scale up our manufacturing operations, commercial product launches and capacity expansion at the Boca Facility. In addition, our end-to-end production cycle from collecting and procuring raw material source plasma 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 had a net loss of \$28.2 million for the year ended December 31, 2023 and although we achieved adjusted net income of \$0.7 million which, as further described under “Non-GAAP Financial Measures”, excludes charges related to the refinancing of our senior debt of \$26.2 million and an IT systems disruption of \$2.7 million (see Management’s Discussion and Analysis of Financial Condition and Results of Operations), at present we cannot be certain that we will be able to generate a sufficient amount of product revenue to achieve profitability on an ongoing basis. If we are unable to continue to generate positive cash flow throughout fiscal 2024, we may 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, that our current cash, cash equivalents and accounts receivable, along with our projected future operating cash flow, will be sufficient to fund our operations, as currently conducted, through the first quarter of fiscal 2025. Our current outlook with respect to cash flows and profitability may change based upon how effective we are in continuing to execute on our commercialization efforts and operational initiatives and whether or not the assumptions underlying our projected revenues and expenses are correct. If we are required to raise additional capital and if such capital is not available due to widespread liquidity constraints or significant market instability that could result from widespread economic or geopolitical conditions, we may 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 Ares Credit Facility provides for total senior secured loans in an aggregate principal amount of up to \$135.0 million, all of which has been drawn down and is currently outstanding. Borrowings under the Ares Credit Facility currently bear interest at a weighted-average rate of approximately 10.4% per annum, which reflects the three-month term SOFR rate; provided, however, that upon, and during the continuance of, an event of default, the interest rate will automatically increase by an additional 200 basis points. We are currently required to make quarterly payments of interest during the term of the Ares Credit Facility of approximately \$3.7 million, with all principal and unpaid interest due at maturity. In addition, our monthly interest rate obligation is subject to rising interest rates. The Ares Credit Facility has a maturity date of December 20, 2027, subject to acceleration pursuant to the Ares Credit Agreement, including upon an event of default. All of our obligations under the Ares 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 and projected cash, cash equivalents and accounts receivable may not be sufficient to repay all of our current outstanding debt obligations as they mature. If we are unable to achieve sufficient positive cash flow to repay our outstanding debt obligations as they mature, we will need to obtain additional financing in the amounts necessary to repay our outstanding debt obligations when due. If we are unable to repay our outstanding debt obligations when they mature, our creditors would be able to accelerate all of the amounts due and, in the case of the Ares 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 result in investors losing confidence in the accuracy and completeness of our financial statements, harm our operating results and negatively affect the market price of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and related rules (the “Sarbanes-Oxley Act”), we are required to maintain internal control over financial reporting and our management is required to report on the effectiveness of our internal control over financial reporting, including any material weaknesses in such internal controls. 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.

Because we became a large accelerated filer effective December 31, 2023, the Sarbanes-Oxley Act requires our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. Our transition to large accelerated filer status and becoming subject to additional requirements of the Sarbanes-Oxley Act will be time-consuming, and there is a risk of noncompliance. Further, the costs associated with the compliance with and implementation of procedures under these and future laws and related rules could have a material impact on our results of operations.

Consequently, we have incurred increased costs related to our compliance with Section 404 of the Sarbanes-Oxley Act and will continue to do so. Our Audit Committee has retained the services of BDO, a Sarbanes-Oxley advisor, to assist with our internal control over financial reporting and information technology related to the Sarbanes-Oxley Act. Moreover, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to assert that our internal controls over financial reporting is effective or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock could be negatively affected. In addition, we could become subject to investigations by any stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources, which could have an adverse impact on our business.

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, 2023, we had federal and state NOLs of \$315.6 million and \$216.4 million, respectively. Federal and state NOLs of approximately \$35.6 million and \$95.1 million, respectively, will begin to expire at various dates beginning in 2028, 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 (“Section 382”) imposes limitations on a company’s ability to use NOLs upon certain changes in such ownership. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs. The acquisition transaction that we completed 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. On October 25, 2021, we completed a public offering of our common stock whereby we issued 57,500,000 shares of our common stock resulting in another change of ownership for ADMA under section 382 of the Code, resulting in an additional write-off of \$3.0 million of Federal NOLs, \$28.1 million of state NOLs and \$1.0 million of research and development credits. Although we did not experience any ownership changes for the years ended December 31, 2023 and 2022, 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;
- 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;
- global and economic uncertainty;
- 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 February 23, 2024, most of our 228,220,236 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, as amended (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, 2023, BlackRock Inc., Vanguard Group and our directors and executive officers and their affiliates owned approximately 16% 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.

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 Ares 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.

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 300,000,000 shares of common stock. As of December 31, 2023, there were 31,033,333 shares remaining available for issuance, after giving effect to 23,066,387 shares of our common stock that were subject to outstanding stock options, RSUs and warrants as of December 31, 2023 that may be issued by us without stockholder approval, as well as an additional 19,837,248 shares reserved for the future issuance of awards under our equity compensation plans.

Item 1B. Unresolved Staff Comments

Not Applicable.

Item 1C. Cybersecurity

Risk Management and Strategy

We recognize the importance of managing the material risks of cybersecurity threats, and we have implemented processes for identifying and assessing cybersecurity risks and incidents. We have also integrated these processes into our overall risk management system, including senior management’s periodic reviews of cybersecurity risks or threats. Senior management oversees and works closely with our IT department to continuously review and evaluate cybersecurity risks in alignment with our business goals and needs.

With respect to cybersecurity risks and threats, we utilize various third-party consultants and advisors to assist us with regular reviews, internal audits and best practices, including threat prevention and detection, security reviews and enhancements, penetration testing and full scope IT audits. ADMA also has strict processes in place for the review of third-party service providers engaged, including thorough security assessments before engagement and annual monitoring of their IT environments and controls.

During the year ended December 31, 2023, as initially disclosed in our Quarterly Report on Form 10-Q for the period ending June 30, 2023 and updated elsewhere in our subsequent filings with the SEC, including this Annual Report on Form 10-K, we experienced an IT Systems Disruption, which did result in a non-recurring charge to our results of operations. There was no original financial systems data loss or any evidence of data exfiltrated due to this disruption. Normal course operations have resumed across the Company’s business units.

Governance

Our Chief Executive Officer and Chief Financial Officer are primarily responsible for timely updating the Board and Audit Committee about any material cybersecurity incidents or threats or any cybersecurity related issues worthy of their attention.

Our Board has designated the Audit Committee as the primary committee responsible for reviewing and managing cybersecurity risks and threats at ADMA. The Audit Committee is comprised of Board members with diverse experience in healthcare, finance and information technology, enabling them to effectively oversee cybersecurity risks and threats. Our management team, with assistance from third-party consultants or advisors as appropriate, provides quarterly updates regarding cybersecurity risks and threats to the Audit Committee and ad hoc updates or communications are provided to the entire Board as needed.

The Data Integrity and IT Operations team are primarily responsible for the timely identification, review, severity assessment and management of cybersecurity incidents. In the event of a cybersecurity incident, the IT Department leadership follows the procedures outlined in our Cybersecurity Incident Response Policy and works closely with management to form a Security Incident Response Team comprised of members from the appropriate functional teams. In accordance with this policy, senior management will also communicate the occurrence of any significant cybersecurity incidents to our Board, Audit Committee and auditors on a timely basis and will keep them informed of the remediation plans and progress.

Item 2. Properties

The table below describes our principal facilities as of December 31, 2023:

Location	Principal Business Activity	Approximate Square Feet	Owned or expiration date of lease
Ramsey, NJ	Corporate Headquarters	4,200	December 31, 2026 *
Boca Raton, FL	Manufacturing and Administration	84,462	Owned
Boca Raton, FL	Laboratory and Administration	44,495	Owned

* Pursuant to a shared services agreement, as amended, with Areth, LLC ("Areth") for office, warehouse space and related services pursuant to which the Company pays Areth monthly lease payments of \$10,000. 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 also have ten plasma collection centers in leased facilities mainly in the southeastern part of the U.S., which require lease payments through the respective lease terms that expire at various dates through 2033 (see Note 12 to the consolidated financial statements appearing elsewhere in this report).

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. Since October 22, 2019, our Common Stock has been listed on the Nasdaq Global Market.

Holders

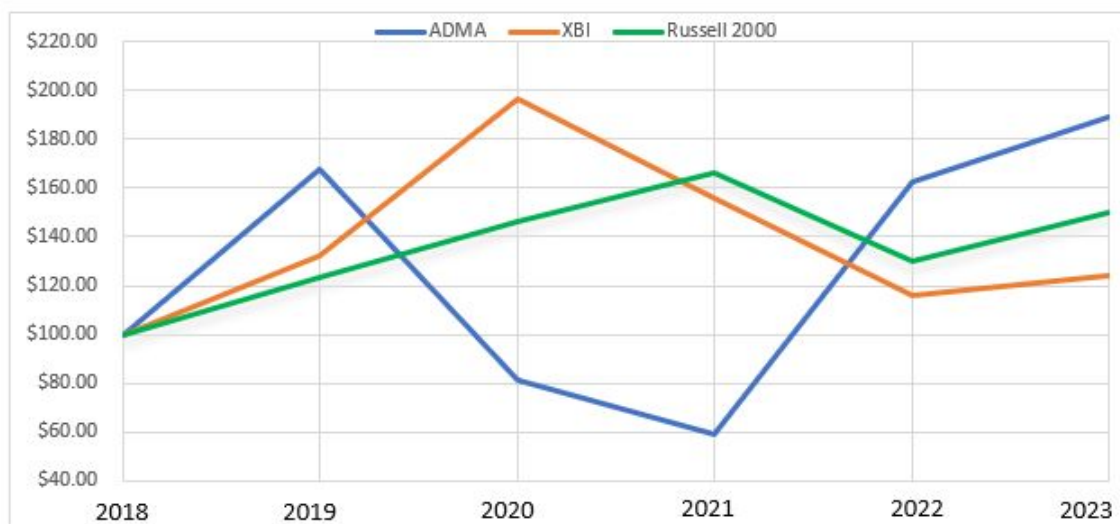
As of December 31, 2023, there were five record holders of our Common Stock, based upon information received from our transfer agent. However, this number does not include beneficial owners whose shares were held of record by nominees or broker dealers. As of February 1, 2024, we estimate that there are more than 30,000 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 Ares preclude 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

The following graph assumes a \$100 investment on December 31, 2018 in each of the Company’s Common Stock, the XBI Biotech Index of biotechnology companies and the Russell 2000 Index.



	<u>2018</u>	<u>2019</u>	<u>2020</u>	<u>2021</u>	<u>2022</u>	<u>2023</u>
ADMA	\$ 100.00	\$ 167.36	\$ 81.59	\$ 59.00	\$ 162.34	\$ 189.12
XBI	\$ 100.00	\$ 132.56	\$ 196.21	\$ 156.04	\$ 115.68	\$ 124.45
Russell 2000	\$ 100.00	\$ 123.73	\$ 146.42	\$ 166.13	\$ 130.22	\$ 149.90

Sale of Unregistered Securities

During the year ended December 31, 2023, we had no sales of unregistered securities that have not been previously disclosed in a Current Report on Form 8-K or Quarterly Report 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, 2023.

Our directors and executive officers may from time to time enter into plans or other arrangements for the purchase or sale of our common stock that are intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or may represent a non-Rule 10b5-1 trading arrangement under the Exchange Act. During the quarter ended December 31, 2023, none of our directors or executive officers adopted or terminated any such contract, instruction or written plans.

Item 6. Reserved

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 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.

Through our ADMA BioManufacturing business segment, 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) ASCENIV (Immune Globulin Intravenous, Human – sIra 10% Liquid), an Intravenous Immune Globulin (“IVIG”) product indicated for the treatment of Primary Humoral Immunodeficiency (“PI”), also known as Primary Immunodeficiency Disease (“PIDD”) or Inborn Errors of immunity in adults and adolescents, for which we received FDA approval on April 1, 2019 and commenced first commercial sales in October 2019; (ii) BIVIGAM (Immune Globulin Intravenous, Human), an IVIG product indicated for the treatment of PI, and for which we received FDA approval on May 9, 2019 and commenced commercial sales in August 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, plasma fractionation and purification facility located in Boca Raton, Florida with a peak annual processing capability of up to 600,000 liters (the “Boca Facility”). Based on current production yields, our completed and ongoing supply chain enhancements and capacity expansion initiatives, we believe this facility has the potential to produce sufficient quantities of our immune globulin (“IG”) products representing annual revenues of approximately \$330 million in 2024 and potentially \$380 million in 2025. At these revenue levels, we forecast achieving consolidated gross margins in the range of 40-50% and net income margins in the range of 20-30%. These assumptions translate to potential fiscal year 2024 and 2025 net income of \$65 million and \$115 million or more and adjusted EBITDA of \$90 million and \$140 million or more, respectively.

For the year ended December 31, 2023 we had a net loss of loss of \$28.2 million and achieved adjusted net income of \$0.7 million which, as further described under “Non-GAAP Financial Measures”, excludes charges related to the refinancing of our senior debt of \$26.2 million and an IT systems disruption of \$2.7 million (see Management’s Discussion and Analysis of Financial Condition and Results of Operations). We also achieved positive cash flow from operations for the year ended December 31, 2023 for the first time in the Company’s history, primarily as a result of our significant revenue growth and continued physician, patient and payer acceptance of ASCENIV and BIVIGAM that we have experienced over the past several years.

Through our ADMA BioCenters subsidiary, we currently operate ten source plasma collection facilities in the U.S., all of which hold FDA licenses. This business unit, which we refer to as our Plasma Collection Centers business segment, provides us with the blood plasma required for the manufacture of our products, and also allows us to sell certain quantities of source and hyperimmune plasma to third-party customers for further manufacturing. In addition, three of our FDA-approved plasma collection centers also have approvals from the Korean Ministry of Food and Drug Safety (“MFDS”), as well as FDA approval to operate a Hepatitis B immunization program. 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 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, through a five-year manufacturing and supply agreement we entered into in January 2020. These intermediate by-products are used as the starting raw material to produce other plasma-derived biologics. In addition, from time to time we provide contract manufacturing services for certain third-party clients. We also provide laboratory contracting services to certain customers and anticipate providing contract filling, labeling and packing services utilizing our FDA-approved in-house fill-finish capabilities.

Our Products

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) became effective April 1, 2021. 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. With our patented testing methods and assay, we are able to identify the high-titer or "hyperimmune" plasma that meets our internal and required specifications for ASCENIV. This type of high-titer plasma is typically found in less than 10% of the total donor collection samples we test.

ASCENIV is approved for the treatment of PIDD or PI, 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 ("SBI") 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 and 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 potentially further evaluate ASCENIV in immune-compromised patients infected with or at-risk for RSV infection or potentially other respiratory viral pathogens at an appropriate time. Due to the COVID-19 pandemic, our plans have been delayed. In the future however, we may elect to work with the FDA and the immunology and infectious disease community to design an appropriate clinical trial to evaluate the use of ASCENIV in this patient population. Following FDA approval in April 2019, commercial sales of ASCENIV commenced in October of 2019 and in 2023 ADMA commenced manufacturing ASCENIV at the 4,400 Liter production scale for the first time in the Company's history. We expect that this expansion should meaningfully improve the product's margin profile and increase plant production capacity as fewer batches will be needed to support our revenue goals. ASCENIV's prescriber and patient base continued to expand during 2023, which drove record utilization and pull-through for this product. These elevated demand trends have sustained into 2024, and ADMA currently expects that this product's rapid growth will continue throughout 2024 and beyond.

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 re-launch and commercialize this product in the U.S. 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. The commercial re-launch and first commercial sales for this product commenced in August of 2019.

On April 28, 2021, we announced that the FDA granted approval for our expanded plasma pool production scale process, allowing for a 4,400-liter plasma pool for the manufacture of our BIVIGAM IVIG product. This increased IVIG plasma pool scale, which allows us to produce BIVIGAM at an expanded capacity utilizing the same equipment, release testing assays and labor force, has had a favorable impact on our gross margins, manufacturing efficiencies and operating results.

On December 12, 2023, we announced that the FDA approved the expansion of BIVIGAM’s label in the U.S. to now include the pediatric setting for those two years of age and older.

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, which is a major global health problem. The Hepatitis B virus can cause chronic infection and places 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.

IT SYSTEMS DISRUPTION

On June 19, 2023, we experienced an IT systems disruption, which rendered certain of our IT systems inaccessible for less than one week. Our investigation of the disruption has been completed with the assistance of third-party consultants. While no definitive root cause was identified, as previously disclosed we believe that this IT systems disruption may have been caused by a third-party who may have gained access to the system. There was no original financial systems or other data loss or any evidence of files exfiltrated due to this disruption. Normal operations have resumed across our business units. At the time of the disruption, we were in production of two batches of BIVIGAM, and after a prolonged hold time, it was deemed to be a prudent GMP quality decision to discard these two in-process production batches as these batches were no longer viable for further production or had any alternative use. As a result, we recorded a one-time, non-recurring charge of \$2.1 million for this inventory in the second quarter of 2023, which is reflected in Cost of product revenue in the accompanying consolidated statements of operations for the year ended December 31, 2023. In addition, the Company’s Plasma center operating expenses were adversely impacted by approximately \$0.7 million due to the temporary closing of our plasma collection centers while their IT systems were restored.

We carry appropriate insurance for these types of instances, and while there can be no assurances ADMA will be reimbursed for the insurance claims made pertaining to these charges, we are actively working with our insurance broker and carriers.

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 rebates and certain other deductions from gross revenues, impairment of long-lived assets, 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 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 estimates and their application are considered to be critical to understanding our business operations, financial condition and results of operations. For a description of our significant accounting policies, see Note 2 to the Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K. Estimates and assumptions used in projecting future liquidity and capital requirements are described in Note 1 to the Consolidated Financial Statements.

Revenues

Our gross product revenues are subject to a variety of deductions, which are estimated and recorded in the same period that the revenues are recognized. These deductions primarily consist of rebates, distribution fees, chargebacks and sales allowances. These deductions represent estimates of the related obligations, some of which are contractual in nature and do not require extensive judgment to be exercised by management, while other estimates require complex or subjective matters of knowledge and judgment when estimating the impact of these revenue deductions on net revenues for a reporting period.

Historically, adjustments to these estimates to reflect actual results or updated expectations have not been material to our overall business. While we have some historical sales and rebate experience from our two primary immunoglobulin products, ASCENIV and BIVIGAM, since their FDA approvals in 2019, it is not extensive. If any of our ratios, factors, assessments, experiences or judgments are not indicative or accurate estimates of our future experience, our results could be materially affected. Estimates that are most at risk for material adjustment are those associated with U.S. Medicaid rebates because of the extensive time delay between the recording of the accrual and its ultimate settlement, an interval that can generally take up to several years or more. These estimates may change from time to time based on changes in utilization, payor and channel mixes. While our results of operations to date have not required any material adjustment due to this risk, the delay between when this obligation is initially recorded and ultimately settled could potentially materially impact our revenues and our results of operations in the future.

Valuation of Inventory

Estimates related to the valuation of inventory include net realizable value of inventory in determining whether the cost of inventory exceeds its net realizable value which, if this were the case, would require a charge against earnings to write down the value of the inventory to its net realizable value. Net realizable value of inventory is based on our management's estimate of the future net selling price of the inventory, which is subject to market conditions and the estimation processes we use for revenues as discussed above. With respect to raw materials inventory, we are required to estimate the level and timing of usage of these materials prior to their expiration dates in determining whether it is appropriate to carry these materials on our balance sheet as a valid asset of the Company. Changes in either of these estimates could potentially materially impact our cost of product revenue and results of operations.

Stock-Based Compensation and Valuation of Warrants

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. For the purpose of valuing stock options granted to our employees, directors and officers, we use the Black-Scholes option pricing model. The Black-Scholes option pricing 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, 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. Any changes in the foregoing Black-Scholes assumptions, or an election by us to utilize an alternative method for valuing stock options granted to employees, directors and officers, could potentially impact our stock-based compensation expense and our results of operations.

We also use the Black-Scholes option pricing model for the purpose of estimating the fair value of warrants we issue from time to time in connection with the issuance of notes payable. Changes in our Black-Scholes assumptions, or an election by us to utilize an alternative method for valuing warrants issued to our lenders, could impact our interest expense and results of operations.

Impairment of Long-Lived Assets

We assess the recoverability of our 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, 2023 and 2022, we determined that there was no impairment of our long-lived assets. Examples of events or circumstances that may be indicative of impairment that would require the use of significant judgment by management include:

- A significant adverse change in legal factors or in the business climate that could affect the value of the asset.
- Significant and continued cash flow losses.
- A significant adverse change in the extent or manner in which an asset is used, such as a restriction imposed by the FDA or other regulatory authorities that could affect our ability to manufacture our products using a particular asset.
- An expectation of losses or reduced profits associated with an asset. This could result, for example, from the introduction of a competitor’s product that impacts projected revenue growth, or a change in the acceptance of a product by patients, physicians and payers that results in an inability to sustain projected product revenues.

Goodwill is not amortized but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. The testing of goodwill for impairment requires us to determine whether or not the fair value of the reporting unit associated with the goodwill is less than its carrying amount, including goodwill and other intangible assets. 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. In order to determine the fair value of the reporting unit, we utilize the fair value of the Company as a whole, as determined by its market capitalization. Determination of the fair value and carrying value of each reporting unit, relative to the fair value of the Company, requires management to employ certain estimates, assumptions and judgment, which we believe are reasonable. However, any changes to these estimates and assumptions could impact our determination of whether or not our goodwill is impaired. We did not recognize any impairment charges related to goodwill for the years ended December 31, 2023, 2022 and 2021.

Deferred Tax Assets

We have historically maintained a full valuation allowance against all of our net deferred tax assets, and as a result have recorded no income tax benefit in the accompanying consolidated financial statements. This valuation allowance reflects our assessment of whether it is more likely than not that we will generate sufficient taxable income in the future to be able to utilize our deferred tax assets. In determining whether a valuation allowance is warranted, we evaluate factors such as prior earnings history, expected future earnings, carryback and carryforward periods and tax strategies. We consider all positive and negative evidence to estimate if sufficient future taxable income will be generated to realize our deferred tax assets. We consider cumulative losses in recent years to be a significant type of negative evidence, and based on our history of losses, at this time we have not included future projected taxable income as a source of income to recognize our deferred tax assets.

Year Ended December 31, 2023 Compared to Year Ended December 31, 2022

The following table presents a summary of the changes in our results of operations for the year ended December 31, 2023, compared to the year ended December 31, 2022:

	Year Ended December 31,		
	2023	2022	Increase (Decrease)
<i>(in thousands)</i>			
Revenues	\$ 258,215	\$ 154,080	\$ 104,135
Cost of product revenue	169,273	118,815	50,458
Gross profit	88,942	35,265	53,677
Research and development expenses	3,300	3,614	(314)
Plasma center operating expenses	4,266	17,843	(13,577)
Amortization of intangibles	724	715	9
Selling, general and administrative expenses	59,020	52,458	6,562
Income (loss) from operations	21,632	(39,365)	60,997
Interest expense	(25,027)	(19,279)	(5,748)
Loss on extinguishment of debt	(26,174)	(6,670)	(19,504)
Other income (expense), net	1,330	(590)	1,920
Net loss	\$ (28,239)	\$ (65,904)	\$ 37,665
Adjusted EBITDA *	\$ 40,251	\$ (27,627)	\$ 67,878
Adjusted net income (loss) *	\$ 705	\$ (59,234)	\$ 59,939

* - See Non-GAAP Financial Measures appearing at the end of this discussion

Revenues

We recorded total revenues of \$258.2 million for the year ended December 31, 2023, as compared to \$154.1 million for the year ended December 31, 2022, an increase of \$104.1 million, or approximately 68%. The increase is primarily related to increased sales of our immunoglobulin products, mainly ASCENIV and BIVIGAM, generated by our Boca Facility manufacturing operations in 2023 of \$105.8 million, as we continue to experience increased physician, payer and patient acceptance and utilization of ASCENIV and expand our customer base for BIVIGAM, partially offset by a decrease in sales of plasma in our Plasma Collection Centers business segment of \$1.5 million. During 2023, we began utilizing a substantial majority of the plasma collected at our plasma collection facilities for our IVIG production, with significantly less emphasis on plasma sales to third-party customers.

Cost of Product Revenue and Gross Profit

Cost of product revenue was \$169.3 million for the year ended December 31, 2023, as compared to \$118.8 million for the year ended December 31, 2022. This increase is primarily attributable to volume-driven increases in product revenue costs related to the increased sales of our immunoglobulin products of \$54.9 million. Cost of product revenue was also impacted by the inventory losses of \$2.1 million related to the June 2023 IT disruption, partially offset by a decrease in other manufacturing expenses of approximately \$6.2 million in 2023, mainly due to a shorter planned shutdown of the Boca Facility in 2023 as compared to 2022.

For the year ended December 31, 2023, we had gross profit of \$88.9 million, as compared to \$35.3 million for the same period of a year ago. This gross profit increase of \$53.7 million was primarily due to the revenue increases and the supply chain and manufacturing enhancements at the Boca Facility which include producing at the increased 4,400 liter scale, along with the reduction in other manufacturing costs discussed above as we elected to extend our otherwise-routine plant shutdown in the first quarter of 2022 in order to complete certain projects. We also experienced a more favorable sales mix in 2023 toward our higher margin products and benefitted from price increases for ASCENIV and BIVIGAM that were implemented late in 2022. As a result, we achieved a gross margin of 34.4% for the year ended December 31, 2023 as compared to 22.9% for the year ended December 31, 2022.

Research and Development Expenses

Research and development (“R&D”) expenses totaled \$3.3 million for the year ended December 31, 2023, as compared to \$3.6 million for the year ended December 31, 2022. The decrease is primarily due to lower expenditures attributable to a third-party service provider in connection with an R&D project that was completed in early 2023.

Plasma Center Operating Expenses

Plasma Center Operating Expenses decreased from \$17.8 million in the year ended December 31, 2022 to \$4.3 million in the year ended December 31, 2023. As a result of our now having ten plasma centers in operation, we were able to more than double the number of liters of plasma collected, with a corresponding reduction in the cost per liter, in 2023 as compared to 2022, coupled with the changes in the market price of normal source plasma and its impact on the net realizable value of our plasma inventory, the amount of plasma center costs we capitalized into inventory increased by approximately \$43.2 million in 2023. This amount was largely offset by increases in donor fees of \$12.8 million, compensation, benefits and temporary labor of \$3.9 million, softgoods and supplies of \$5.0 million, donor testing expenses of \$4.8 million, depreciation of \$0.8 million, software maintenance expense of \$0.9 million, janitorial, security and utilities expense of \$0.5 million, travel expenses of \$0.1 million, advertising expense of \$0.2 million, repairs and maintenance expense of \$0.2 million and rent of \$0.2 million. In addition, our plasma center collections and operating costs were unfavorably impacted by approximately \$0.7 million due to the temporary closing of our plasma collection centers attributable to an IT disruption occurring in June 2023, of which all systems have since been fully restored.

Amortization of Intangibles

Amortization expense mainly pertains to the amortization of intangible assets acquired in a 2017 acquisition transaction and was \$0.7 million for the years ended December 31, 2023 and 2022.

Selling, General and Administrative Expenses

Selling, general and administrative (“SG&A”) expenses were \$59.0 million for the year ended December 31, 2023, an increase of \$6.6 million from the year ended December 31, 2022. The increase reflects higher expenses for employee-related costs including salaries, benefits, stock-based compensation, travel, relocation and recruiting of \$2.4 million, data services and market intelligence fees in support of the continued ASCENIV and BIVIGAM commercialization efforts in the amount of \$1.8 million, marketing and advertising expenses of \$1.0 million, insurance expense of \$0.6 million, software maintenance expense of \$0.6 million and state and local taxes of \$0.2 million.

Income/Loss from Operations

For the year ended December 31, 2023, we had operating income of \$21.6 million, as compared to an operating loss of \$39.4 million for the year ended December 31, 2022. The \$61.0 million improvement in operating results was mainly due to the improved gross profit of \$53.7 million and the lower total operating expenses of \$7.3 million.

Interest Expense

Interest expense for the year ended December 31, 2023 was \$25.0 million, as compared to \$19.3 million for the year ended December 31, 2022. The increase is mainly due to approximately \$51.8 million of additional debt principal resulting from the refinancing of our senior credit facility on March 23, 2022, additional debt principal resulting from interest payments made “in kind” in the form of additional indebtedness of approximately \$6.8 million, as well as an increase in the stated interest rate on our senior debt from 10.75% in 2022 to as high as 14.4% at certain points in fiscal 2023 as a result increases in the Secured Overnight Financing Rate (“SOFR”). We expect our interest expense to decrease in 2024 as a result of the refinancing transaction we completed in December of 2023 (see “Liquidity and Capital Resources”), which resulted in a lower debt principal balance and a reduction in the interest rate.

Loss on Extinguishment of Debt

In connection with the foregoing refinancing of our senior debt in December of 2023, we incurred a loss on extinguishment of debt in the amount of \$26.2 million, which is comprised of a prepayment penalty paid to our previous lender in the amount of \$11.1 million, and the write-off of unamortized discount related to the retired indebtedness in the approximate amount of \$15.1 million (see “Liquidity and Capital Resources”).

In connection with the refinancing of our senior credit facility on March 23, 2022, we incurred a loss on the extinguishment of debt in the amount of \$6.7 million as a result of the redemption premium we paid to retire our previously existing credit facility in the amount of \$2.0 million, and the write-off of unamortized debt discount of \$4.7 million related to that facility (see Note 7 to the Consolidated Financial Statements).

Other Income (Expense), Net

Other income, net, for the year ended December 31, 2023 was \$1.3 million, as compared to other expense, net, of \$0.6 million for the year ended December 31, 2022. The increase is mainly due to an increase in interest income of approximately \$1.6 million in 2023 due to higher interest earned on our cash balances in 2023.

Net Loss

Our net loss was \$28.2 million for the year ended December 31, 2023, as compared to \$65.9 million for the year ended December 31, 2022. The \$37.7 million decrease in net loss was mainly due to the improvement in operating income/loss of \$61.0 million and the \$1.9 million increase in other income/expense, partially offset by a higher loss on extinguishment of debt of \$19.5 million and higher interest expense of \$5.7 million.

Year Ended December 31, 2022 Compared to December 31, 2021

The following table presents a summary of the changes in our results of operations for the year ended December 31, 2022 compared to the year ended December 31, 2021:

	Year Ended December 31,		
	2022	2021	Increase (Decrease)
<i>(in thousands)</i>			
Revenues	\$ 154,080	\$ 80,943	\$ 73,137
Cost of product revenue	118,815	79,770	39,045
Gross profit	35,265	1,173	34,092
Research and development expenses	3,614	3,646	(32)
Plasma center operating expenses	17,843	12,289	5,554
Amortization of intangibles	715	715	-
Selling, general and administrative expenses	52,458	42,897	9,561
Loss from operations	(39,365)	(58,374)	19,009
Interest expense	(19,279)	(13,057)	(6,222)
Loss on extinguishment of debt	(6,670)	-	(6,670)
Other expense, net	(590)	(217)	(373)
Net loss	<u>\$ (65,904)</u>	<u>\$ (71,648)</u>	<u>\$ 5,744</u>
Adjusted EBITDA *	<u>\$ (27,627)</u>	<u>\$ (49,608)</u>	<u>\$ 21,981</u>
Adjusted net loss *	<u>\$ (59,234)</u>	<u>\$ (71,648)</u>	<u>\$ 12,414</u>

* - See Non-GAAP Financial Measures appearing at the end of this discussion

Revenues

We recorded total revenues of \$154.1 million during the year ended December 31, 2022, as compared to \$80.9 million during the year ended December 31, 2021, an increase of \$73.1 million, or approximately 90%. The increase is mainly due to increased sales of our immunoglobulin products and intermediate fractions generated by our Boca Facility manufacturing operations in 2022 totaling \$69.2 million as we concluded our third full year of commercial sales of BIVIGAM and ASCENIV. We attribute this increase in revenue to the continued expansion of our customer base in 2022 and to increasing physician, payer and patient acceptance of both BIVIGAM and ASCENIV. We also experienced a \$4.0 million increase in plasma revenues generated by our Plasma Collection Centers business segment due to increased sales of plasma through spot market opportunities beyond our long-term supply agreement.

Cost of Product Revenue and Gross Profit

Cost of product revenue was \$118.8 million for the year ended December 31, 2022, as compared to \$79.8 million for the year ended December 31, 2021. This increase of \$39.0 million is primarily attributable to volume-related increases in product revenue costs related to the sale of our immunoglobulin products of \$30.4 million and increased product revenue costs related to our ADMA BioCenters business segment in the amount of \$4.3 million. In addition, we also experienced an increase in other manufacturing expenses of approximately \$4.4 million in fiscal 2022 as compared to fiscal 2021, which is indicative of certain inflationary pressures being experienced by our industry for labor, materials, freight, fuel surcharges and third-party services.

Our gross profit of \$35.3 million for the year ended December 31, 2022 represents an improvement over the same period of a year ago of \$34.1 million and is mainly due to the higher sales volume, the improved margins we are experiencing with BIVIGAM at the larger plasma pool production scale, and to the increased relative contribution of ASCENIV to our total revenues. As a result, we achieved a gross margin of 22.9% for the year ended December 31, 2022, as compared to a gross margin of 1.4% for the year ended December 31, 2021.

Subsequent to the FDA approvals for BIVIGAM and ASCENIV received in 2019 through December 31, 2022, substantially all of the normal source plasma ("NSP") used in our Boca Facility IG production was sourced under a supply agreement we had in place with Grifols Worldwide Operations Limited ("Grifols"). This agreement expired on December 31, 2022 and was not renewed. Although we have executed additional agreements with other third-party suppliers of NSP, we anticipate that the NSP used in IG production in 2023 and beyond will be sourced from our ADMA BioCenters plasma collection facilities. As a number of these facilities are still in their initial stages of operation, we expect that the cost of collecting NSP at many of these facilities will exceed the price per liter of NSP we were paying to Grifols and other third-party suppliers. As a result, we expect the production costs for our immune globulin products to increase in the near term, which could adversely impact our cost of product revenue and gross margins, without giving effect to other supply chain initiatives completed and anticipated manufacturing efficiencies expected in the future.

Research and Development Expenses

R&D expenses of \$3.6 million for the year ended December 31, 2022 was essentially unchanged from the year ended December 31, 2021, as the lower compensation costs (including stock-based compensation) in 2022 resulting from the 2021 resignation of our former Chief Medical and Chief Scientific Officer were offset by increased expenses associated with post-marketing commitment clinical studies for ASCENIV and BIVIGAM (see Note 10 to the Consolidated Financial Statements).

Plasma Center Operating Expenses

Plasma center operating expenses increased by \$5.6 million to \$17.8 million for the year ended December 31, 2022, as compared to \$12.3 million for the year ended December 31, 2021. Plasma center operating expenses consist of certain general and administrative plasma center costs, initial opening, marketing and start-up costs, rent expense, maintenance, utilities, compensation and benefits for center and administrative staff, advertising and promotion expenses and computer software fees related to donor collections. The majority of our plasma collection centers have been in a development or start-up stage in fiscal 2022 and 2021.

During fiscal 2022, we opened three new plasma collection facilities, and an additional facility opened in March of 2023. In addition, for those plasma collection centers that were in construction or development but not yet operational, we still needed to incur staffing, training, travel and other costs during the build-out period so that these facilities can be operational on the day they open. The increase in plasma center operating expenses in 2022 is mainly attributable to increases in donor fees, some of which are specialty programs and promotions by the newly opened centers, of \$10.7 million, employee compensation costs of \$5.8 million, softgoods and supplies of \$3.8 million, depreciation expense of \$1.1 million, rent expense of \$0.5 million, plasma testing expenses of \$2.8 million, travel expense of \$0.2 million, software maintenance expense of \$0.4 million, janitorial and utilities expense of \$0.5 million, professional services of \$0.4 million, postage and freight of \$0.3 million and advertising expenses of \$0.3 million. These amounts were partially offset by a substantial increase in plasma collections which resulted in a reduction in our plasma center operating expenses by approximately \$21.4 million.

Selling, General and Administrative Expenses

SG&A expenses were \$52.5 million for the year ended December 31, 2022, an increase of \$9.6 million from the year ended December 31, 2021. As we continued to support the increase in the size and scope of our Boca Facility manufacturing and commercial operations in 2022, we experienced increases in employee compensation and related expenses, including travel, relocation and recruiting, of \$4.6 million, \$1.8 million of which is stock-based compensation. We also experienced increases in insurance expense of \$1.4 million and utilities of \$0.5 million in 2022, as well as an increase in data services and market intelligence fees in the amount of \$1.5 million in support of the commercialization efforts for BIVIGAM and ASCENIV. In addition, we incurred professional fees in connection with the Morgan Stanley strategic alternatives process in the amount of \$1.4 million, with no comparable amount in 2021.

Amortization of Intangibles

Amortization expense for intangible assets acquired in an acquisition transaction was \$0.7 million for the years ended December 31, 2022 and 2021.

Loss from Operations

Our operating loss was \$39.4 million for the year ended December 31, 2022, as compared to \$58.4 million for the year ended December 31, 2021. The decrease in operating loss was mainly due to the improved gross profit for the year ended December 31, 2022 of \$34.1 million, partially offset by the increases in plasma center operating expenses and SG&A.

Interest Expense

Interest expense was \$19.3 million for the year ended December 31, 2022, as compared to \$13.1 million for the year ended December 31, 2021. The increase reflects the additional indebtedness and increase in amortization of debt discount resulting from the refinancing of our senior credit facility on March 23, 2022. The refinancing transaction resulted in additional indebtedness at closing in the approximate amount of \$51.8 million, and our debt principal increased by an additional \$3.0 million subsequent to closing as the Hayfin Credit Agreement (see "Liquidity and Capital Resources") allowed us to pay "in kind" a portion of our monthly interest obligation in the form of additional indebtedness to the lender. We expect to continue to pay a portion of our monthly interest obligation "in kind" during 2023. As a result, and given the expected continued rise in SOFR, we expect our principal debt balance and the associated interest expense to increase over the course of fiscal 2023 as compared to previous years.

Loss on Extinguishment of Debt

In connection with the refinancing of our senior credit facility on March 23, 2022, we incurred a loss on the extinguishment of debt in the amount of \$6.7 million as a result of the redemption premium we paid to retire our previously existing credit facility in the amount of \$2.0 million, and the write-off of unamortized debt discount of \$4.7 million related to that facility (see Note 7 to the Consolidated Financial Statements).

Net Loss

Our net loss was \$65.9 million for the year ended December 31, 2022, as compared to \$71.6 million for the year ended December 31, 2021. The decrease in net loss of \$5.7 million was mainly due to the decrease in operating loss, largely offset by the higher interest expense and loss on extinguishment of debt in 2022.

Non-GAAP Financial Measures

Earnings Before Interest, Taxes, Depreciation and Amortization (“EBITDA”), Adjusted EBITDA and Adjusted Net Income (Loss)

EBITDA, Adjusted EBITDA and Adjusted net income (loss) are important non-GAAP financial measures used by our management and Board of Directors to assess our operating performance. We use EBITDA, Adjusted EBITDA and Adjusted net income (loss) as key performance measures because we believe that they facilitate operating performance comparisons from period to period that exclude, in the case of Adjusted net income (loss), items that are expected to be non-recurring, and in the case of EBITDA and Adjusted EBITDA, potential differences driven by the impact of variations of non-cash items such as depreciation and amortization, as well as, in the case of Adjusted EBITDA, stock-based compensation or certain one-time and non-recurring items. In addition, we believe that EBITDA, Adjusted EBITDA and Adjusted net loss and similar measures are widely used by investors, securities analysts, ratings agencies and other parties in evaluating companies in our industry as a measure of financial performance and debt-service capabilities. See below for a reconciliation of our EBITDA, Adjusted EBITDA and Adjusted net income (loss) to net loss, the most directly comparable financial measure calculated and presented in accordance with U.S. GAAP.

Because EBITDA, Adjusted EBITDA and Adjusted net income (loss) are measures not deemed to be in accordance with U.S. GAAP and are susceptible to varying calculations, our EBITDA, Adjusted EBITDA and Adjusted net income (loss) may not be comparable to similarly titled measures of other companies, including companies in our industry, because other companies may calculate EBITDA, Adjusted EBITDA and Adjusted net income (loss) in a different manner than we calculate these measurements. Although the Company uses Adjusted EBITDA as one of several financial measures to assess its operating performance, its use is limited as it excludes certain significant operating expenses. EBITDA, Adjusted EBITDA and Adjusted net income (loss) are not intended to represent cash flows for the periods presented, nor have they been presented as an alternative to operating income/loss, net income/loss or as an indicator of operating performance and should not be considered in isolation or as a substitute for measures of performance prepared in accordance with U.S. GAAP. The following table presents the reconciliation of net loss to EBITDA and Adjusted EBITDA for the years ended December 31, 2023, 2022 and 2021:

	Years Ended December 31,		
	2023	2022	2021
<i>(in thousands)</i>			
Net loss	\$ (28,239)	\$ (65,904)	\$ (71,648)
Depreciation	7,608	6,398	4,780
Amortization	724	715	715
Interest expense	25,027	19,279	13,057
EBITDA	<u>5,120</u>	<u>(39,512)</u>	<u>(53,096)</u>
Stock-based compensation	6,187	5,215	3,488
IT systems disruption	2,770	-	-
Loss on extinguishment of debt	26,174	6,670	-
Adjusted EBITDA	<u>\$ 40,251</u>	<u>\$ (27,627)</u>	<u>\$ (49,608)</u>

Adjusted EBITDA increased by \$67.9 million for the year ended December 31, 2023 as compared to the same period of a year ago. The improvement is driven primarily by an increase in operating income in 2023 of \$61.0 million. Adjusted EBITDA improved by \$22.0 million for the year ended December 31, 2022 as compared to the year ended December 31, 2021, mainly due to the decreasing in operating loss in 2022 of \$19.0 million.

The following table presents the reconciliation of Net loss to Adjusted net income (loss) for the years ended December 31, 2023, 2022 and 2021:

	Years Ended December 31,		
	2023	2022	2021
<i>(in thousands)</i>			
Net loss	\$ (28,239)	\$ (65,904)	\$ (71,648)
Loss on extinguishment of debt	26,174	6,670	-
IT systems disruption	2,770	-	-
Adjusted net income (loss)	<u>\$ 705</u>	<u>\$ (59,234)</u>	<u>\$ (71,648)</u>

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2023, we had working capital of \$207.2 million, primarily consisting of \$172.9 million of inventory, cash and cash equivalents of \$51.4 million and \$27.4 million of accounts receivable, partially offset by current liabilities of \$49.8 million, as compared to working capital at December 31, 2022 of \$231.1 million, primarily consisting of \$163.3 million of inventory, cash and cash equivalents of \$86.5 million and accounts receivable of \$15.5 million, partially offset by current liabilities of \$39.3 million. We have incurred an accumulated deficit of \$506.3 million since inception and although we had positive cash flow from operations of \$8.8 million for the year ended December 31, 2023, we had negative cash flows from operations of \$59.5 million and \$112.4 million for the years ended December 31, 2022 and 2021, respectively. We have funded our operations over the past few years primarily from the sale of our equity securities and debt financings. Our material cash requirements are primarily comprised of:

- The collection and procurement of raw material source plasma, which includes plasma donor fees and plasma center supplies, and other raw materials necessary to maintain and scale up our manufacturing operations;
- Employee compensation and benefits;
- Capital expenditures for equipment upgrades and capacity expansion at the Boca Facility and to maintain our plasma collection facilities;
- Interest on our debt;
- Marketing programs, medical education and continued commercialization efforts;
- Boca Facility maintenance, repairs and supplies;
- Conducting required post-marketing clinical trials for our FDA-approved products; and
- Continuous improvements and updates to our IT infrastructure, laboratory equipment and assays, and facilities and engineering equipment.

In addition, our end-to-end production cycle time from procurement of raw materials to commercial release of finished product can take between seven and 12 months or potentially longer, requiring substantial inventories of raw material plasma and other manufacturing and laboratory testing materials and single use disposables.

For the year ended December 31, 2023 we had a net loss of loss of \$28.2 million and achieved adjusted net income of \$0.7 million which, as further described under “Non-GAAP Financial Measures”, excludes charges related to the refinancing of our senior debt of \$26.2 million and an IT systems disruption of \$2.7 million, as well as positive cash flow from operations, both for the first time in our history. However, at present we cannot be certain that we will be able to continue to generate a sufficient amount of product revenue to achieve profitability on an ongoing basis. We currently anticipate, based upon our projected revenue and expenditures, that our current cash, cash equivalents and accounts receivable, along with our projected future operating cash flow, will be sufficient to fund our operations, as currently conducted, through the end of the first quarter of fiscal 2025. However, our current outlook with respect to cash flows and profitability may change based upon several factors, including the success of our commercial efforts with respect to the sale of our products and the continued acceptability of our immune globulin products by physicians, patients or payers, and whether or not the assumptions underlying our projected revenues and expenses are correct. If we are unable to maintain positive cash flow throughout fiscal 2024, we may need to raise additional capital and if such capital is not available due to widespread liquidity constraints or significant market instability that could result from international or global conflicts, economic uncertainty, COVID-19 or other pandemics, inflationary pressures or other factors beyond our control, we may have to delay, curtail or eliminate some of our commercialization efforts or product development activities. If we are unable to generate sufficient revenue to maintain positive cash flow throughout fiscal 2024 and need to raise additional capital, we may decide to do so through public or private equity offerings or debt financings, or we may enter into a corporate collaboration or licensing arrangement. The sale of additional equity securities or debt financings, if convertible, could result in dilution to our stockholders and, in such event, the value and potential future market price of our common stock may decline.

ADMA continues to evaluate a variety of strategic alternatives, and the exploration of value-creating opportunities remains a top corporate priority.

On December 18, 2023 (the “Ares Closing Date”), we and all of our subsidiaries entered into a new senior secured credit facility (the “Ares Credit Agreement”) with Ares Capital Corporation and certain credit funds affiliated with Ares Capital Corporation (collectively, “Ares”). The Ares Credit Agreement provides for a total of \$135.0 million in senior secured credit facilities (the “Ares Credit Facility”) consisting of (i) a term loan in the aggregate principal amount of \$62.5 million and (ii) a revolving credit facility in the aggregate principal amount of \$72.5 million (collectively, the “Ares Loans”), both of which were fully drawn on the Ares Closing Date. The Ares Credit Facility has a maturity date of December 20, 2027 (the “Ares Maturity Date”). On the Ares Closing Date, we used the proceeds from the Ares Loans, along with a portion of our existing cash on hand, to terminate and pay in full all of the outstanding obligations under our previous senior credit facility (the “Hayfin Credit Facility”) with Hayfin Services LLP (“Hayfin”) including the outstanding principal in the amount of \$158.6 million, a prepayment penalty in the amount \$11.1 million, an exit fee of \$1.6 million, all accrued and unpaid interest outstanding on the Hayfin Credit Facility as of the Ares Closing date, as well as certain fees and expenses related thereto. In connection with the payoff and termination of the Hayfin Credit Facility, we also wrote off \$15.0 million of unamortized debt discount related to the Hayfin Credit Facility. As a result of this transaction, we recorded a loss on the extinguishment of the Hayfin Credit Facility in the amount of \$26.2 million, which is mainly comprised of the write-off of unamortized debt discount and the prepayment penalty.

Borrowings under the term loan initially bear interest at the adjusted Term SOFR for a three-month tenor in effect on the day that is two business days prior to the first day of the applicable calendar quarter plus 6.50% (the “Initial SOFR Term Loan Applicable Margin”). Borrowings under the revolving facility initially bear interest at the adjusted Term SOFR for a three-month tenor in effect on the day that is two business days prior to the first day of the applicable calendar quarter plus 3.75% (the “SOFR Revolving Facility Applicable Margin”). On the Ares Closing Date, the interest rate on the term loan was approximately 11.9% and the interest rate on the revolving facility was approximately 9.1%, representing a weighted-average interest rate of approximately 10.4%. Prior to the Ares Closing Date, the interest rate on the Hayfin Credit Facility was approximately 13.9%.

On the Ares Maturity Date, we are required to pay Ares the entire outstanding principal amount underlying the Ares Loans and any accrued and unpaid interest thereon. Prior to the Ares Maturity Date, there are no scheduled principal payments on the Ares Credit Facility, and we are required to make quarterly interest payments during the term of Ares Credit Facility of approximately \$3.7 million. We may prepay the outstanding principal under the revolving facility, together with any accrued but unpaid interest on the prepaid principal amount, at any time and from time to time upon three business days’ prior written notice with no prepayment premium. However, in the event that we prepay an amount under the revolving facility that is greater than 50% of the current \$72.5 million outstanding balance, we will still be required to pay interest on 50% of this balance, or \$36.3 million, through the term of Ares Credit Facility. We may prepay the outstanding principal on the term loan, together with any accrued but unpaid interest on the prepaid principal amount, at any time and from time to time upon three business days’ prior written notice, subject to the payment to Ares of a prepayment premium equal to (i) the present value as of such date of all remaining required interest payments on the principal amount being repaid plus 1.5% of the prepaid principal amount, if prepaid on or prior to the first anniversary of the Ares Closing Date, (ii) 1.5% of the prepaid principal amount, if prepaid after the first anniversary of the Ares Closing Date and on or prior to the second anniversary of the Ares Closing Date, or (iii) 1.0% of the prepaid principal amount, if prepaid on or prior to the third anniversary of the Ares Closing Date.

In connection with the closing of the Ares Credit Facility, we incurred fees and expenses related to the transaction of approximately \$2.7 million, including a \$1.7 million original issue discount payable to Ares, all of which was deducted from the Ares loan proceeds. In addition, we are also required to pay Ares an exit fee of \$1.7 million upon the earlier of any prepayment date or the Ares Maturity Date, and this amount has been accrued as a separate liability in our consolidated balance sheet as of December 31, 2023. As a result, we recognized an aggregate debt discount of \$4.4 million as of the Ares Closing Date, and the weighted-average effective interest rate on the Ares Loans as of December 31, 2023 was 11.39%.

All of our obligations under the Ares 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 Ares Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings. The negative covenants include certain financial covenants, including maximum total leverage ratios and a \$15.0 million liquidity covenant, and also restrict or limit our ability and the ability of our subsidiaries to, among other things and subject to certain exceptions contained in the Ares 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 Ares Credit Agreement); 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 Ares Credit Agreement. As of December 31, 2023, we were in compliance with all of the covenants contained in the Ares Credit Agreement.

Events of default on the Ares Loans 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. If there is an event of default, we will incur an increase in the rate of interest on the Ares Loans of 2% per annum.

On March 23, 2022 (the “Hayfin Closing Date”), we and all of our subsidiaries entered into the Hayfin Credit Agreement with Hayfin. The Hayfin Credit Agreement, as amended, provided for a senior secured term loan facility in a principal amount of up to \$175.0 million (the “Hayfin Credit Facility”), composed of (i) a term loan made on the Hayfin Closing Date in the principal amount of \$150.0 million (the “Hayfin Closing Date Loan”), and (ii) a delayed draw term loan in the principal amount of \$25.0 million (the “Hayfin Delayed Draw Loan” and, together with the Hayfin Closing Date Loan, the “Hayfin Loans”). The Hayfin Delayed Draw Loan was not drawn prior to the Hayfin Closing Date. The Hayfin Credit Facility had a maturity date of March 23, 2027 (the “Hayfin Maturity Date”), subject to acceleration pursuant to the Hayfin Credit Agreement, including upon an Event of Default (as defined in the Hayfin Credit Agreement).

On the Hayfin Closing Date, we used \$100.0 million of the Hayfin Closing Date Loan to terminate and pay in full all of the outstanding obligations under our previous senior credit facility with Perceptive (see Note 7 to the Consolidated Financial Statements). We also used \$2.0 million of the Hayfin Closing Date Loan proceeds to pay a redemption premium to Perceptive and used approximately \$1.0 million of the Hayfin Closing Date Loan proceeds to pay certain fees and expenses incurred in connection with this transaction. In addition, a \$1.8 million upfront fee payable to Hayfin was paid “in kind” and was added to the outstanding principal balance in accordance with the terms of the Hayfin Credit Agreement.

Borrowings under the Hayfin Credit Agreement bore interest at the adjusted Term SOFR for either a one-month or three-month tenor, as elected by us, and subject to a floor of 1.25%, plus an applicable margin of 9.5% (the “Applicable Margin”); provided, however, that upon, and during the continuance of, an Event of Default, the Applicable Margin would increase by an additional 3% per annum. On May 1, 2023 the Hayfin Credit Agreement was amended to reduce the Applicable Margin from 9.5% to 8.5%. On the last day of each calendar month prior to the Ares Closing Date we paid accrued interest to Hayfin. On the Hayfin Closing Date, December 31, 2022 and the Ares Closing Date, the stated interest rate on the Hayfin Loans was 10.75%, approximately 13.7% and approximately 13.9%, respectively. We were also permitted to pay “in kind” a portion of the interest on the Hayfin Loans for each monthly interest period in an amount equal to 2.5% per annum, which was added to the principal amount of the outstanding debt under the Hayfin Credit Facility. From the Hayfin Closing Date through December 31, 2022, \$3.0 million of interest was paid in kind and added to the balance of the outstanding Hayfin Loans. For the year ended December 31, 2023, \$3.8 million of interest was paid in kind and added to the balance of the outstanding Hayfin Loans.

On the Ares Closing Date, we paid Hayfin the entire outstanding principal amount underlying the Hayfin Loans and any accrued and unpaid interest thereon, as well as an exit fee of 1.0% of the outstanding principal amount being paid. In accordance with the terms of the Hayfin Credit Agreement, we also paid Hayfin the early prepayment fee in the amount equal 7.0% of the prepaid principal amount, or \$11.1 million.

All of our obligations under the Hayfin Credit Agreement were 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 Hayfin Credit Agreement contained certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings. The negative covenants restricted or limited our ability and the ability of our subsidiaries to, among other things and subject to certain exceptions contained in the Hayfin 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 Hayfin 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 Hayfin Credit Agreement. In addition, we were required (i) at all times prior to the Hayfin Maturity Date to maintain a minimum cash balance of \$6.0 million; and (ii) as of the last day of each fiscal quarter, report IVIG product and related revenues for the trailing 12-month period that exceed the amounts set forth in the Hayfin Credit Agreement, which ranged from \$75.0 million for the fiscal quarter ending June 30, 2022 to \$110.0 million for the fiscal quarter ending September 30, 2023. As of the Ares Closing Date and December 31, 2022, we were in compliance with all of the financial covenants contained in the Hayfin Credit Agreement.

On December 9, 2022, we completed an underwritten public offering whereby we issued 24,125,873 shares of our common stock. Net proceeds after underwriting discounts and expenses associated with the offering were approximately \$64.6 million and were used to accelerate commercialization and production activities, complete plasma center buildouts and obtain FDA approvals, to conclude post-FDA marketing approval research and development projects, and for working capital, capital expenditures and general corporate purposes.

On October 25, 2021, we completed an underwritten public offering whereby we issued 57.5 million shares of our common stock and received gross proceeds of \$57.5 million. Net proceeds, after underwriting discounts and expenses associated with the offering, were approximately \$53.8 million, and were used to advance the commercial sales of our FDA approved products through the procurement of raw materials for the manufacturing of BIVIGAM and ASCENIV, to expand our plasma collection facility network, to scale up the manufacturing capacity of the Boca Facility and make continuous improvements in order to adhere to cGMP compliance, to explore business development opportunities and for general corporate purposes and other capital expenditures.

On September 3, 2021, we entered into a distribution agreement with Raymond James & Associates, Inc., as agent (“Agent”), pursuant to which we may offer and sell, from time to time, at our option, through or to the Agent, up to an aggregate of \$50 million of shares of our common stock (the “Distribution Agreement”). We currently intend to use any net proceeds from the sale of our common stock under the Distribution Agreement for general corporate purposes, including procurement of source plasma and other raw materials, supply chain initiatives and production expenditures, working capital, capital expenditures, expansion and resources for commercialization activities, and other potential research and development and business opportunities. During the year ended December 31, 2021, we issued 5,540,831 shares of our common stock under the Distribution Agreement and received net proceeds of \$6.9 million. We did not issue any shares under this agreement during the years ended December 31, 2023 and 2022, and we currently have approximately \$42.8 million of shares available to sell under the Distribution Agreement.

Cash Flows

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

	Years Ended December 31,		
	2023	2022	2021
<i>(in thousands)</i>			
Net cash provided by (used in) operating activities	\$ 8,800	\$ (59,508)	\$ (112,369)
Net cash used in investing activities	(4,981)	(13,911)	(13,511)
Net cash (used in) provided by financing activities	(38,989)	108,852	121,048
Net change in cash and cash equivalents	(35,170)	35,433	(4,832)
Cash and cash equivalents - beginning of year	86,522	51,089	55,921
Cash and cash equivalents - end of year	\$ 51,352	\$ 86,522	\$ 51,089

Net Cash Provided by (Used in) Operating Activities

Cash provided by operations for the year ended December 31, 2023 was \$8.8 million, as compared to cash used in operations of \$59.5 million for the same period of a year ago. This improvement was mainly due to the improvement in our operating results, driven by higher revenues and gross margins, and a lower increase in inventories. Cash used in operations for the year ended December 31, 2022 of \$59.5 million represents a decrease of \$52.9 million from the same period of a year ago, mainly due to the improvement in our operating results after giving effect to non-cash items, driven by higher revenues and gross margins, and reductions in accounts receivable related to the timing of shipments and collections from customers. The following table illustrates the primary components of our cash flows from operations:

	Years Ended December 31,		
	2023	2022	2021
(in thousands)			
Net loss	\$ (28,239)	\$ (65,904)	\$ (71,648)
Non-cash expenses, gains and losses	47,162	24,682	10,959
Changes in accounts receivable	(11,917)	13,072	(15,340)
Changes in inventories	(9,625)	(38,556)	(43,188)
Changes in prepaid expenses and other current assets	(239)	(756)	(1,293)
Changes in accounts payable and accrued expenses	11,369	8,334	9,697
Other	289	(380)	(1,556)
Cash provided by (used) in operations	<u>\$ 8,800</u>	<u>\$ (59,508)</u>	<u>\$ (112,369)</u>

Net Cash Used in Investing Activities

Cash used in investing activities for the year ended December 31, 2023 was \$5.0 million, which was primarily comprised of capital expenditures of \$3.0 million for equipment purchases and facilities upgrades at the Boca Facility, and \$1.8 million to complete the buildout of our plasma collection facilities. Net cash used in investing activities for the year ended December 31, 2022 was \$13.9 million, which consisted of \$8.7 million for the construction and buildout of several new plasma collection facilities and \$5.2 million for equipment purchases and upgrades to the Boca Facility. Net cash used in investing activities for the year ended December 31, 2021 was \$13.5 million, which consisted of \$8.6 million for the construction and buildout of new plasma collection facilities and \$4.9 million of capital expenditures at the Boca Facility, which included equipment purchases and continued implementation of our in-house fill/finish capabilities. While we do not have any firm commitments for material capital expenditures in 2024, we expect our total capital expenditures will be between \$8.0 million and \$12.0 million for fiscal 2024.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities for the year ended December 31, 2023 was \$39.0 million, as we reduced our outstanding debt principal by \$23.6 million with the refinancing of our senior debt on December 18, 2023 and paid approximately \$12.7 million to exit the Hayfin Credit Facility. Net cash provided by financing activities for the year ended December 31, 2022 was \$108.9 million, as we received approximately \$47.0 million in net proceeds from the refinancing of our senior credit facility in March of 2022 and \$64.6 million in net proceeds from the December 9, 2022 public offering of our common stock. Cash provided by financing activities during the year ended December 31, 2021 was \$121.0 million, which is mainly comprised of the net proceeds of \$67.3 million from the sale of our common stock through several sale agreements and \$53.8 million from the October 2021 underwritten public offering.

Effect of Inflation

Inflation impacted a number of facets of our business during the years ended December 31, 2023, 2022 and 2021 at each of our business segments. We experienced price increases for, among other items, certain raw materials, consumable supplies, services for repairs and maintenance of our facilities, utilities, shipping and freight charges, fuel surcharges and labor costs, among other expenses. Based upon the macroeconomic environment, publicly available information and reports from the U.S. government, we expect this trend to continue in 2024 and potentially longer, which could potentially have a significant impact on our future results of operations. In addition, some of our third-party inventory purchase agreements provide for annual price increases that are tied to various consumer price indices, which have resulted in higher than historical percentage price increases and has resulted in and could continue to result in higher source plasma and other raw material and supplies costs in 2024 and beyond. Also, in a higher inflationary environment, we may not be able to raise the prices of our products to keep up with the rate of inflation. We are unable to predict when these external drivers of inflation will subside.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk as the result of changes in interest rates. Our senior credit facility with Ares requires quarterly payments of interest based on the adjusted Term SOFR plus the Applicable Margin. We currently do not utilize any derivative financial instruments, such as interest rate swaps or caps, to mitigate this risk. As of December 31, 2023, we had \$135.0 million outstanding under our senior credit facility that is subject to a variable interest rate. As a result, the effect of a hypothetical, instantaneous and unfavorable change of 100 basis points in the interest rate would have an approximate \$1.4 million annualized negative impact on our earnings and cash flows.

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, 2023. 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 set of 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, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Annual Report on Internal Control Over Financial Reporting

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

Report of Independent Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by CohnReznick LLP, an independent registered public accounting firm, as stated in their report which appears in Item 8 of this Annual Report on Form 10-K.

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, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

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 2024 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2023.

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 2024 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2023.

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 2024 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2023.

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, 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 2024 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2023.

The text of our Code of Ethics and Business Conduct, 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 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 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 2024 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2023.

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 2024 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2023.

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 2024 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2023.

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 2024 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2023.

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.

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(2) Financial Statement Schedules.
Required information is included in the footnotes to the financial statements.

(3) Index to Exhibits.

INDEX TO EXHIBITS

Exhibit No.	Description
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).
3.1.1	Certificate of Amendment of the Second Amended and Restated Certificate of Incorporation of ADMA Biologics, Inc., dated as of May 27, 2021 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 28, 2021).
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 21, 2021).
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	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).
4.3	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).
4.4	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).
4.5	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).
4.6	Warrant to Purchase Stock, dated December 8, 2020, issued by the Company to Perceptive Credit Holdings II, LP (incorporated by reference to Exhibit 4.7 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 24, 2021).
4.7	Description of Securities Registered under Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.11 to the Company's Annual Report on Form 10-K, filed with the SEC on March 24, 2022).
4.8	Form of Warrant to Purchase Common Stock, in the form issued by the Company to various entities affiliated with Hayfin Services LLP, dated as of March 23, 2022 (incorporated by reference to Exhibit 4.13 to the Company's Annual Report on Form 10-K, filed with the SEC on March 24, 2022).
4.9	Form of Warrant to Purchase Common Stock, in the form issued by the Company to various entities affiliated with Hayfin Services LLP, dated as of May 1, 2023 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 2, 2023).

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).
10.3.1†	Amendment to Employment Agreement, dated as of September 29, 2021, by and between ADMA Biologics, Inc. and Adam Grossman (incorporated by reference to Exhibit 10.2 to the Company’s Current Report on Form 8-K, filed with the SEC on October 1, 2021).
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).
10.4.1†	Amendment to Employment Agreement, dated as of September 29, 2021, by and between ADMA Biologics, Inc. and Brian Lenz (incorporated by reference to Exhibit 10.3 to the Company’s Current Report on Form 8-K, filed with the SEC on October 1, 2021).
10.5+	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).
10.5.1+	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).
10.5.2	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).
10.5.3	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).
10.5.4+	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).
10.6+	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).

10.6.1+	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).
10.7	Amended and Restated Agreement for Services, effective as of January 1, 2016, as amended, by and between ADMA BioManufacturing, 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).
10.8	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).
10.9+	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).
10.9.1	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).
10.10	Amendment 3 to the Amended and Restated Agreement for Services, effective as of November 7, 2019, by and between ADMA BioManufacturing, LLC and Areth LLC (incorporated herein by reference to the Exhibit 10.27 to the Company’s Annual Report on Form 10-K filed March 12, 2020).
10.11	Amendment 4 to the Amended and Restated Agreement For Services Between ADMA BioManufacturing, LLC and Areth LLC (incorporated by reference to Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q filed on November 9, 2022).
10.12	Distribution Agreement, dated September 3, 2021, by and between ADMA Biologics, Inc. and Raymond James & Associates, Inc. (incorporated by reference to Exhibit 1.1 to the Company’s Current Report on Form 8-K filed on September 3, 2021).
10.13	Form of Retention Bonus Agreement (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on October 1, 2021).
10.14†	ADMA Biologics, Inc. 2022 Equity Compensation Plan (incorporated herein by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K filed with the Commission on June 21, 2022)
10.15	Credit Agreement, dated as of December 18, 2023, by and among the Company, as Administrative Borrower, ADMA BioManufacturing, LLC, ADMA Plasma Biologics, Inc. and ADMA BioCenters Georgia Inc., each as Borrowers, certain subsidiaries of the Company, as Guarantors, from time to time party thereto, the Lenders from time to time party thereto, Ares Capital Corporation, as Administrative Agent and as Collateral Agent, and ACF FINCO I LP, as Revolving Agent (incorporated herein by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K filed with the Commission on December 18, 2023)
10.16	Security Agreement, dated as of December 18, 2023, by and among the Company, ADMA BioManufacturing, LLC, ADMA Plasma Biologics, Inc. and ADMA BioCenters Georgia, Inc., as Grantors, and Ares Capital Corporation, as Collateral Agent (incorporated herein by reference to Exhibit 10.2 to the Registrant’s Current Report on Form 8-K filed with the Commission on December 18, 2023)

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.
97*	ADMA Biologics, Inc. Compensation Recoupment Policy
101*	The following materials from ADMA Biologics, Inc. Form 10-K for the year ended December 31, 2023, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at December 31, 2023 and December 31, 2022, (ii) Consolidated Statements of Operations for the years ended December 31, 2023, 2022 and 2021, (iii) Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2023, 2022 and 2021, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2023, 2022 and 2021; 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.

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: February 28, 2024

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
<u>/s/ Adam S. Grossman</u> Adam S. Grossman	President and Chief Executive Officer (Principal Executive Officer) and Director	February 28, 2024
<u>/s/ Brian Lenz</u> Brian Lenz	Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 28, 2024
<u>/s/ Steven A. Elms</u> Steven A. Elms	Chairman of the Board of Directors	February 28, 2024
<u>/s/ Dr. Jerrold B. Grossman</u> Dr. Jerrold B. Grossman	Vice Chairman of the Board of Directors	February 28, 2024
<u>/s/ Alison Finger</u> Alison Finger	Director	February 28, 2024
<u>/s/ Bryant E. Fong</u> Bryant E. Fong	Director	February 28, 2024
<u>/s/ Lawrence P. Guiheen</u> Lawrence P. Guiheen	Director	February 28, 2024
<u>/s/ Young T. Kwon</u> Young T. Kwon	Director	February 28, 2024

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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Management's Annual Report on Internal Control Over Financial Reporting

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

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

Management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of its internal control over financial reporting as of December 31, 2023. 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, 2023 based on those criteria.

Our independent registered public accounting firm, which has audited the consolidated financial statements included in this Annual Report on Form 10-K, has also issued an audit report on the effectiveness of our internal control over financial reporting as of December 31, 2023. Their report appears on page F-3 of this Annual Report on Form 10-K.

/s/ Adam S. Grossman
Adam S. Grossman
President and Chief Executive Officer

February 28, 2024

/s/ Brian Lenz
Brian Lenz
Executive Vice President and Chief Financial Officer

February 28, 2024

Board of Directors and Stockholders
ADMA Biologics, Inc.

Opinion on the Consolidated Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying consolidated balance sheets of ADMA Biologics, Inc. and subsidiaries (the “Company”) as of December 31, 2023 and 2022, and the related consolidated statements of operations, changes in stockholders’ equity, and cash flows for each of the years in the three-year period ended December 31, 2023 and the related notes and financial statement schedule II – valuation and qualifying accounts (collectively referred to as the “consolidated financial statements”). We also have audited the Company’s internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Basis for Opinion

The Company’s management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Annual Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on the entity’s consolidated financial statements and on the entity’s internal control over financial reporting 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 audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control Over Financial Reporting

An entity’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. An entity’s internal control over financial reporting 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 entity; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the entity are being made only in accordance with authorizations of management and directors of the entity; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the entity’s assets that could have a material effect on the consolidated financial statements.

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of Inventory

Description of the matter

As of December 31, 2023, the Company's inventory totaled \$172.9 million. 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 significance of the inventory value, the importance of inventory to the Company's operations, the various components and the multiple locations and the complexity of the computations, auditing the inventory was challenging and involved a relatively high degree of auditor judgment and subjectivity, extensive testing, and 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 controls related to the Company's process to estimate labor and overhead in the inventory as well as controls over estimating the lower of cost or net realizable value. We performed substantive 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 tested the completeness and accuracy of the data used in management's valuation and 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 sales transactions and net sales proceeds.

Variable Consideration Estimates - Rebates

Description of the matter

As disclosed in Note 2 to the consolidated financial statements, revenue from the sale of the Company's products is recorded net of estimated rebates, price protection arrangements and customer incentives, including prompt pay discounts, wholesaler chargebacks and other wholesaler fees. Estimated rebates are also attributable to government programs that mandate various reductions from list price, which are reflected as liabilities and settled through cash payments.

Auditing the variable consideration estimates, more specifically rebates related to U.S. Medicaid, Medicare Part D, and managed care is complex because of the subjectivity of certain assumptions and judgements required to develop estimates. These significant assumptions and judgments include consideration of legal interpretations of applicable laws and regulations, historical claims experience, payer channel mix, current contract prices, unbilled claims and claims submission time lags. Additionally, auditing this matter is challenging given the Company's limited history in selling certain of its products.

How we addressed the matter in our audit

We obtained an understanding of, and tested controls related to the Company's process to estimate variable consideration as it relates to rebates, specifically U.S. Medicaid, Medicare Part D and managed care. We performed a combination of substantive procedures including recalculations of the percentages of rebates processed against related rebate eligible revenue for certain products, confirmations of underlying data used in the calculations and an evaluation of actual rebates processed against historical estimates. Our testing focused on the appropriateness of significant assumptions and mathematical accuracy used in the calculation and the completeness and accuracy of the data used in the estimates. To address the completeness of the reserves, we also assessed the historical accuracy of management's estimates by comparing actual activity to previous estimates (lookback). Finally, we considered subsequent events and any new information after the financial statement date that would require an adjustment to the accruals.

/s/ CohnReznick LLP

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

Parsippany, New Jersey

February 28, 2024

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
Years Ended December 31, 2023 and 2022

	December 31, 2023	December 31, 2022
	<i>(In thousands, except share data)</i>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 51,352	\$ 86,522
Accounts receivable, net	27,421	15,505
Inventories	172,906	163,280
Prepaid expenses and other current assets	5,334	5,095
Total current assets	257,013	270,402
Property and equipment, net	53,835	58,261
Intangible assets, net	499	1,013
Goodwill	3,530	3,530
Right-to-use assets	9,635	10,485
Deposits and other assets	4,670	4,770
TOTAL ASSETS	\$ 329,182	\$ 348,461
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 15,660	\$ 13,229
Accrued expenses and other current liabilities	32,919	24,990
Current portion of deferred revenue	182	143
Current portion of lease obligations	1,045	905
Total current liabilities	49,806	39,267
Senior notes payable, net of discount	130,594	142,833
Deferred revenue, net of current portion	1,690	1,833
End of term fee	1,688	1,500
Lease obligations, net of current portion	9,779	10,704
Other non-current liabilities	419	350
TOTAL LIABILITIES	193,976	196,487
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, 300,000,000 shares authorized, 226,063,032 and 221,816,930 shares issued and outstanding	23	22
Additional paid-in capital	641,439	629,969
Accumulated deficit	(506,256)	(478,017)
TOTAL STOCKHOLDERS' EQUITY	135,206	151,974
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 329,182	\$ 348,461

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,		
	2023	2022	2021
	<i>(In thousands, except share and per share data)</i>		
REVENUES	\$ 258,215	\$ 154,080	\$ 80,943
Cost of product revenue	169,273	118,815	79,770
Gross profit	88,942	35,265	1,173
OPERATING EXPENSES:			
Research and development	3,300	3,614	3,646
Plasma center operating expenses	4,266	17,843	12,289
Amortization of intangible assets	724	715	715
Selling, general and administrative	59,020	52,458	42,897
Total operating expenses	67,310	74,630	59,547
INCOME (LOSS) FROM OPERATIONS	21,632	(39,365)	(58,374)
OTHER INCOME (EXPENSE):			
Interest income	1,617	45	35
Interest expense	(25,027)	(19,279)	(13,057)
Loss on extinguishment of debt	(26,174)	(6,670)	-
Other expense	(287)	(635)	(252)
Other expense, net	(49,871)	(26,539)	(13,274)
NET LOSS	\$ (28,239)	\$ (65,904)	\$ (71,648)
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ (0.13)	\$ (0.33)	\$ (0.51)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:			
Basic and Diluted	223,977,315	197,874,895	139,578,538

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2020	104,902,888	\$ 10	\$ 428,704	\$ (340,465)	\$ 88,249
Stock-based compensation	-	-	3,488	-	3,488
Issuance of common stock, net of offering expenses	90,846,029	9	121,135	-	121,144
Vesting of Restricted Stock Units, net of shares withheld for taxes and retired	64,900	1	(61)	-	(60)
Net loss	-	-	-	(71,648)	(71,648)
Balance at December 31, 2021	195,813,817	20	553,266	(412,113)	141,173
Stock-based compensation	-	-	5,215	-	5,215
Issuance of common stock, net of offering expenses	24,125,873	2	64,642	-	64,644
Vesting of Restricted Stock Units, net of shares withheld for taxes	1,808,561	-	(2,899)	-	(2,899)
Warrants issued in connection with note payable	-	-	9,570	-	9,570
Exercise of stock options	68,679	-	175	-	175
Net loss	-	-	-	(65,904)	(65,904)
Balance at December 31, 2022	221,816,930	22	629,969	(478,017)	151,974
Stock-based compensation	-	-	6,187	-	6,187
Vesting of Restricted Stock Units, net of shares withheld for taxes	833,722	-	(1,415)	-	(1,415)
Warrants issued in connection with notes payable	-	-	5,595	-	5,595
Exercise of stock options	1,444,533	1	1,103	-	1,104
Cashless exercise of warrants	1,967,847	-	-	-	-
Net loss	-	-	-	(28,239)	(28,239)
Balance at December 31, 2023	<u>226,063,032</u>	<u>\$ 23</u>	<u>\$ 641,439</u>	<u>\$ (506,256)</u>	<u>\$ 135,206</u>

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2023	2022	2021
	<i>(In thousands)</i>		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (28,239)	\$ (65,904)	\$ (71,648)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	8,332	7,113	5,496
Loss on disposal of fixed assets	182	427	221
Interest paid in kind	3,836	2,998	-
Stock-based compensation	6,187	5,215	3,488
Amortization of debt discount	2,594	2,402	1,897
Loss on extinguishment of debt	26,174	6,670	-
Amortization of license revenue	(143)	(143)	(143)
Changes in operating assets and liabilities:			
Accounts receivable	(11,916)	13,072	(15,340)
Inventories	(9,626)	(38,556)	(43,188)
Prepaid expenses and other current assets	(239)	(756)	(1,293)
Deposits and other assets	1,080	122	(1,775)
Accounts payable	3,839	800	1,356
Accrued expenses	7,530	7,534	8,341
Other current and non-current liabilities	(791)	(502)	219
Net cash provided by (used in) operating activities	<u>8,800</u>	<u>(59,508)</u>	<u>(112,369)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(4,771)	(13,911)	(13,511)
Acquisition of intangible assets	(210)	-	-
Net cash used in investing activities	<u>(4,981)</u>	<u>(13,911)</u>	<u>(13,511)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:			
Principal payments on notes payable	(158,584)	(100,000)	-
Proceeds from issuance of common stock, net of offering expenses	-	64,645	121,144
Payment of debt refinancing fees	(11,140)	(2,000)	-
Proceeds from issuance of note payable	135,000	151,750	-
Taxes paid on vested Restricted Stock Units	(1,415)	(2,899)	(62)
Payments on finance lease obligations	(17)	(36)	(34)
Net proceeds from the exercise of stock options	1,104	175	-
Payment of end of term fee	(1,586)	-	-
Payment of deferred financing fees	(2,351)	(2,783)	-
Net cash (used in) provided by financing activities	<u>(38,989)</u>	<u>108,852</u>	<u>121,048</u>
Net (decrease) increase in cash and cash equivalents	(35,170)	35,433	(4,832)
Cash and cash equivalents - beginning of year	86,522	51,089	55,921
Cash and cash equivalents - end of year	<u>\$ 51,352</u>	<u>\$ 86,522</u>	<u>\$ 51,089</u>

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO 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 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 certain assets held by the Company’s former third-party contract manufacturer, which included the U.S. Food and Drug Administration (“FDA”)-licensed BIVIGAM and Nabi-HB immunoglobulin products, and an FDA-licensed plasma fractionation manufacturing facility located in Boca Raton, FL (the “Boca Facility”). ADMA BioCenters is the Company’s source plasma collection business with ten plasma collection facilities located throughout the U.S., all of which hold an approved license with the FDA.

The Company has three FDA-approved products, all of which are currently marketed and commercially available: (i) ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), an intravenous immune globulin (“IVIG”) product indicated for the treatment of Primary Humoral Immunodeficiency (“PI”), also known as Primary Immunodeficiency Disease (“PIDD”) or Inborn Errors of Immunity, for which the Company received FDA approval on April 1, 2019 and commenced first commercial sales in October 2019; (ii) BIVIGAM (Immune Globulin Intravenous, Human), an IVIG product indicated for the treatment of PI, and for which the Company received FDA approval on May 9, 2019 and commenced commercial sales in August 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 generates revenues from the sale of intermediate by-products that result from the immunoglobulin production process and from time to time provides contract manufacturing and laboratory services for certain clients. 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, 2023, the Company had working capital of \$207.2 million, including \$51.4 million of cash and cash equivalents, accounts receivable of \$27.4 million and \$172.9 million of inventories, partially offset by \$49.8 million of current liabilities. Based upon the Company’s current projected revenue and expenditures, including capital expenditures and continued implementation of the Company’s commercialization and expansion activities, the Company’s management currently believes that its cash, cash equivalents and accounts receivable, along with its projected future operating cash flow, will be sufficient to fund ADMA’s operations, as currently conducted, through the end of the first quarter of 2025. However, the Company’s current outlook on cash flows and profitability may change based upon several factors, including the success of the Company’s commercial sales of its products, whether or not the assumptions underlying the Company’s projected revenues and expenses are correct and the continued acceptability of ADMA’s immune globulin products by physicians, patients or payers. 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, inflationary pressures, supply chain constraints, 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 3 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, 2023, 2022 and 2021, comprehensive loss was equal to the net loss amounts presented for the respective periods in the accompanying consolidated statements of operations.

Use of estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include rebates and chargebacks deducted from gross revenues, 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.

Accounts receivable

Accounts receivable is reported at realizable value, net of allowances for contractual credits and doubtful accounts in the amount of \$0.1 million at December 31, 2023 and 2022, 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 16).

Inventories

Raw materials inventory consists of normal source plasma ("NSP") and Respiratory Syncytial Virus ("RSV") high titer plasma collected at the Company's plasma collection facilities, along with various materials purchased from suppliers, 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. For both the Company's immune globulin products and plasma intended for resale and internal use, 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. In addition, costs associated with the production of 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 4) 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, 2023 and 2022 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, 2023, 2022 and 2021.

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, not to exceed the total amount of goodwill allocated to that reporting unit. The Company performs its annual goodwill impairment test as of October 1 of each year. The Company's annual goodwill impairment tests as of October 1, 2023, 2022 and 2021 did not result in any impairment charges related to goodwill for the years ended December 31, 2023, 2022 and 2021.

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, 2023, 2022 and 2021, the Company determined that there was no impairment of its long-lived assets.

Revenue recognition

Revenues for the years ended December 31, 2023, 2022 and 2021 are comprised of (i) revenues from the sale of the Company's immunoglobulin products, ASCENIV, BIVIGAM and Nabi-HB, (ii) product revenues from the sale of human plasma collected 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, AG ("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 amortized into income over the term of the Biotest license, representing a period of approximately 22 years.

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, wholesaler distribution and related fees, customer incentives, including prompt pay discounts, wholesaler chargebacks, group purchasing organization fees and reimbursements for patient assistance. These estimates are based on contractual arrangements, historical experience and certain other assumptions, and while the Company believes that such estimates are reasonable, they are subject to change based on future developments and other factors. 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 and intermediates and for the collection 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 and salaries, benefits and stock-based compensation for employees directly related to research and development activities. All research and development costs are expensed as incurred.

Plasma center operating expenses

Plasma center operating expenses consist of certain general and administrative plasma center costs, initial opening, marketing and start-up costs, rent expense, maintenance, utilities and compensation and benefits for administrative staff.

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 expenses incurred for attracting donors to the Company's plasma collection centers. All advertising and marketing expenses are expensed as incurred. Advertising and marketing expenses were \$3.3 million, \$2.2 million and \$1.4 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Stock-based compensation

The Company follows recognized accounting guidance which requires all equity-based payments, including grants of stock options and restricted stock unit awards ("RSUs"), 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 to employees under the Company's equity incentive plans generally have a four-year vesting period and a term of 10 years. RSUs granted to employees also have a four-year vesting period. For milestone-based equity awards (see Note 8) the Company periodically assesses the probability of vesting for each milestone-based award and adjusts compensation expense based on its probability assessment. 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 equity awards is fully reversed at the time of forfeiture.

Income taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or its tax returns. Under this method, deferred tax assets and liabilities are recognized for the temporary differences between the tax bases of assets and liabilities and their respective financial reporting amounts at enacted tax rates in effect for the years in which the temporary differences are expected to reverse. The Company records a valuation allowance on its deferred tax assets if it is more likely than not that the Company will not generate sufficient taxable income to utilize its deferred tax assets (see Note 11). The Company is subject to income tax examinations by major taxing authorities for all tax years since 2019 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, 2023, 2022 and 2021, 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,		
	2023	2022	2021
Stock Options	5,906,184	8,256,211	7,862,722
Restricted Stock Units	4,657,297	2,866,987	4,485,133
Warrants	12,502,906	13,525,148	4,528,160
	<u>23,066,387</u>	<u>24,648,346</u>	<u>16,876,015</u>

Fair value of financial instruments

The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable and accounts payable are shown at cost, which approximates fair value due to the short-term nature of these instruments. The debt outstanding under the Company's senior notes payable (see Note 7) approximates fair value due to the variable interest rate on this debt.

Recent Accounting Pronouncements

In November of 2023 the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. The amendments in this Update are intended to provide financial statement users with more disaggregated expense information about a public entity's reportable segments, however the Update does not change the definition of a business segment or the method for determining reportable segments. This update becomes effective for fiscal years beginning after December 15, 2023. The Company does not expect this update to have a material impact on its consolidated financial statements.

In December of 2023 the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This Update requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid and becomes effective for public business entities for fiscal years beginning after December 15, 2024. The Company has yet to determine the impact this Update may have on the Company's consolidated financial statements.

There were no new accounting pronouncements adopted during the years ended December 31, 2023, 2022 and 2021 that had a significant impact on the Company's consolidated financial statements.

3. INVENTORIES

The following table provides the components of inventories:

	<u>December 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
	<i>(In thousands)</i>	
Raw materials	\$ 52,999	\$ 48,644
Work-in-process	49,621	56,171
Finished goods	70,286	58,465
Total inventories	<u>\$ 172,906</u>	<u>\$ 163,280</u>

Raw materials includes plasma and other materials expected to be used in the production of ASCENIV, BIVIGAM and Nabi-HB. These materials will be consumed in the production of products expected to be available for sale or otherwise have alternative uses that provide a probable future benefit. All other activities and materials associated with the production of inventories used in research and development activities are expensed as incurred.

Work-in-process inventory primarily consists of the Company's IVIG products that are manufactured to the bulk drug substance and unlabeled filled vials stage of production.

Finished goods inventory is comprised of the Company's immunoglobulin products that have reached the filled, labeled and serialized vial stage of production and related intermediates that are available for commercial sale, as well as plasma collected at the Company's plasma collection centers which is expected to be sold to third-party customers.

4. PROPERTY AND EQUIPMENT

Property and equipment at December 31, 2023 and 2022 is summarized as follows:

	<u>December 31, 2023</u>	<u>December 31, 2022</u>
	<i>(In thousands)</i>	
Manufacturing and laboratory equipment	\$ 21,093	\$ 18,768
Office equipment and computer software	6,062	5,319
Furniture and fixtures	5,776	5,110
Construction in process	2,273	6,727
Leasehold improvements	20,811	17,931
Land	4,339	4,339
Buildings and building improvements	<u>20,218</u>	<u>19,544</u>
	80,572	77,738
Less: Accumulated depreciation	<u>(26,737)</u>	<u>(19,477)</u>
Total property, plant and equipment, net	<u>\$ 53,835</u>	<u>\$ 58,261</u>

The Company recorded depreciation expense on property and equipment of \$7.6 million, \$6.4 million and \$4.8 million for the years ended December 31, 2023, 2022 and 2021, respectively.

5. INTANGIBLE ASSETS

Intangible assets at December 31, 2023 and 2022 consist of the following:

	<u>December 31, 2023</u>			<u>December 31, 2022</u>		
	<i>(In thousands)</i>					
	<u>Cost</u>	<u>Accumulated Amortization</u>	<u>Net</u>	<u>Cost</u>	<u>Accumulated Amortization</u>	<u>Net</u>
Trademark and other intangible rights related to Nabi-HB	\$ 4,100	\$ 3,856	\$ 244	\$ 4,100	\$ 3,270	\$ 830
Internally developed software	210	9	201	-	-	-
Rights to intermediates	907	853	54	907	724	183
	<u>\$ 5,217</u>	<u>\$ 4,718</u>	<u>\$ 499</u>	<u>\$ 5,007</u>	<u>\$ 3,994</u>	<u>\$ 1,013</u>

Under the previous contract manufacturing agreement between ADMA and Biotest, intermediate by-products derived from the manufacture of ASCENIV were property of Biotest. As a result of the acquisition of certain assets from Biotest on June 6, 2017, 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. During the year ended December 31, 2023, the Company implemented an internally developed data intelligence and analytics program at a cost of approximately \$0.2 million which is being amortized over a period of four years.

Amortization expense related to the Company's intangible assets for the years ended December 31, 2023, 2022 and 2021 was \$0.7 million. Estimated aggregate future aggregate amortization expense is expected to be as follows (in thousands):

2024	\$	351
2025		52
2026		52
2027		44

6. ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other current liabilities at December 31, 2023 and 2022 are as follows:

	<u>December 31, 2023</u>	<u>December 31, 2022</u>
	<i>(In thousands)</i>	
Accrued rebates	\$ 16,608	\$ 11,437
Accrued distribution fees	5,954	3,167
Accrued incentives	4,961	4,194
Accrued testing	282	310
Accrued payroll and other compensation	2,203	4,086
Other	2,911	1,796
Total accrued expenses and other current liabilities	<u>\$ 32,919</u>	<u>\$ 24,990</u>

7. NOTES PAYABLE

Senior Notes Payable

A summary of outstanding senior notes payable is as follows:

	<u>December 31, 2023</u>	<u>December 31, 2022</u>
	<i>(In thousands)</i>	
Term loan	\$ 62,500	\$ 154,748
Revolving credit facility	72,500	-
Less:		
Debt discount	(4,406)	(11,915)
Senior notes payable	<u>\$ 130,594</u>	<u>\$ 142,833</u>

On December 18, 2023 (the "Ares Closing Date"), the Company and all of its subsidiaries entered into a new senior secured credit facility (the "Ares Credit Agreement") with Ares Capital Corporation and certain credit funds affiliated with Ares Capital Corporation (collectively, "Ares"). The Ares Credit Agreement provides for a total of \$135.0 million in senior secured credit facilities (the "Ares Credit Facility") consisting of (i) a term loan in the aggregate principal amount of \$62.5 million and (ii) a revolving credit facility in the aggregate principal amount of \$72.5 million (collectively, the "Ares Loans"), both of which were fully drawn on the Ares Closing Date. The Ares Credit Facility has a maturity date of December 20, 2027 (the "Ares Maturity Date"). On the Ares Closing Date, the Company used the proceeds from the Ares Loans, along with a portion of its existing cash on hand, to terminate and pay in full all of the outstanding obligations under the Company's previous senior credit facility (the "Hayfin Credit Facility") with Hayfin Services LLP ("Hayfin") including the outstanding principal in the amount of \$158.6 million, a prepayment penalty in the amount \$11.1 million, an exit fee of \$1.6 million, all accrued and unpaid interest outstanding on the Hayfin Credit Facility as of the Ares Closing date, as well as certain fees and expenses related thereto. In connection with the payoff and termination of the Hayfin Credit Facility, the Company also wrote off \$15.0 million of unamortized debt discount related to the Hayfin Credit Facility. As a result of this transaction, the Company recorded a loss on the extinguishment of the Hayfin Credit Facility in the amount of \$26.2 million, which is mainly comprised of the write-off of unamortized debt discount and the prepayment penalty.

Borrowings under the term loan initially bear interest at the adjusted Term SOFR for a three-month tenor in effect on the day that is two business days prior to the first day of the applicable calendar quarter plus 6.50% (the "Initial SOFR Term Loan Applicable Margin"). Borrowings under the revolving facility initially bear interest at the adjusted Term SOFR for a three-month tenor in effect on the day that is two business days prior to the first day of the applicable calendar quarter plus 3.75% (the "SOFR Revolving Facility Applicable Margin"). On the Ares Closing Date, the interest rate on the term loan was 11.8774% and the interest rate on the revolving facility was 9.12774%.

On the Ares Maturity Date, the Company is required to pay Ares the entire outstanding principal amount underlying the Ares Loans and any accrued and unpaid interest thereon. Prior to the Ares Maturity Date, there are no scheduled principal payments on the Ares Credit Facilities, and the Company is required to make quarterly interest payments to Ares of approximately \$3.7 million. The Company may prepay the outstanding principal under the revolving facility, together with any accrued but unpaid interest on the prepaid principal amount, at any time and from time to time upon three business days' prior written notice with no prepayment premium. However, in the event the Company prepays an amount under the Revolving Facility that is greater than 50% of the current \$72.5 million outstanding balance, the Company will still be required to pay interest on 50% of this balance, or \$36.3 million, through the term of Ares Credit Facility. The Company may prepay the outstanding principal on the term loan, together with any accrued but unpaid interest on the prepaid principal amount, at any time and from time to time upon three business days' prior written notice, subject to the payment to Ares of a prepayment premium equal to (i) the present value as of such date of all remaining required interest payments on the principal amount being repaid plus 1.5% of the prepaid principal amount, if prepaid on or prior to the first anniversary of the Ares Closing Date, (ii) 1.5% of the prepaid principal amount, if prepaid after the first anniversary of the Ares Closing Date and on or prior to the second anniversary of the Ares Closing Date, or (iii) 1.0% of the prepaid principal amount, if prepaid on or prior to the third anniversary of the Ares Closing Date.

In connection with the closing of the Ares Credit Facility, the Company incurred fees and expenses related to the transaction of \$2.8 million, including a \$1.7 million original discount payable to Ares, all of which was deducted from the Ares loan proceeds. In addition, the Company is also required to pay Ares an exit fee of \$1.7 million upon the earlier of any prepayment date or the Ares Maturity Date, and this amount has been accrued as a separate liability in the Company's consolidated balance sheet as of December 31, 2023. As a result, the Company recognized an aggregate debt discount of \$4.4 million as of the Ares Closing Date, and the weighted-average effective interest rate on the Ares Loans as of December 31, 2023 was 11.39%. This debt discount was recorded as a reduction to the face amount of the debt and is being amortized as interest expense over the term of the debt using the interest method.

All of the Company's obligations under the Ares 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 Ares Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar debt financings. The negative covenants include certain financial covenants, including maximum total leverage ratios and a \$15,000,000 minimum liquidity covenant, and also restrict or limit the Company's ability and the ability of the Company's subsidiaries to, among other things and subject to certain exceptions contained in the Ares 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 the Company's subsidiaries' business activities; make certain Investments or Restricted Payments (each as defined in the Ares Credit Agreement); 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 Ares Credit Agreement. As of December 31, 2023 the Company was in compliance with all of the covenants contained in the Ares Credit Agreement.

Events of Default on the Ares Loans 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. If there is an event of default, the Company will incur an increase in the rate of interest on the Ares Loans of 2% per annum.

On March 23, 2022 (the "Hayfin Closing Date"), the Company and all of its subsidiaries entered into the Hayfin Credit Agreement with Hayfin. The Hayfin Credit Agreement provided for a senior secured term loan facility in a principal amount of up to \$175.0 million (the "Hayfin Credit Facility"), composed of (i) a term loan made on the Hayfin Closing Date in the principal amount of \$ 150.0 million (the "Hayfin Closing Date Loan"), and (ii) a delayed draw term loan in the principal amount of \$25.0 million (the "Hayfin Delayed Draw Loan" and, together with the Hayfin Closing Date Loan, the "Hayfin Loans"). The Hayfin Delayed Draw Loan was not drawn prior to the Ares Closing Date. The Hayfin Credit Facility had a maturity date of March 23, 2027 (the "Hayfin Maturity Date"), subject to acceleration pursuant to the Hayfin Credit Agreement, including upon an Event of Default (as defined in the Hayfin Credit Agreement).

On the Hayfin Closing Date, the Company used \$100.0 million of the Hayfin Closing Date Loan to terminate and pay in full all of the outstanding obligations under the Company's previously existing credit facility (the "Perceptive Credit Facility") with Perceptive Credit Holdings II, LP ("Perceptive"). The Company also used \$2.0 million of the Hayfin Closing Date Loan proceeds to pay a redemption premium to Perceptive and used approximately \$1.0 million of the Hayfin Closing Date Loan proceeds to pay certain fees and expenses incurred in connection with this transaction. In addition, a \$1.8 million upfront fee payable to Hayfin was paid "in kind" and was added to the outstanding principal balance in accordance with the terms of the Hayfin Credit Agreement. In connection with the retirement of the Perceptive Credit Facility and all of the obligations thereunder, the Company recorded a loss on extinguishment of debt in the amount of \$6.7 million, consisting of the write-off of unamortized discount related to the Perceptive indebtedness and the redemption premium paid to Perceptive.

Borrowings under the Hayfin Credit Agreement bore interest, at the Company's election, at the adjusted Term SOFR for a one-month tenor, subject to a floor of 1.25%, plus an applicable margin of 9.5% (the "Applicable Margin"); provided, however, that upon, and during the continuance of, an Event of Default, the Applicable Margin would increase by an additional 3% per annum. On May 1, 2023 the Hayfin Credit Agreement was amended to reduce the Applicable Margin from 9.5% to 8.5%. On the last day of each calendar month prior to the Ares Closing Date, the Company paid accrued interest to Hayfin. The rate of interest in effect as of the Hayfin Closing Date, December 31, 2022 and the Ares Closing Date was 10.75%, approximately 13.7% and approximately 13.9%, respectively. The Company was also permitted to pay "in kind" a portion of the interest on the Hayfin Loans for each monthly interest period in an amount equal to 2.5% per annum, which was added to the principal amount of the outstanding debt under the Hayfin Credit Facility. From the Hayfin Closing Date through December 31, 2022, \$3.0 million of interest was paid in kind and added to the balance of the outstanding Hayfin Loans. For the year ended December 31, 2023, \$3.8 million of interest was paid in kind and added to the balance of the outstanding Hayfin Loans.

On the Ares Closing Date, the Company paid Hayfin the entire outstanding principal amount underlying the Hayfin Loans and all accrued and unpaid interest thereon, as well as the exit fee of 1.0% of the outstanding principal amount paid. This exit fee had been recorded separately as a non-current liability on the accompanying consolidated balance sheet as of December 31, 2022. In accordance with the terms of the Hayfin Credit Agreement, the Company also paid Hayfin the early prepayment fee in the amount equal 7.0% of the prepaid principal amount of \$158.6 million, or \$11.1 million.

All of the Company's obligations under the Hayfin Credit Agreement were 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 Hayfin Credit Agreement contained certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar debt financings. The negative covenants restricted or limited the ability of the Company and its subsidiaries to, among other things and subject to certain exceptions contained in the Hayfin 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 Hayfin Credit Agreement); change its fiscal year; pay dividends; repay certain other 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 Hayfin Credit Agreement. In addition, the Company was required (i) at all times prior to the Hayfin Maturity Date to maintain a minimum cash balance of \$6.0 million; and (ii) as of the last day of each fiscal quarter, report IVIG product and related revenues for the trailing 12-month period that exceed the amounts set forth in the Hayfin Credit Agreement, which ranged from \$75.0 million for the fiscal quarter ended June 30, 2022 to \$110.0 million for the fiscal quarter ended September 30, 2023. As of the Ares Closing Date and December 31, 2022, the Company was in compliance with all of the covenants contained in the Hayfin Credit Agreement.

As consideration for the Hayfin Credit Agreement, on the Hayfin Closing Date the Company issued to various entities affiliated with Hayfin warrants to purchase an aggregate of 9,103,047 shares of the Company's common stock (the "Hayfin Warrants"). The Hayfin Warrants have an exercise price equal to \$1.6478 per share, which is equal to the trailing 30-day Volume Weighted-average Price of the Company's common stock on the business day immediately prior to the Hayfin Closing Date. The Hayfin Warrants were valued by the Company at approximately \$9.6 million as of the Hayfin Closing Date and have an expiration date of March 23, 2029 (see Note 8). As consideration for the foregoing amendment to the Hayfin Credit Agreement on May 1, 2023, the Company issued additional warrants to the lenders to purchase 2,391,244 shares of the Company's common stock at an exercise price of \$3.2619 per share (the "Hayfin Second Amendment Warrants"). The Hayfin Second Amendment Warrants were valued at approximately \$5.6 million and have an expiration date of May 1, 2030.

As a result of the upfront fee and exit fee paid or payable to Hayfin, the expenses incurred by the Company in connection with this transaction and the value of the Hayfin Warrants and Hayfin Second Amendment Warrants, the Company recognized a discount on the Hayfin Loans in the amount of \$13.9 million for the year ended December 31, 2022 and an additional debt discount in the year ended December 31, 2023 in the amount of \$5.7 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. As of the Ares Closing Date, \$15.0 million of the aggregate debt discount associated with the Hayfin Credit Facility was unamortized, and this amount is reflected in the loss on extinguishment of debt for the year ended December 31, 2023. Based on the fair value of the Hayfin Warrants and the aggregate amount of fees and expenses associated with obtaining the Hayfin Credit Facility, the effective interest rate on the Hayfin Loans as of the Hayfin Closing Date and as of December 31, 2022 was approximately 13.0% and 16.1%, respectively.

8. STOCKHOLDERS' EQUITY

Preferred Stock

The Company is currently authorized to issue up to 10 million shares of preferred stock, \$0.0001 par value per share. There were no shares of preferred stock outstanding at December 31, 2023 and 2022.

Common Stock

As of December 31, 2023 and 2022, the Company was authorized to issue 300,000,000 shares of its common stock, \$0.0001 par value per share, and 226,063,032 and 221,816,930 shares of common stock were outstanding as of December 31, 2023 and 2022, respectively. On May 27, 2021, the Company amended its Second Amended and Restated Certificate of Incorporation to increase the number of shares of common stock that the Company is authorized to issue from 150,000,000 to 300,000,000. After giving effect to shares reserved for the issuance of warrants and for awards issued under the Company's equity incentive plans, 31,033,333 shares of common stock were available for issuance as of December 31, 2023.

On December 9, 2022, the Company completed an underwritten public offering whereby the Company issued 24,125,873 shares of its common stock. Net proceeds after underwriting discounts and expenses associated with the offering were approximately \$64.6 million and were used to accelerate commercialization and production activities, complete plasma center buildouts and obtain FDA approvals, to conclude post-FDA marketing approval research and development projects, and for working capital, capital expenditures and general corporate purposes.

During the year ended December 31, 2022, outstanding stock options aggregating to 68,679 shares of common stock were exercised, and the Company received net proceeds from the exercises of approximately \$0.2 million.

On October 25, 2021, the Company completed an underwritten public offering whereby the Company issued 57.5 million shares of common stock and received gross proceeds of \$57.5 million. Net proceeds after underwriting discounts and expenses associated with the offering were approximately \$53.8 million, and were used to advance the commercial sales of the Company's FDA approved products through the procurement of raw materials for the manufacturing of BIVIGAM and ASCENIV, to expand the Company's plasma collection facility network, to scale up the manufacturing capacity of the Boca Facility and make continuous improvements in order to adhere to cGMP compliance, to explore business development opportunities and for general corporate purposes and other capital expenditures.

On September 3, 2021, the Company entered into a distribution agreement with Raymond James & Associates, Inc., as agent (“Agent”), pursuant to which the Company may offer and sell, from time to time, at its option, through or to the Agent, up to an aggregate of \$50 million of shares of the Company’s common stock (the “Distribution Agreement”). The Company currently intends to use any net proceeds from the sale of its common stock under the Distribution Agreement for general corporate purposes, including procurement of source plasma and other raw materials, supply chain initiatives and production expenditures, working capital, capital expenditures, expansion and resources for commercialization activities, and other potential research and development and business opportunities. The Company currently has approximately \$42.8 million of shares available to sell under the Distribution Agreement. There were no sales under the Distribution Agreement during the year ended December 31, 2022. During the year ended December 31, 2021, the Company issued 5,540,831 shares of its common stock under the Distribution Agreement and received net proceeds of \$6.9 million.

On August 5, 2020, the Company entered into an open market sale agreement (as amended from time to time, 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. On November 5, 2020 and February 3, 2021, the Company and Jefferies amended the Sale Agreement to provide for increases in the aggregate offering amount under the Sale Agreement such that the Company could sell shares having an aggregate offering price of up to \$105.4 million under the Sale Agreement, as amended. The Sale Agreement was terminated on August 31, 2021. For the year ended December 31, 2021, the Company issued and sold 27,805,198 shares of common stock under the 2020 Sale Agreement and received net proceeds of \$60.4 million.

Warrants

On June 16, 2023, various entities affiliated with Hayfin exercised 3,388,686 Hayfin Warrants in a cashless exercise transaction resulting in the Company issuing 1,967,847 shares of its common stock to such entities. On May 1, 2023 the Company issued the Hayfin Second Amendment Warrants (see Note 7), which were valued at \$5.6 million using the Black-Scholes option-pricing model assuming an expected term of seven years, a volatility of 67.8%, a dividend yield of 0% and a risk-free rate of interest of 3.62%.

On March 23, 2022, the Company issued the Hayfin Warrants, whereby affiliates of Hayfin may purchase an aggregate of 9,103,047 shares of common stock at an exercise price of \$1.6478 per share (see Note 7). The Hayfin Warrants were valued at \$9.6 million, using the Black-Scholes option pricing model assuming an expected term of 7 years, a volatility of 68.1%, a dividend yield of 0% and a risk-free interest rate of 2.36%.

During the year ended December 31, 2022, warrants to purchase 106,059 shares of common stock that had been issued to former noteholders of the Company expired. At December 31, 2023 and 2022, the Company had outstanding warrants to purchase an aggregate of 12,502,906 and 13,525,148 shares, respectively, of common stock, with a weighted average exercise price of \$2.32 and \$1.99 per share, respectively, and expiration dates ranging between May 2023 and December 2030. The following table summarizes information about warrants outstanding as of December 31, 2023, 2022 and 2021:

	Shares	Weighted Average Exercise Price
Warrants outstanding at December 31, 2020	4,528,160	\$ 2.82
Expired	-	\$ -
Granted	-	\$ -
Exercised	-	\$ -
Warrants outstanding at December 31, 2021	4,528,160	\$ 2.82
Expired	(106,059)	\$ 8.23
Granted	9,103,047	\$ 1.65
Exercised	-	\$ -
Warrants outstanding at December 31, 2022	13,525,148	\$ 1.99
Expired	(24,800)	\$ 6.37
Granted	2,391,244	\$ 3.26
Exercised	(3,388,686)	\$ 1.65
Warrants outstanding at December 31, 2023	12,502,906	\$ 2.32

Equity Incentive Plans

From time to time the Company granted stock options or other equity-based awards under the Company’s Amended and Restated 2014 Omnibus Incentive Compensation Plan (the “2014 Plan”).

The 2014 Plan, as amended, was approved by the Company’s Board of Directors (the “Board”) on March 15, 2017 and by the Company’s stockholders on May 25, 2017. The maximum number of shares that were reserved for grant under the 2014 Plan was: (a) 2,334,940 shares; 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, 2021, an aggregate of 69,090 shares were available for issuance under the 2014 Plan. In accordance with the foregoing, on January 1, 2022 the aggregate number of shares available for issuance increased to 7,901,643.

During the years ended December 31, 2022 and 2021, the Company granted options to purchase an aggregate of 1,194,032 and 1,895,550 shares of common stock, respectively, to its directors and employees under the 2014 Plan.

On June 21, 2022, the Company’s stockholders approved the ADMA Biologics, Inc. 2022 Compensation Plan (the “2022 Equity Plan”). Approval of the 2022 Equity Plan resulted in approximately 18 million additional shares of the Company’s common stock being reserved for future awards. The 2022 Equity Plan provides for the Board or a Committee of the Board (the “Committee”) to grant awards to optionees and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the awards, including acceleration of the vesting of an award at any time. Any options granted under the 2022 Equity 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.

For the year ended December 31, 2023, the Company granted options to purchase an aggregate of 1,826,380 shares of common stock to employees and directors under the 2022 Equity Plan. Also during the year ended December 31, 2023, options to purchase 3,814,122 shares of common stock were exercised, for which 2,109,722 shares were withheld to cover the aggregate exercise prices and 259,867 shares were withheld to cover payroll taxes, and the Company received aggregate net exercise proceeds of \$1.1 million.

The fair value of stock options granted was determined on the date of grant using the Black-Scholes model. The Black-Scholes option pricing 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 term of the awards granted by the Company. 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, 2023, 2022 and 2021, 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, 2023, 2022 and 2021 were determined using the Black-Scholes option pricing model with the following assumptions:

	Years Ended		
	December 31, 2023	December 31, 2022	December 31, 2021
Expected term	5.5-6.3 years	5.5-6.3 years	5.5-6.3 years
Volatility	68%	68%	68-70%
Dividend yield	0.0	0.0	0.0
Risk-free interest rate	4.20-4.62%	1.72-1.73%	0.80-1.27%

The following table summarizes information about stock options outstanding as of December 31, 2023, 2022 and 2021:

	Shares	Weighted Average Exercise Price
Options outstanding, vested and expected to vest at December 31, 2020	6,922,931	\$ 4.40
Forfeited	(529,202)	\$ 2.89
Expired	(426,557)	\$ 4.91
Granted	1,895,550	\$ 2.14
Exercised	-	\$ -
Options outstanding, vested and expected to vest at December 31, 2021	7,862,722	\$ 3.93
Forfeited	(31,540)	\$ 2.37
Expired	(700,324)	\$ 6.86
Granted	1,194,032	\$ 1.67
Exercised	(68,679)	\$ 2.55
Options outstanding, vested and expected to vest at December 31, 2022	8,256,211	\$ 3.37
Forfeited	(99,345)	\$ 2.73
Expired	(262,940)	\$ 6.42
Granted	1,826,380	\$ 3.36
Exercised	(3,814,122)	\$ 3.15
Options outstanding, vested and expected to vest at December 31, 2023	5,906,184	\$ 3.38
Options exercisable	3,410,131	\$ 3.79

As of December 31, 2023, the Company had \$3.8 million of unrecognized compensation expense related to stock options granted under the Company's equity incentive plans, which is expected to be recognized over a weighted-average period of 2.6 years. The weighted average remaining contractual term of stock options outstanding and expected to vest at December 31, 2023 is 6.6 years. The weighted average remaining contractual term of stock options exercisable at December 31, 2023 is 5.2 years. The following table summarizes additional information regarding outstanding and exercisable options under the stock option plans at December 31, 2023:

Range of Exercise Prices	Stock Options Outstanding				Stock Options Exercisable			
	Options Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value (\$000's)	Options Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value (\$000's)
\$1.10 - \$1.67	1,175,410	7.7	\$ 1.60	\$ 3,428	590,275	7.3	\$ 1.56	\$ 1,748
\$1.73 - \$2.60	1,028,392	6.6	\$ 2.33	2,253	712,704	6.4	\$ 2.34	1,551
\$2.67 - \$4.01	2,905,506	7.4	\$ 3.41	3,211	1,310,276	5.3	\$ 3.49	1,343
\$4.01 - \$6.02	383,535	3.5	\$ 5.09	22	383,535	3.5	\$ 5.09	22
\$6.26 - \$9.39	279,841	1.1	\$ 8.48	-	279,841	1.1	\$ 8.48	-
\$10.80 - \$16.20	133,500	1.1	\$ 10.80	-	133,500	1.1	\$ 10.80	-
	<u>5,906,184</u>	6.6	\$ 3.38	<u>\$ 8,914</u>	<u>3,410,131</u>	5.2	\$ 3.79	<u>\$ 4,664</u>

During the years ended December 31, 2023, 2022 and 2021, the Company granted RSUs representing an aggregate of 3,389,760, 1,174,266 and 4,384,744 shares, respectively, to certain employees of the Company and to members of the Board. Except for the RSUs granted under the Company's retention incentive program discussed below, the RSUs generally vest annually over a period of four years for employees and semi-annually over a period of one year for directors. The RSUs granted during the year ended December 31, 2021 include 3,832,500 shares granted under a retention incentive program implemented by the Company for its executive management and certain employees (see Note 10), whereby the Company issued an aggregate of 2,685,000 time-based RSUs and 1,147,500 milestone-based RSUs. Fifty percent of the time-based RSUs granted under the retention incentive program vested on December 31, 2022, with the remainder vesting in quarterly installments through December 31, 2024. The milestone-based RSUs vested upon achievement of the applicable milestone, and all of the milestone-based RSUs vested during the year ended December 31, 2022. The milestones required to be achieved in order for the milestone-based RSUs to vest were determined by the Board and were consistent with the 2022 operating plan approved by the Board.

During the years ended December 31, 2023, 2022 and 2021, 1,199,445, 2,727,412 and 92,750 shares, respectively, vested in connection with grants of RSUs. With respect to RSUs vested during the year ended December 31, 2023, 365,722 shares valued at approximately \$1.3 million were withheld by the Company to cover employees' tax liabilities. With respect to the RSUs vested during the year ended December 31, 2022, 918,851 shares valued at approximately \$2.9 million were withheld by the Company to cover employees' tax liabilities. For the RSUs vested during the year ended December 31, 2021, 27,850 shares valued at approximately \$62,000 were withheld by the Company to cover employees' tax liabilities. All of these shares have been retired by the Company or were otherwise no longer outstanding as of December 31, 2023. 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, 2020	326,000	\$ 2.81
Granted	4,384,744	\$ 1.30
Vested	(92,750)	\$ 2.82
Forfeited	(132,861)	\$ 2.51
Balance at December 31, 2021	4,485,133	\$ 1.34
Granted	1,174,266	\$ 1.74
Vested	(2,727,412)	\$ 1.25
Forfeited	(65,000)	\$ 1.40
Balance at December 31, 2022	2,866,987	\$ 1.59
Granted	3,389,760	\$ 3.42
Vested	(1,199,445)	\$ 1.63
Forfeited	(400,005)	\$ 2.71
Balance at December 31, 2023	<u>4,657,297</u>	\$ 2.81

As of December 31, 2023, the Company had \$10.4 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 2.9 years.

Total stock-based compensation expense for all awards granted under the Company's equity incentive plans for the years ended December 31, 2023, 2022 and 2021 was as follows (in thousands):

	<u>2023</u>	<u>2022</u>	<u>2021</u>
Research and development	\$ 40	\$ 19	\$ 154
Plasma center operating expenses	146	82	60
Selling, general and administrative	5,331	4,717	2,958
Cost of product revenue	670	397	316
Total stock-based compensation expense	<u>\$ 6,187</u>	<u>\$ 5,215</u>	<u>\$ 3,488</u>

9. RELATED PARTY TRANSACTIONS

The Company leases an office building and equipment from Areth, LLC ("Areth") pursuant to an agreement for services effective as of January 1, 2016, as amended from time to time, and pays monthly rent on this facility in the amount of \$10,000. On October 18, 2022, the Company amended the agreement to extend its term to December 31, 2026, with automatic successive one-year renewals thereafter. Either party may terminate the agreement by providing the other party with one year's prior written notice. Rent expense for the years ended December 31, 2023, 2022 and 2021 amounted to \$0.1 million. Areth is a company controlled by Dr. Jerrold B. Grossman, the Vice Chairman of the Board, 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, 2023, 2022 and 2021.

During the years ended December 31, 2023, 2022 and 2021, 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 \$0.4 million, \$0.2 million and \$0.2 million, respectively. Genesis is owned by Dr. Grossman and Adam Grossman.

On August 15, 2023, two of the Company's executive officers exercised options to purchase 2,909,721 shares of the Company's common stock on a cashless basis, and 688,657 shares of common stock were issued to these executive officers, net of 257,867 shares of common stock to cover a portion of their tax liabilities (see Note 8).

See Note 7 for a discussion of the Company's prior credit facility and related transactions with Perceptive, a holder of more than 5% of the Company's common stock during the year ended December 31, 2022. In connection with the 2022 public offering of the Company's common stock (see Note 8) on December 9, 2022: (i) Mr. Grossman purchased 14,983 shares of common stock directly and 14,982 shares of common stock indirectly through an entity he controls, and (ii) Brian Lenz, the Company's Executive Vice President and Chief Financial Officer, purchased 6,993 shares of common stock, all at the public offering price of \$2.86 per share.

During the year ended December 31, 2021, in connection with the resignation of Dr. James Mond, the Company's former Chief Scientific and Medical Officer, the Company recognized an expense and corresponding liability in the amount of \$0.8 million for payments to be made under a separation and transition agreement with Dr. Mond. These payments were made in scheduled installments over a period of 10 months.

In connection with the 2021 public offering of the Company's common stock (see Note 8) on October 25, 2021: (i) Mr. Grossman purchased 100,000 shares of common stock directly and 250,000 shares of common stock indirectly through an entity he controls, (ii) Dr. Grossman purchased 100,000 shares of common stock, (iii) Dr. Young Kwon, a member of the Board, purchased 100,000 shares of common stock, and (iv) Brian Lenz, the Company's Executive Vice President and Chief Financial Officer, purchased 30,000 shares of common stock, all at the public offering price of \$1.00 per share.

10. COMMITMENTS AND CONTINGENCIES

General Legal Matters

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

IT Systems Disruption

On June 19, 2023, the Company experienced an IT systems disruption, which rendered certain of the Company's IT technology systems inaccessible for less than one week. The Company's investigation of the disruption has essentially been completed with the assistance of third-party consultants, and no definitive root cause was identified. At the time of the disruption, the Company was in production of two batches of BIVIGAM, and after a prolonged hold time, it was deemed to be a prudent GMP quality decision to discard these two in-process production batches as these batches were no longer viable for further production or had any alternative use. As a result, the Company recorded a one-time, non-recurring charge of \$2.1 million in the second quarter of 2023 for this inventory, which is reflected in Cost of product revenue in the accompanying consolidated statements of operations for the year ending December 31, 2023. In addition, the Company's Plasma center operating expenses were adversely impacted by approximately \$0.7 million due to the temporary closing of the Company's plasma collection centers while their IT systems were restored.

The Company carries appropriate insurance for these types of instances, and while there can be no assurances ADMA will be reimbursed for the insurance claims made pertaining to these charges, the Company is actively working with its insurance broker and carriers.

Vendor Commitments

Pursuant to the terms of a plasma purchase agreement dated as of November 17, 2011 (the “2011 Plasma Purchase Agreement”), the Company agreed to purchase from its former contract manufacturer 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 the counterparty, and under the original 2011 Plasma Purchase Agreement the Company was permitted to also collect high-titer RSV plasma from up to five wholly-owned ADMA plasma collection facilities. During 2015, the Company amended the 2011 Plasma Purchase Agreement to (i) allow the Company to collect its raw material RSV high-titer plasma from any number of wholly-owned ADMA plasma collection facilities and (ii) allow the Company to purchase its raw material RSV high-titer plasma from other third-party collection organizations, in each case, provided that the annual minimum volumes from the Company’s former contract manufacturer were met, 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. On December 10, 2018, the Company’s former contract manufacturer 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 June 6, 2017, the Company entered into a Plasma Supply Agreement with its former contract manufacturer, pursuant to which the counterparty 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 Plasma Supply Agreement was amended to provide, among other things, that in the event the counterparty 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 the counterparty, then the counterparty shall reimburse ADMA BioManufacturing for the difference in price ADMA BioManufacturing incurs. On December 10, 2018, the Company’s former contract manufacturer assigned its rights and obligations under the Plasma Supply Agreement to Grifols, effective January 1, 2019.

Post-Marketing Commitments

In connection with the FDA 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 were required to be completed by June 30, 2023. Both studies have been completed and the study reports have been submitted to the FDA. ADMA had assumed the remaining obligations, and the costs of the studies were expensed as incurred as research and development expenses. For the years ended December 31, 2023, 2022 and 2021, the Company incurred expenses related to these studies of \$1.7 million, \$2.2 million and \$1.7 million, respectively.

In connection with the FDA 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. For the years ended December 31, 2023, 2022 and 2021, the Company incurred expenses related to this study in the amount of \$1.0 million, \$0.5 million and \$0.6 million, respectively. The Company expects to incur expenses of approximately \$1.5 million to complete this study, which is required to be completed by June of 2026.

Employment Contracts

The Company has entered into employment agreements with Mr. Grossman and Mr. Lenz.

Other Commitments

On September 28, 2021, following the approval of the Board upon recommendation of the Compensation Committee of the Board, and in consultation with an independent compensation consultant, the Company implemented a retention incentive program, consisting of cash payments and awards of RSUs (see Note 8), to the Company's management, including Mr. Grossman and Mr. Lenz, and to certain other employees. The purpose of the retention program was to promote and ensure business continuity and provide an incentive to the Company's executive management and certain other employees, considering the operational challenges presented by the COVID-19 pandemic and the competitive work environment in which the Company operates as an FDA regulated manufacturer of specialized biologic therapies. The retention awards were granted considering the nationwide labor shortages and the increased employee turnover rates that the Company, its pharmaceutical peers and other companies outside of the Company's industry have reported experiencing.

The cash portion of the retention program consisted of two tranches. The first tranche was paid to employees on September 30, 2021 in the amount of \$1.3 million, and the second tranche aggregating to approximately \$1.3 million was paid on June 15, 2022. Based on the terms of the retention agreements the Company entered into with each applicable executive and employee, approximately \$0.8 million of each tranche was recognized over the retention service period, which began on October 1, 2021 and ended on December 31, 2022, with the remainder having been recognized as expense when paid.

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, 2023. The Company does not anticipate recognizing any significant losses relating to these arrangements.

11. INCOME TAXES

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

	Years Ended December 31,		
	<i>(In thousands)</i>		
	2023	2022	2021
Benefit at U.S. federal statutory rate	\$ (5,930)	\$ (13,840)	\$ (15,046)
State taxes - deferred	(763)	(1,773)	(252)
Increase in valuation allowance	4,696	15,117	14,619
Research and development credits	-	(211)	(240)
Decrease in federal net operating loss	-	-	624
162(m) disallowance	1,183	862	64
Other	814	(155)	231
Benefit for income taxes	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

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

	Year Ended December 31,	
	2023	2022
Federal and state net operating loss carryforwards	\$ 77,757	\$ 81,526
Federal and state research credits	140	407
Interest expense limitation carryforwards	21,165	12,194
Transaction costs	778	882
Deferred revenue	434	480
Accrued expenses and other	1,148	1,236
Total gross deferred tax assets	<u>101,422</u>	<u>96,725</u>
Less: valuation allowance for deferred tax assets	<u>(101,422)</u>	<u>(96,725)</u>
Net deferred tax assets	<u>\$ -</u>	<u>\$ -</u>

As of December 31, 2023, the Company had federal and state (post-apportioned basis) net operating losses ("NOLs") of \$315.6 million and \$216.4 million, respectively, as well as federal research and development tax credit carryforwards of approximately \$0.1 million. Approximately \$35.6 million and \$95.1 million of the foregoing Federal and state NOLs, respectively, will expire at various dates from 2028 through 2043, 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 ("Section 382") 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, 2023, the Company performed a substantive analysis of limitations imposed by Section 382 on historical information and concluded that no ownership changes occurred as of December 31, 2023 and 2022. As part of the substantive analysis, the Company did determine that an additional \$14.2 million of state NOLs were not subject to limitation of prior ownership changes and are therefore available to offset future taxable income.

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 50% 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, 2023 and 2022 and does not anticipate a significant change in unrecognized tax benefits during the next 12 months.

12. LEASE OBLIGATIONS

The Company leases certain properties and equipment for its ADMA BioCenters and ADMA BioManufacturing subsidiaries, 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 2033. 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 and lease expense for such leases are recognized on a straight-line basis over the lease term. 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 lease commencement date. For the lease liabilities recognized during the years ended December 31, 2023 and 2022, the Company used discount rates of 13% to 16% 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 in the accompanying consolidated statements of operations. Aggregate lease expense for the Company's operating leases for the years ended December 31, 2023, 2022 and 2021 was \$2.4 million, \$2.1 million and \$1.4 million, respectively. Aggregate cash paid on these leases for the years ended December 31, 2023, 2022 and 2021 was \$2.4 million, \$1.8 million and \$1.4 million, respectively.

During the year ended December 31, 2023, the Company recognized one additional right-to-use asset and corresponding lease liability in the amount of \$0.1 million for office equipment leased for the Boca Facility. During the year ended December 31, 2022, the Company recognized additional right-to-use assets and corresponding lease liabilities aggregating to approximately \$4.0 million in connection with two new property leases where the Company has opened additional plasma collection facilities, a property lease for the storage of raw materials inventory and a property lease for the building that the Company utilizes as its corporate headquarters (see Note 9). Including a finance lease the Company entered into in June 2018, the Company has aggregate lease liabilities of \$10.8 million and \$11.6 million as of December 31, 2023 and 2022, 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 7.6 years. Scheduled payments under the Company's lease obligations are as follows (in thousands):

Year ended December 31, 2024	\$	2,397
2025		2,420
2026		2,157
2027		2,041
2028		2,088
Thereafter		6,151
Total payments		<u>17,254</u>
Less: imputed interest		(6,430)
Current portion		<u>(1,045)</u>
Balance at December 31, 2023	\$	<u>9,779</u>

13. SEGMENTS

The Company is dedicated to manufacturing, marketing and developing 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 ten plasma collection facilities as of December 31, 2023, all of which were operational, collecting plasma, and hold an approved license with the FDA (and of which three facilities have received approvals from the Korean Ministry of Food and Drug Safety as well as FDA approval to implement a Hepatitis B immunization program). 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, 2023

<i>(in thousands)</i>	<u>ADMA BioManufacturing</u>	<u>Plasma Collection Centers</u>	<u>Corporate</u>	<u>Consolidated</u>
Revenues	\$ 249,738	\$ 8,334	\$ 143	\$ 258,215
Cost of product revenue	161,157	8,116	-	169,273
Income (loss) from operations	47,525	(4,048)	(21,845)	21,632
Interest and other expense, net	(258)	(1)	(23,438)	(23,697)
Loss on extinguishment of debt	-	-	(26,174)	(26,174)
Net income (loss)	47,267	(4,049)	(71,457)	(28,239)
Capital expenditures	2,952	1,819	-	4,771
Depreciation and amortization expense	5,156	3,176	-	8,332
Total assets	246,719	34,733	47,730	329,182

Year Ended December 31, 2022

<i>(in thousands)</i>	<u>ADMA BioManufacturing</u>	<u>Plasma Collection Centers</u>	<u>Corporate</u>	<u>Consolidated</u>
Revenues	\$ 144,070	\$ 9,867	\$ 143	\$ 154,080
Cost of product revenue	108,882	9,933	-	118,815
Income (loss) from operations	879	(17,908)	(22,336)	(39,365)
Interest and other expense, net	(505)	(3)	(19,361)	(19,869)
Loss on extinguishment of debt	-	-	(6,670)	(6,670)
Net income (loss)	374	(17,911)	(48,367)	(65,904)
Capital expenditures	5,247	8,664	-	13,911
Depreciation and amortization expense	4,709	2,404	-	7,113
Total assets	238,159	37,071	73,231	348,461

Year Ended December 31, 2021

<i>(in thousands)</i>	<u>ADMA BioManufacturing</u>	<u>Plasma Collection Centers</u>	<u>Corporate</u>	<u>Consolidated</u>
Revenues	\$ 74,936	\$ 5,864	\$ 143	\$ 80,943
Cost of product revenue	74,126	5,644	-	79,770
Loss from operations	(29,294)	(12,056)	(17,024)	(58,374)
Interest and other expense, net	(218)	(6)	(13,050)	(13,274)
Net loss	(29,512)	(12,062)	(30,074)	(71,648)
Capital expenditures	4,877	8,634	-	13,511
Depreciation and amortization expense	4,218	1,273	5	5,496
Total assets	208,391	24,682	43,180	276,253

14. OTHER EMPLOYEE BENEFITS

The Company sponsors a 401(k) savings plan. Under the plan, employees may make contributions which are eligible for a Company discretionary percentage contribution as defined in the plan and determined by the Board. The Company recognized \$1.3 million, \$1.3 million and \$1.1 million of related compensation expense for the years ended December 31, 2023, 2022 and 2021, respectively.

15. SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Supplemental cash flow information for the years ended December 31, 2023, 2022 and 2021 is as follows:

	<u>2023</u>	<u>2022</u>	<u>2021</u>
		<i>(In thousands)</i>	
SUPPLEMENTAL CASH FLOW INFORMATION:			
Cash paid for interest	\$ 18,051	\$ 13,880	\$ 11,159
Noncash Financing and Investing Activities:			
Equipment acquired reflected in accounts payable and accrued liabilities	\$ 86	\$ 1,495	\$ 1,353
Right-to-use assets in exchange for lease obligations	\$ 130	\$ 4,048	\$ 3,554
Warrants issued in connection with notes payable	\$ 5,595	\$ 9,570	\$ -

16. CONCENTRATIONS

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents and accounts receivable. At December 31, 2023, five customers accounted for approximately 98% of the Company's consolidated accounts receivable. At December 31, 2022, two customers accounted for approximately 92% of the Company's consolidated accounts receivable.

For the year ended December 31, 2023, two customers accounted for approximately 72% of the Company's consolidated revenues. For the year ended December 31, 2022, two customers accounted for approximately 74% of the Company's consolidated revenues. For the year ended December 31, 2021, four customers accounted for approximately 81% of the Company's consolidated revenues.

During the years ended December 31, 2023 and 2022, plasma purchases from Grifols totaled approximately \$9.5 million and \$47.7 million, respectively, or approximately 21% and 65%, respectively, of the Company's total inventory purchases.

Net revenues according to geographic area, based on the location of where the product is shipped, is as follows:

	Years Ended December 31,			
	<i>(in thousands)</i>	<u>2023</u>	<u>2022</u>	<u>2021</u>
United States		\$ 244,881	\$ 146,427	\$ 70,626
International		13,334	7,653	10,317
Total revenues		<u>\$ 258,215</u>	<u>\$ 154,080</u>	<u>\$ 80,943</u>

**Schedule II – Valuation and Qualifying Accounts
Years ended December 31, 2023, 2022 and 2021**

	<i>(in thousands)</i>	<u>Balance at beginning of year</u>	<u>Additions</u>		<u>Deductions</u>	<u>Balance at end of year</u>
			<u>Charged to costs and expenses</u>	<u>Other</u>		
Year ended December 31, 2023						
Accrued rebates	\$	11,437	\$ 8,448	\$ -	\$ 3,277	\$ 16,608
Inventory valuation allowance	\$	5,400	\$ 6,963	\$ 6	\$ 9,377	\$ 2,992
Deferred tax asset valuation allowance	\$	96,725	\$ 4,696	\$ -	\$ -	\$ 101,421
Year ended December 31, 2022						
Accrued rebates	\$	5,040	\$ 8,227	\$ -	\$ 1,830	\$ 11,437
Inventory valuation allowance	\$	8,577	\$ 2,744	\$ -	\$ 5,921	\$ 5,400
Deferred tax asset valuation allowance	\$	81,608	\$ 15,117	\$ -	\$ -	\$ 96,725
Year ended December 31, 2021						
Accrued rebates	\$	2,604	\$ 2,815	\$ -	\$ 379	\$ 5,040
Inventory valuation allowance	\$	13,108	\$ 4,722	\$ 2	\$ 9,255	\$ 8,577
Deferred tax asset valuation allowance	\$	66,990	\$ 14,618	\$ -	\$ -	\$ 81,608

ADMA BioCenters Georgia Inc.

Jurisdiction of incorporation: Delaware
Name under which business conducted: ADMA BioCenters Georgia Inc.

ADMA Plasma Biologics, Inc.

Jurisdiction of incorporation: Delaware
Name under which business conducted: ADMA Plasma Biologics, Inc.

ADMA BioManufacturing, LLC

Jurisdiction of incorporation: Delaware
Name under which business conducted: ADMA BioManufacturing, LLC

**Consent of Independent Registered
Public Accounting Firm**

We consent to the incorporation by reference in the registration statements on Form S-8 (File Nos. 333-266291, 333-263345, 333-254770, 333-237658, 333-229921, 333-224492, 333-220058, 333-204590 and 333-193635) and Form S-3 (File Nos. 333-256643, 333-234107 and 333-225048) of our report, dated February 28, 2024, with respect to the consolidated balance sheets of ADMA Biologics, Inc. and subsidiaries as of December 31, 2023 and 2022, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows and financial statement schedule II – valuation and qualifying accounts for each of the years in the three-year period ended December 31, 2023, and our report dated February 28, 2024 with respect to the effectiveness of internal control over financial reporting of ADMA Biologics, Inc. and subsidiaries as of December 31, 2023, included in this Annual Report on Form 10-K of ADMA Biologics, Inc. and subsidiaries for the year ended December 31, 2023.

/s/ CohnReznick LLP

Parsippany, New Jersey

February 28, 2024

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, 2023;
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.

February 28, 2024

/s/ Adam S. Grossman

Name: Adam S. Grossman

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

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

I, Brian Lenz, certify that:

1. I have reviewed this Annual Report on Form 10-K of ADMA Biologics, Inc. for the year ended December 31, 2023;
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.

February 28, 2024

/s/ Brian Lenz

Name: Brian Lenz

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

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

In connection with the annual report of ADMA Biologics, Inc., a Delaware corporation (the “Company”), on Form 10-K for the year ended December 31, 2023, 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.

February 28, 2024

/s/ Adam S. Grossman

Name: Adam S. Grossman

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

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

In connection with the annual report of ADMA Biologics, Inc., a Delaware corporation (the “Company”), on Form 10-K for the year ended December 31, 2023, 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.

February 28, 2024

/s/ Brian Lenz

Name: Brian Lenz

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

ADMA BIOLOGICS, INC.
COMPENSATION RECOUPMENT POLICY

I. Defined Terms.

- (a) “Applicable Rules” means Section 10D of the Exchange Act and Rule 10D-1 promulgated thereunder, Listing Rule 5608 of the Listing Rules of Nasdaq, and any other national stock exchange rules that the Company is or may become subject to.
 - (b) “Clawback Event” means a required recoupment of Incentive-Based Compensation in the event of a Restatement under the Applicable Rules.
 - (c) “Exchange Act” means the Securities Exchange Act of 1934, as amended.
 - (d) “Executive Officer” means each officer of the Company who is the Company’s president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice president of the Company in charge of a principal business unit, division or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar significant policy-making functions for the Company, as determined under 17 CFR §229.401(b).
 - (e) “Financial Reporting Measures” means (i) measures that are determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements, and any measures that are derived wholly or in part from such measures, (ii) the Company’s stock price, and (iii) total shareholder return in respect of the Company. A “Financial Reporting Measure” need not be presented within the financial statements or included in a filing with the SEC.
 - (f) “Incentive-Based Compensation” means any compensation that is granted, earned, or vested, based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive-Based Compensation does not include, among other forms of compensation, equity awards that vest exclusively upon completion of a specified employment period, without any performance condition, and bonus awards that are discretionary or based on subjective goals or goals unrelated to Financial Reporting Measures.
 - (g) “Nasdaq” means the Nasdaq Stock Market LLC.
 - (h) “Received” – Incentive-Based Compensation is deemed “Received” for the purposes of this Policy in the Company’s fiscal period during which the Financial Reporting Measure applicable to the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period.
 - (i) “Recovery Period” means the three completed fiscal years immediately preceding the date on which the Company is required to prepare a Restatement, which date is the earlier of (i) the date the Board, a committee of the Board, or the officer(s) of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement or (ii) a date that a court, regulator, or other legally authorized body directs the Company to prepare a Restatement.
 - (j) “Regulators” means, as applicable, the SEC and Nasdaq.
 - (k) “Restatement” means that the Company is required to prepare an accounting restatement due to a material noncompliance of the Company with any financial reporting requirement under applicable securities laws, including any required accounting restatement to correct an error in previously issued financial statements (i) that is material to the previously issued financial statements, or (ii) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.
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(l) “SEC” means the U.S. Securities and Exchange Commission.

II. Purpose.

The Board of Directors (“**Board**”) of ADMA Biologics, Inc. (the “**Company**”), based upon the recommendation of its Compensation Committee (the “**Committee**”), has adopted this Compensation Recoupment Policy (this “**Policy**”) in order to implement a mandatory clawback policy in the event of a Restatement in compliance with the Applicable Rules. Any capitalized terms used, but not immediately defined, in this Policy have the meanings set forth in Section I.

III. Administration.

This Policy shall be administered by the Committee, which shall make all determinations with respect to this Policy in its sole discretion; *provided* that this Policy shall be interpreted in a manner consistent with the requirements of the Applicable Rules. Notwithstanding the foregoing, subject to the Applicable Rules, the Board may assume any or all powers and authority of the Committee with respect to this Policy, in which case references to the Committee shall be deemed to include the Board, as applicable.

IV. Recovery on a Restatement.

In the event that the Company is required to prepare a Restatement, the Company shall reasonably promptly recover from an Executive Officer the amount of any erroneously awarded Incentive-Based Compensation that is Received by such Executive Officer during the Recovery Period. The amount of erroneously Received Incentive-Based Compensation will be the excess of the Incentive-Based Compensation Received by the Executive Officer (whether in cash or in shares) based on the erroneous data in the original financial statements over the Incentive-Based Compensation (whether in cash or in shares) that would have been Received by the Executive Officer had such Incentive-Based Compensation been based on the restated results, without respect to any tax liabilities incurred or paid by the Executive Officer.

Recovery of any erroneously awarded compensation under this Policy is not dependent on fraud or misconduct by any Executive Officer in connection with a Restatement.

Without limiting the foregoing, for Incentive-Based Compensation based on the Company’s stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in the Restatement, (i) the amount shall be based on the Company’s reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received and (ii) the Company shall maintain documentation of the determination of that reasonable estimate and provide such estimate to the Regulators as required by the Applicable Rules.

In addition to the foregoing, in the event that an Executive Officer fails to promptly repay or reimburse erroneously awarded compensation that is subject to recovery, the Committee may require an Executive Officer to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering erroneously awarded compensation under this Policy.

V. Coverage and Application.

This Policy covers all persons who are Executive Officers at any time during the Recovery Period for which Incentive-Based Compensation is Received. Incentive-Based Compensation shall not be recovered under this Policy to the extent Received by any person before the date the person served as an Executive Officer. Subsequent changes in an Executive Officer’s employment status, including retirement or termination of employment, do not affect the Company’s right to recover Incentive-Based Compensation pursuant to this Policy.

This Policy shall apply to Incentive-Based Compensation that is Received by any Executive Officer on or after the Effective Date and that results from attainment of a Financial Reporting Measure based on or derived from financial information for any fiscal period ending on or after the Effective Date. For the avoidance of doubt, this will include Incentive-Based Compensation that may have been approved, awarded, or granted to an Executive Officer on or before the Effective Date if such Incentive-Based Compensation is Received after the Effective Date.

VI. Exceptions to Policy.

No recovery of Incentive-Based Compensation shall be required if any of the following conditions are met and the Committee determines that, on such basis, recovery would be impracticable:

- (a) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered; *provided* that prior to making a determination that it would be impracticable to recover any Incentive-Based Compensation based on the expense of enforcement, the Company shall (i) have made a reasonable attempt to recover the Incentive-Based Compensation, (ii) have documented such reasonable attempts to recover, and (iii) provide the documentation to the Regulators as required by the Applicable Rules;
- (b) recovery would violate home country law where that law was adopted prior to November 28, 2022; or
- (c) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended (the "Code"), and U.S. Treasury regulations promulgated thereunder.

VII. Methods of Recovery.

In the event of a Clawback Event, subject to applicable law, the Committee may take any such actions as it deems necessary or appropriate, including, without limitation:

- (a) the reduction or cancellation of any Incentive-Based Compensation in the form of vested or unvested equity or equity-based awards that have not been distributed or otherwise settled prior to the date of determination;
- (b) the recovery of any Incentive-Based Compensation that was previously paid to the Executive Officer;
- (c) the recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any Incentive-Based Compensation in the form of equity or equity-based awards;
- (d) the offset, withholding, or elimination of any amount that could be paid or awarded to the Executive Officer after the date of determination;
- (e) the recoupment of any amount in respect of Incentive-Based Compensation contributed to a plan that takes into account Incentive-Based Compensation (excluding certain tax-qualified plans, but including long-term disability, life insurance, supplemental executive retirement plans and deferred compensation plans, in each case to the extent permitted by applicable law, including Section 409A of the Code) and any earnings accrued to date on any such amount; and
- (f) the taking of any other remedial and recovery action permitted by law, as determined by the Committee.

In addition, the Committee may authorize legal action for breach of fiduciary duty or other violation of law and take such other actions to enforce the Executive Officer's obligations to the Company as the Committee deems appropriate.

VIII. Miscellaneous.

- (a) *Effective Date.* This Policy shall be effective as of December 1, 2023 ("Effective Date").
- (b) *Public Disclosure.* The Company shall make all required disclosures and filings with the Regulators with respect to this Policy in accordance with the requirements of the Applicable Rules, and any other requirements applicable to the Company, including any disclosures required in connection with SEC filings.
- (c) *Notice.* Before the Company takes action to seek recovery of compensation pursuant to this Policy against an Executive Officer, the Company shall take commercially reasonable steps to provide such individual with advance written notice of such clawback; provided that this notice requirement shall not in any way delay the reasonably prompt recovery of any erroneously awarded Incentive-Based Compensation.
- (d) *No Indemnification.* The Company shall not indemnify any current or former Executive Officer against the loss of erroneously awarded compensation and shall not pay or reimburse any Executive Officer for premiums incurred or paid for any insurance policy to fund such Executive Officer's potential recovery obligations.
- (e) *No Substitution of Rights; Non-Exhaustive Rights.* Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to (i) any equity or equity-based incentive compensation plan or any successor plan thereto, any cash-based bonus plan or any other incentive plan of the Company or any of its subsidiaries or affiliates or (ii) the terms of any similar policy or provision in any employment agreement, compensation agreement or arrangement, or similar agreement and any other legal remedies available to the Company. In addition to recovery of compensation as provided for in this Policy, the Company may take any and all other actions as it deems necessary, appropriate and in the Company's best interest in connection with a Clawback Event, including termination of an Executive Officer's employment and initiating legal action against an Executive Officer, and nothing in this Policy limits the Company's rights to take any such or other appropriate actions.
- (f) *Governing Law.* This Policy and all determinations made and actions taken pursuant hereto, to the extent not otherwise governed by mandatory provisions of the Applicable Rules, shall be governed by and construed in accordance with the laws of the State of Delaware without regard to choice of law principles. If any provision of this Policy shall be held illegal or invalid for any reason, such illegality or invalidity shall not affect the remaining parts of this Policy, but this Policy shall be construed and enforced as if the illegal or invalid provision had never been included in this Policy.
- (g) *Amendment; Termination; Sunset.* The Board, based upon the recommendation of the Committee, may amend this Policy at any time for any reason, subject to any limitations under the Applicable Rules. Unless otherwise required by applicable law, this Policy shall no longer be effective from and after the date that the Company no longer has a class of securities publicly listed on a U.S. national securities exchange or is otherwise not subject to the Applicable Rules.