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, 2024

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number: 001-36728

ADMA BIOLOGICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**56-2590442**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
465 State Route 17, Ramsey, New Jersey	**07446**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(201) 478-5552**
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common stock, par value $0.0001 per share	ADMA	**Nasdaq Global Market**

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one): ☒ Large Accelerated Filer ☐ Accelerated Filer ☐ Non-accelerated Filer ☐ Smaller Reporting Company ☐ Emerging Growth Company

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No ☐

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 $2,535,856,298 as of June 30, 2024 (the last business day of the registrant's most recently completed second fiscal quarter), based on a total of 226,820,778 shares of common stock held by non-affiliates and a closing price of $11.18 as reported on the Nasdaq Global Market on June 28, 2024.

As of March 10, 2025, there were 237,615,100 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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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 further commercialize ASCENIV and BIVIGAM;
- 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, suppliers 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 U.S. Food and Drug Administration (the "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 (including source plasma containing certain levels of antibodies to Respiratory Syncytial Virus), 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, SG-001 or other future pipeline product candidates;
- our ability to develop, manufacture, receive regulatory approval and commercialize our potential pipeline of any new hyperimmune globulins, including SG-001;
- 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, net income, Adjusted EBITDA, expenses, capital requirements, ASCENIV's growth, ability to maintain profitability and positive cash flows and the potential need for and availability of additional financing;
- our ability to realize our deferred tax assets or the need for a valuation allowance, or the effects of changes in tax laws on our deferred tax assets;
- our estimates of future taxable income and the timing of a potential full or partial release of the valuation allowance against our net deferred tax assets, which could have a material impact on our financial condition or financial results;
- our estimates of future effective tax rates and corresponding tax obligations, which could have a material impact on our financial condition or financial results;
- 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 conflicts in Europe and in the Middle East and surrounding areas and international trade and U.S. tariff policies and any anticipated effects of such policies on the pricing and availability of imported raw materials used in the production of our products.

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

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

PART I

Item 1. Business

Unless the context otherwise requires, references in this Business section to "ADMA," "ADMA Biologics," the "Company," "we," "us" and "our" refer to ADMA Biologics, Inc., a Delaware corporation, as well as its wholly-owned 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.

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 – 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, in adults and adolescents, for which we received FDA approval on April 1, 2019 and commenced first commercial sales in October 2019; (ii) BIVIGAM , 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 Nos. 10,259,865 and 11,084,870 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*. We have successfully completed production of a pilot-scale batch and are conducting animal studies for our *S. pneumoniae* hyperimmune globulin program, SG-001. 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 projected annual revenues greater than $490 million in 2025 and $605 million in 2026. These revenue targets translate to potential fiscal year 2025 and 2026 Adjusted Net Income exceeding $175 million and $235 million, respectively, and Adjusted EBITDA exceeding $225 million and $305 million, respectively. The foregoing financial targets do not account for the potential FDA approval of our innovative yield enhancement production process described below.

In December 2024, we successfully submitted a Prior Approval Supplement (the "PAS") for potential approval of our innovative yield enhancement production process. Following FDA review of the submission, we anticipate receiving FDA approval by mid-2025, with potential revenue and earnings accretion expected in the second half of the year. This innovative process has demonstrated an ability to increase production yields by approximately 20% from the same starting plasma volume, potentially driving significant increases to financial targets, if approved.

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.

From time to time we may provide contract manufacturing services for certain third-party clients. We also provide laboratory contracting services to certain customers and may provide contract filling, labeling and packing services utilizing our FDA-approved in-house fill-finish capabilities.

For the year ended December 31, 2024 we achieved net income of $197.7 million, the first time in our history that we achieved net income on a GAAP basis, and generated positive cash flow from operations of $118.7 million. Our improved operating results are primarily the result of the substantial revenue growth and continued physician, patient and payer acceptance of ASCENIV.

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 were delayed. In the future, 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, we commenced manufacturing ASCENIV at the 4,400 Liter production scale. This expansion has improved the product's margin profile and increased plant production capacity as fewer batches are needed to support our revenue goals. ASCENIV's prescriber and patient base continued to expand during 2024, which drove record utilization and pull-through for this product. These elevated demand trends have sustained into 2025, and ADMA currently expects that this product's rapid growth will continue throughout 2025 and beyond.

We anticipate filing our supplemental Biologics License Application ("sBLA") in mid-2025, with potential FDA approval in the first half of 2026, for the expansion of ASCENIV's label to include the pediatric setting for patients who are two years and older.

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 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 $12 billion in 2023 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 ("IND") 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.

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 and notably drive a revenue mix shift favoring sales of ASCENIV 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.

- **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 plan to leverage our previously conducted randomized, double-blind, placebo-controlled Phase II clinical trial evaluating RI-001, ASCENIV's predecessor product candidate, as well as the drug's real-world impact on patient outcomes, to drive further penetration into ASCENIV's targeted market principally comprised of patients suffering from complex and comorbid primary immunodeficiencies.

- **Improve the Boca Facility's and ADMA BioCenters' operating efficiencies, yields and gross margins.** During 2025, 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 and requisite regulatory review. In December 2024, we successfully submitted a PAS for potential approval of our innovative yield enhancement production process. Following FDA review of the submission, we anticipate receiving FDA approval by mid-2025, with potential revenue and earnings accretion expected in the second half of the year. This innovative process has demonstrated an ability to increase production yields by approximately 20% from the same starting plasma volume, potentially driving significant increases to financial targets, if approved. 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, we commenced manufacturing ASCENIV at the 4,400 Liter production scale, and for the full year ended December 31, 2024, substantially all of our production batches sold were produced at the expanded 4,400 Liter scale. This expansion has improved the product's margin profile and increased plant production capacity as fewer batches are needed to support revenue goals.

- **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. In early 2024, we successfully produced our first batch of ASCENIV utilizing our innovative ADMAlytics software to prospectively automate and realize efficiency improvements to plasma pooling during commercial manufacturing. In the third quarter of 2024, we successfully expanded implementation of ADMAlytics to our commercial division. When fully implemented, ADMAlytics is expected to further optimize our commercial growth strategy. The benefits of ADMAlytics include increased production efficiency, enhanced visibility into the 7–12-month manufacturing process, optimized commercial planning, streamlined plasma pooling, and reduced variability and personnel hours. These efficiencies are expected to further benefit our rapid earnings growth outlook.

- **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. We anticipate filing our sBLA in mid-2025, with potential FDA approval in the first half of 2026, for the expansion of ASCENIV's label in the U.S. to include the pediatric setting for patients who are two years and older.

- **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 developing an S. pneumonia hyperimmune globulin, and in 2024 we successfully produced a pilot-scale batch of this pipeline program, named SG-001. We are currently conducting animal studies for SG-001. 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. Approximately one million U.S. adults contract pneumococcal pneumonia annually, 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-naive 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 annual revenue of $300-500 million.

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 2023* and *Marketing Research Bureau Inc., October 2023*, the U.S. market for IG in 2023 was approximately $12 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 55.4 million liters of source plasma were collected in the U.S. in 2023. 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 2023* and *Marketing Research Bureau Inc., October 2023*, the U.S. sales of immune and hyperimmune globulin products for all its uses were reported to be approximately $12 billion in 2023 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 ASCENIV and 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 normal 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 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 high-titer plasma from any number of wholly-owned ADMA plasma collection facilities and (ii) allow us to purchase our raw material 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. 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. Effective October 1, 2024, we entered into an Amended and Restated Plasma Purchase Agreement with Grifols (the "A&R Grifols Agreement") with a term expiring in September 2039, after which it may be renewed for two additional multi-year periods if agreed to by the parties. Pursuant to the A&R Grifols Agreement, Grifols supplies, on a non-exclusive basis, to ADMA BioManufacturing a minimum of 35,000 liters of RSV plasma annually to be used in the manufacture of ASCENIV, with an escalating price per liter depending on the volume supplied in a given 12-month period, with a minimum annual price increase every 12 months. Additionally, Grifols will be entitled to receive a fixed bonus payment in the event that a specified liter amount of high-titer plasma is supplied to us in any 12-month period during the term of the A&R Grifols Agreement.

Effective August 6, 2024, we entered into a Plasma Purchase Agreement with KEDPlasma LLC ("KEDPlasma") with a term expiring in July 2031, after which it may be renewed for an additional multi-year period if agreed to by the parties (the "KEDPlasma Agreement"). Pursuant to the KEDPlasma Agreement, KEDPlasma supplies, on a non-exclusive basis, to ADMA BioManufacturing a minimum of 35,000 liters of RSV plasma annually commencing with the 12-month period ending July 31, 2026, with an escalating price per liter depending on the volume supplied in a given 12-month period. The price per liter of high titer plasma supplied pursuant to the KEDPlasma Agreement is also scheduled to increase on an annual basis. Additionally, KEDPlasma will be entitled to receive a fixed bonus payment in the event that a specified liter amount of RSV plasma is supplied to us in any 12-month period during the term of the KEDPlasma Agreement.

The A&R Grifols Agreement, the KEDPlasma Agreement, our other plasma agreements with third parties and ADMA's collection centers should allow us to source high titer plasma from approximately 250 collection centers in the U.S.

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, 2024, 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 BPL/Kedrion. 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 therapy approved by the FDA in 2021 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, nondisclosure, non-competition, 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. Additional U.S. and numerous 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, 11,084,870 and 11,897,943, each with a term through 2037, pertain to various aspects of this technology. Additional U.S. and numerous 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 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 methodologies and proprietary reagents, controls, testing standards, standard operating procedures and methods used 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, non-competition and invention assignment 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 continue to invest in growing brand awareness globally. Our brand marketing is designed to increase awareness of the ADMA Biologics trade name and our product offerings by building on our industry reputation and strength of relationships. We hold multiple trademarks, including but not limited to ADMA, ADMA Biologics (including logo), ASCENIV, BIVIGAM, CIVACIR, Nabi-HB, Designed to Deliver, Partner in Protection and Advantage Ig. We will continue to allocate and expend resources to maintain and build market and consumer awareness and will defend our brand 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, fines, refusal by the government to approve our marketing applications and supplemental applications or to allow us to manufacture or market our products, and criminal prosecution, 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 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 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, 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 implementation. 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

In the United States, our activities are potentially subject to additional regulation by various federal, state and local authorities in addition to the FDA, including CMS, other divisions of HHS (e.g., the Office of Inspector General), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ, and state and local governments. If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 as well as the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 (the "OBRA"), the Veterans Health Care Act of 1992, Deficit Reduction Act of 2005, Patient Protection and Affordable Care Act (the "ACA"), and the Inflation Reduction Act of 2022, each as amended. Among other things, the OBRA requires drug manufacturers to calculate and report complex pricing metrics used to determine rebates paid on prescription drugs to state Medicaid programs. Under the Veterans Health Care Act (the "VHCA"), drug companies are required to offer "covered drugs" (including all drugs approved under an NDA) at no more than a statutory ceiling price, calculated based on a manufacturer's required price calculations, to four federal agencies, including the U.S. Department of Veterans Affairs ("VA"), Indian Health Service, and Department of Defense ("DoD"), and the Public Health Service ("PHS"). Also, under the VHCA, manufacturers are required to offer drugs for sale at no more than a separate statutory ceiling price calculated by the manufacturer to Public Health Service designated entities in order to participate in other federal funding programs including Medicaid. Legislation subsequent to the VHCA has required that certain discounted prices under the VHCA also be offered for specified DoD purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulation.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government, suspension or debarment prohibiting us from participating in federal procurement and non-procurement transactions, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in some states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing specified physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit other specified sales and marketing practices. Additionally, some states have enacted laws that cap increases in prices charged for drugs in that state. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

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. Our products are reimbursed or purchased under several government programs, including Medicaid, Medicare Parts B and D, the 340B Drug Pricing Program/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. Third-party payers also may choose not to cover our products or implement measures such as prior authorizations and step-throughs to secure coverage and reimbursement. 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 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. Similarly, the Inflation Reduction Act of 2022 requires manufacturers of selected drugs to negotiate discounted prices with the Secretary of the Department of Health and Human Services. Failure to reach an agreement can subject manufacturers to an excise tax or withdraw of all drug products from coverage under Medicare and Medicaid. 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. Adoption of price controls and cost-containment measures, along with adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved product(s). 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, less favorable coverage policies and reimbursement rates may be implemented in the future. Any reduction in reimbursement from Medicare and/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 the generation of revenue, attainment of profitability, or commercialization of products. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations.

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. Effective for calendar quarters beginning January 1, 2022, manufacturers are 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). Previously, the rebate was capped at 100% of the average manufacturer price, but, effective January 1, 2024, this cap on the rebate was 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 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, including the VA, DoD, Coast Guard, and 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 the 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 expect further 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 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 and funded 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.

Employee Development

The ongoing development of our employees continues to be a catalyst for our growth and success as a company. Many of our employees have obtained advanced degrees in their professions. We support our employees' further development with individualized development plans, mentoring, coaching, department-level training, and conference attendance. Pursuant to our educational assistance policy, we also provide employees interested in furthering their formal education with tuition reimbursement for pre-approved coursework. We often require employees to complete a training effectiveness evaluation for instructor-led trainings at ADMA, and we use the results of these evaluations to improve future in-house trainings.

Health and Safety

We remain focused on promoting the total wellness of our employees, including resources, programs and services to support their physical, mental and financial well-being. For example, we host an internal health and wellness portal where employees can learn more about, among other things, mental health and stress management, weight management and financial wellness. The portal includes, among other things, mindfulness and meditation podcasts, flyers and newsletters dedicated to promoting mental health and gym discounts. We have recently bolstered our health insurance to cover the reimbursement of weight management therapies which were previously excluded by our insurance carrier. We have established safety policies and protocols, and we regularly update our employees with respect to any changes. We also encourage those who may be ill to stay home. To further protect our on-site employees, we have provided personal protective equipment and cleaning supplies. We have also provided general information updates and support for our employees to ensure that they have resources and information to protect their health and that of those around them, including their families and co-workers. Furthermore, we offer, at no cost, an Employee Assistance Program ("EAP") to help employees and their dependents confidentially manage personal problems that they feel may adversely affect job performance or personal well-being. The EAP offers personal counseling services for a wide range of concerns, including alcohol abuse, drug abuse, parenting support, marital/family relationships, interpersonal problems on the job, stress, depression, and referrals for financial and/or legal challenges.

Employee Communications and Engagement

We employ a variety of tools to facilitate open and direct communication including open forums with executives (such as regular town hall meetings and management meetings), employee surveys and an open-door policy. We endeavor to further refine our employee programs through our employee engagement survey. We actively monitor employee engagement to foster a supportive and high-performing workplace. In 2023, our engagement survey achieved a 92% participation rate, exceeding 91% in 2020, despite a 14% workforce increase - well above industry benchmarks. Results showed a 3% rise in overall engagement and an 11% improvement in leadership communication compared to the 2020 survey. Survey results are shared across the organization to provide greater transparency into employee responses and to reinforce how employee feedback directly informs leadership decisions. By consistently tracking and acting on engagement data, we strengthen our commitment to a collaborative, communicative, and employee-focused culture.

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, 2024, we had a total of 685 employees, eight of whom are part-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.

- Although we achieved net income on a GAAP basis for the year ended December 31, 2024 for the first time, we may not be able to maintain profitability and continue to generate positive cashflows in the future.

- We contract with third parties for the filling, packaging, testing and labeling of the drug substance we manufacture, and we also obtain source plasma from certain third parties. This reliance on third parties carries the risk that the services and raw materials 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.

- 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, 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, 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 unless additional clinical trials are conducted successfully and the FDA approves a Biologics License Application ("BLA") or other required submission for review.

- 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.

- We depend on third-party researchers, developers and vendors to develop, manufacture, supply materials for or test our 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 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 accruals for U.S. Medicaid rebates and other liabilities related to the sale of our immunoglobulin products are estimates based on historical experience and other assumptions. These estimates are subject to change based on actual results and other factors. Any such change could have a material effect on our business, financial position and operating results.

- 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 maintain profitability may be adversely impacted.

- Our ADMA BioCenters operations collect information from donors in the United States 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 or otherwise penetrate our network, 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 and high-titer plasma with proper specifications or other necessary raw materials.

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

- Fluctuations in our tax obligations and effective tax rate and realization of our net deferred tax assets may result in volatility of our operating results and materially impact our financial condition or financial results.

- 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

Although we achieved net income on a GAAP basis for the year ended December 31, 2024 for the first time, we may not be able to maintain profitability andcontinue to generate positive cash flows in the future.

We have a history of losses through December 31, 2023, and we may not be able to maintain profitability. Although we achieved net income of $197.7 million for the year ended December 31, 2024, for the years ended December 31, 2023 and 2022, we incurred net losses of $28.2 million and $65.9 million, respectively. From our inception in 2004 through December 31, 2024, we have incurred an accumulated deficit of $308.6 million. We may not be able to maintain profitability in 2025 or beyond, and if we are unable to continue to consistently achieve positive cash flows we may need to finance our operations through additional equity or debt financings or corporate collaboration and licensing agreements. If, in the future, our operating or financial results for a particular period do not meet our guidance, analyst estimates or the expectations of investors, or if we reduce our guidance for future periods, our stock price may decline. Any sustained or increased profitability or financial performance may contribute to increased scrutiny from the investment community and applicable federal, state and foreign regulatory authorities and government bodies. 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;

- expand our research and development programs;

- 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 continue 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 unforeseeable 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 and raw materials 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, raw materials 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 contractors 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, or a cyberattack or data breach, could adversely affect our contractors' 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 or in accordance with our specifications 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 production, 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, strikes, embargoes, 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. pneumoniae* hyperimmune globulin are subject to significant variables that can be difficult to measure, estimate or quantify. Additionally, we anticipate receiving FDA approval by mid-2025 for the PAS for our innovative yield enhancement production process, which has demonstrated an ability to increase production yields by approximately 20% from the same starting plasma volume, potentially driving significant increases to financial targets beginning in the second half of 2025, if approved. Although our financial targets for 2025 and 2026 described in Part 1, Item 1. Business- Overview do not account for the potential FDA approval of our innovative yield enhancement production process, in the event that the FDA does not approve the PAS, or in the event that such approval occurs after mid-2025, our growth rate may be materially impacted.

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 and economic 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. Additionally, rapid changes in U.S. trade policy, such as the imposition of additional tariffs and trade barriers, as well as potential retaliatory measures taken by other governments, could increase the price of and/or affect the availability of imported raw materials used in the production of our products. We are unable to predict whether geopolitical or economic conditions, 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, warning letters or other enforcement actions.

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 and breakdown, cyberattacks on our operations and information technology systems as well as the systems of our customers, suppliers and related entities, human error, employee issues, global health occurrences such as a pandemic, global and economic uncertainty, war, terrorism, 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 IND applications 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 the 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 contract research organizations ("CROs");
- Regulators requiring us to perform additional or unanticipated clinical trials to obtain approval or becoming subject to additional post-marketing testing, surveillance, or Risk Evaluation and Mitigation Strategies 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;
- 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 United States, 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 and revenues generated from new contract manufacturing arrangements with third parties. 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 for 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 United States.

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 United States 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 United States 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 United States 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, supply materials for or test our 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. We also depend on third-party suppliers for materials used in our operations. 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. Additionally, certain of our third-party suppliers may be single-sourced or may not be able to supply sufficient materials for our operations, and it may be time-consuming, expensive or otherwise not feasible to locate an alternative supplier. 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 or we may not be able to produce forecasted amounts of product. 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, required 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 years ended December 31, 2024 and 2023, two customers, BioCARE, Inc. ("BioCare") and Priority Healthcare Distribution, Inc. d/b/a CuraScript SD Specialty Distribution ("Curascript"), represented an aggregate of approximately 72% of our consolidated revenues.

As of December 31, 2024, three customers, BioCare, Healix Infusion Therapy, LLC ("Healix") and Cencora, Inc. (f/k/a AmerisourceBergen Corporation), represented an aggregate of approximately 91% of our consolidated accounts receivable. As of December 31, 2023, five customers, BioCare, Healix, Curascript, Cencora, Inc. and Reliance Life Sciences Pvt. Limited ("Reliance"), represented an aggregate of approximately 98% of our consolidated accounts receivable.

The loss of any key customers or a material change in the revenue generated by any of these customers, other than Reliance, 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;
- the impact of a cyberattack or data breach on our customers or related entities; 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 and 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 losses or write-downs occur in any given period. Additionally, 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 accruals for U.S. Medicaid rebates and other liabilities related to the sale of our immunoglobulin products are estimates based on historical experience and other assumptions. These estimates are subject to change based on actual results and other factors. Any such change could have a material effect on our business, financial position, and operating results.

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. Significant estimates include, among other things, accruals for U.S. Medicaid rebates related to the sale of our immunoglobulin products. We accrue these rebates at the time of sale based on our estimates of the sales mix of our products and the portion of the products we sell that will be prescribed to Medicaid beneficiaries. These estimates are based on historical experience and certain other assumptions, and while we believe that such estimates are reasonable, they are subject to change based on future experience, Medicaid utilization trends and other factors. 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 include 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, payer and channel mixes or the ultimate settlement or resolution of payor claims. For example, during 2024 we engaged a third-party specialist to assist in the evaluation of our accrual for U.S. Medicaid rebates related to the sale of our immunoglobulin products. As a result of this evaluation, we recognized a reduction in this accrual and a corresponding increase to net revenues of $12.6 million for the year ended December 31, 2024. We considered several qualitative factors when evaluating our rebate accrual, such as the absence of a statutory limitation on the rebate amounts drug manufacturers pay to state Medicaid programs and general uncertainty that pharmaceutical manufacturers have historically seen with government payors often submitting lagged claims many periods after the initial dispensing of a product to an end patient. There was additional new information that arose during June 2024 that suggested our liabilities for certain payor claims were successfully resolved, which resulted in the $12.6 million adjustment to the accrual for U.S. Medicaid rebates in June 2024.

In addition, the Patient Protection and Affordable Care Act (“ACA”) included a significant expansion of state Medicaid programs. As more individuals become eligible for coverage under these programs, Medicaid utilization of our products could increase, resulting in a corresponding increase in our rebate payments. Such rebate payments may exceed what we have accrued for during the applicable period. Increases in Medicaid rebate payments could decrease our net revenues from product sales, which in turn could adversely affect our business, financial position, and operating results.

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 maintain 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 and plasma attributable to the operations of ADMA BioCenters to support our operations.

Our ADMA BioCenters operations collect information from donors in the United States 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" 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 numbers, 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 credit agreement with Ares (the "Ares Credit Agreement") (see "Liquidity and Capital Resources"). The Ares Credit Agreement provided 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"). On August 14, 2024, we repaid $30.0 million against the revolving credit facility and on December 19, 2024 we repaid $30.0 million against the term loan. As of December 31, 2024, we had $42.5 million and $32.5 million of borrowings outstanding under the revolving credit facility and the term loan, respectively. 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 United States and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater 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, intellectual property assignment agreements 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, invention assignment, 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 United States 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 United States and in foreign jurisdictions. If our products, methods, processes and other technologies are found to infringe third-party patent rights, we could be prohibited from manufacturing and commercializing the infringing technology, process or product unless we obtain a license under the applicable third-party patent and pay royalties or are able to design around such patent. We may be unable to obtain a license on terms acceptable to us, or at all, and we may not be able to redesign our products or processes to avoid infringement. Even if we are able to redesign our products or processes to avoid an infringement claim, our efforts to design around the patent could require significant time, effort and expense and ultimately may lead to an inferior or more costly product and/or process. Any claim of infringement by a third party, even those without merit, could cause us to incur substantial costs defending against the claim and could distract our management from our business. Furthermore, if any such claim is successful, a court could order us to pay substantial damages, including compensatory damages for any infringement, plus prejudgment interest and could, in certain circumstances, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently prohibit us, our licensees, if any, 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 or otherwise penetrate our network, 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. Cybersecurity vulnerabilities can also arise from human error, fraud or malice on the part of our employees, other insiders or third parties, or from technology or product enhancements or the migration of information and data to new technology platforms, systems or applications. Hackers may impersonate our vendors, suppliers or other third parties with whom we do business, which may result in financial harm to our business. 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 United States are enforceable on the federal, state and local levels by criminal, civil and administrative sanctions. Violations of laws such as the FDCA, 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 FDCA can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct. In addition, while regulatory authorities generally do not regulate physicians' discretion in their choice of treatments for their patients, they do restrict communications by manufacturers on unapproved uses of approved products or on the potential safety and efficacy of unapproved products in development. Companies in the United States, Canada and the European Union cannot promote approved products for other indications that are not specifically approved by the competent regulatory authorities such as the FDA in the United States, nor can companies promote unapproved products. In limited circumstances, companies may disseminate to physicians information regarding unapproved uses of approved products or results of studies involving investigational products. If such activities fail to comply with applicable regulations and guidelines of the various regulatory authorities, we may be subject to warnings from, or enforcement action by, these authorities. Furthermore, if such activities are prohibited, it may harm demand for our products. Promotion of unapproved drugs or devices or unapproved indications for a drug or device is a violation of the FDCA 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 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 United States, we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, which would preclude us from commercializing products in those markets.

In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of 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 United States has increasingly focused on regulating the conduct by U.S. businesses occurring outside of the United States, generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business. To enhance compliance with applicable 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 United States and other countries, with regulations differing from country to country. In the United States, 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 United States 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. Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections at domestic and foreign manufacturing facilities from March 2020 until July 2021. If a prolonged government shutdown or regulatory agency disruption 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 capital that may be necessary 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 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 on Form 10-K.

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 we have in place to counter 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 normal source plasma supply self-sufficiency with the approval of our tenth plasma collection center in November 2023, we remain reliant on the purchase of RSV plasma from third parties and the collection of RSV and normal source 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, or that third parties will be able to supply plasma to us in accordance with plasma purchase agreements. 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.

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 United States, 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 ACA and the companion Healthcare and Education Reconciliation Act (which together are referred to as 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 United States, 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 United States may adversely affect our business.

Through the March 2010 adoption of the Healthcare Reform Law in the United States, substantial changes are being made to the current system for paying for healthcare in the United States, including programs to extend medical benefits to millions of individuals who currently lack insurance coverage. 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 rating services. 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

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 provided for total senior secured loans in an aggregate principal amount of $135.0 million, of which $75.0 million is currently outstanding. Borrowings under the Ares Credit Facility currently bear interest at a weighted-average rate of approximately 9.4% 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 remaining term of the Ares Credit Facility of approximately $1.8 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 maintain sufficient positive cash flow to repay our outstanding debt obligations as they mature, we would 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 will 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 has been and will continue to 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 control 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, 2024, we had federal and state NOLs of $265.6 million and $203.4 million, respectively. Federal and state NOLs of approximately $33.4 million and $62.0 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, 2024 and 2023, 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.

Fluctuations in our tax obligations and effective tax rate and realization of our net deferred tax assets may result in volatility of our operating results and materially impact our financial condition or financial results.

We are subject to taxes by the U.S. federal, state, and local tax authorities. We record income tax expense based on our estimates of future payments, which may include the recording of, or adjustments to, liabilities for uncertain tax positions, and changes in the valuation allowance related to our net deferred tax assets. In addition, at any one time multiple tax years may be subject to audit by various tax authorities. The results of these audits and negotiations with taxing authorities may affect the ultimate settlement of these issues and impact our results of operations. We expect that during fiscal year 2025 and beyond there could be ongoing variability in our effective tax rate as events occur and exposures are evaluated. The volatility of our future effective tax rate could be materially impacted by a number of factors, including:

- changes in the valuation of our deferred tax assets and liabilities;
- expected timing and amount of the release of any valuation allowance on our deferred tax assets; or
- changes in U.S. federal, state and local tax rates, tax laws, regulations, or interpretations thereof.

In addition, our effective tax rate in a given financial statement period may be materially impacted by a variety of factors including, but not limited to, changes in the mix and level of earnings, deductible expenses and availability of NOLs in the different states in which we operate, fluctuations in the valuation allowance on our deferred tax assets, or by changes to existing accounting rules or regulations. Further, tax legislation may be enacted or amended, as applicable, in the future which could materially impact our current or future tax structure and effective tax rates. We may be subject to audits of our income, sales, and other transaction taxes by U.S. federal, state, and local taxing authorities. Outcomes from these audits could have a material effect on our financial condition or financial results.

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 March 10, 2025, most of our 237,615,100 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, 2024, BlackRock Inc., The Vanguard Group, Inc., State Street Corporation, Invesco Ltd. and our directors and executive officers and their affiliates owned approximately 37% 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, 2024, there were 36,093,118 shares remaining available for issuance, after giving effect to 11,854,060 shares of our common stock that were subject to outstanding stock options, RSUs and warrants as of December 31, 2024 that may be issued by us without stockholder approval, as well as an additional 15,432,277 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, 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 quickly resumed across the Company's business units.

Governance

Our President and Chief Executive Officer and Chief Operating 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, 2024:

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

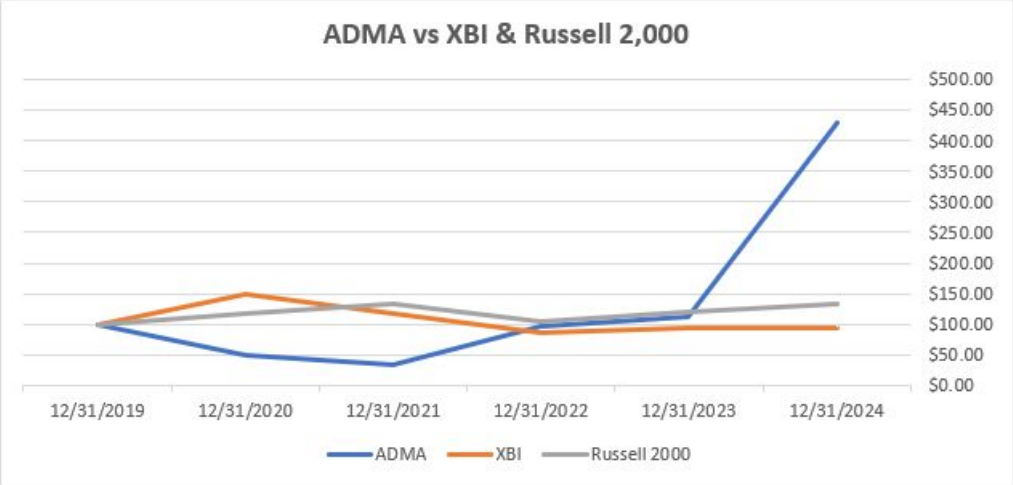
As of December 31, 2024, there were five record holders of our Common Stock, based upon information received from our transfer agent. However, this number does not include beneficial owners whose shares were held of record by nominees or broker dealers. As of February 1, 2025, we estimate that there 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, 2019 in each of the Company's Common Stock, the XBI Biotech Index of biotechnology companies and the Russell 2000 Index.



	2019	2020	2021	2022	2023	2024
ADMA	$ 100.00	$ 48.75	$ 35.25	$ 97.00	$ 113.00	428.75
XBI	$ 100.00	$ 148.02	$ 117.72	$ 87.27	$ 93.88	94.69
Russell 2000	$ 100.00	$ 118.34	$ 134.27	$ 105.25	$ 121.15	133.37

Sale of Unregistered Securities

During the year ended December 31, 2024, 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, 2024.

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 – 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 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 Nos. 10,259,865 and 11,084,870 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*. We have successfully completed production of a pilot-scale batch and are conducting animal studies for our *S. pneumoniae* hyperimmune globulin program, SG-001. 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 projected annual revenues greater than $490 million in 2025 and $605 million in 2026. These revenue targets translate to potential fiscal year 2025 and 2026 Adjusted Net Income exceeding $175 million and $235 million, respectively, and Adjusted EBITDA exceeding $225 million and $305 million, respectively. The foregoing financial targets do not account for the potential FDA approval of our innovative yield enhancement production process described below.

In December 2024, we successfully submitted a Prior Approval Supplement (the "PAS") for potential approval of our innovative yield enhancement production process. Following FDA review of the submission, we anticipate receiving FDA approval by mid-2025, with potential revenue and earnings accretion expected in the second half of the year. This innovative process has demonstrated an ability to increase production yields by approximately 20% from the same starting plasma volume, potentially driving significant increases to financial targets, if approved.

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.

From time to time we may provide contract manufacturing services for certain third-party clients. We also provide laboratory contracting services to certain customers and may provide contract filling, labeling and packing services utilizing our FDA-approved in-house fill-finish capabilities.

For the year ended December 31, 2024 we achieved net income of $197.7 million, the first time in our history that we achieved net income on a GAAP basis, and generated positive cash flow from operations of $118.7 million. Our improved operating results are primarily the result of the substantial revenue growth and continued physician, patient and payer acceptance of ASCENIV.

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 we commenced manufacturing ASCENIV at the 4,400 Liter production scale. This expansion has improved the product's margin profile and increased plant production capacity as fewer batches are needed to support our revenue goals. ASCENIV's prescriber and patient base continued to expand during 2024, which drove record utilization and pull-through for this product. These elevated demand trends have sustained into 2025, and ADMA currently expects that this product's rapid growth will continue throughout 2025 and beyond.

We anticipate filing our supplemental Biologics License Application ("sBLA") in mid-2025, with potential FDA approval in the first half of 2026 for the expansion of ASCENIV's label to include the pediatric setting for patients who are two years and older.

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.

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 condensed 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.

Some of the estimates and assumptions we have to make under U.S. GAAP require very difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, we have identified those as critical accounting estimates, which are considered critical to an understanding of our historical financial condition and results of operations and are reasonably likely to have a material impact on our future results of operations and financial condition. Critical accounting estimates include rebates and potentially certain other deductions from gross revenues, assumptions used in the fair value of awards granted under our equity incentive plans and estimates related to the valuation allowance for our deferred tax assets. For a description of our significant accounting policies, see Note 2 to the Consolidated Financial Statements.

Revenue Deductions for Rebates and Chargebacks

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.

Prior to 2024, 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, our historical experience 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, payer and channel mixes. During 2024, we engaged a third-party specialist to assist in the evaluation of our accrual for U.S. Medicaid rebates related to the sale of our immunoglobulin products. As a result of this evaluation, we recognized a reduction in this accrual and a corresponding increase to net revenues of $12.6 million during the year ended December 31, 2024 (see Note 2 to the Consolidated Financial Statements). We considered several qualitative factors when evaluating our rebate accrual, such as the absence of a statutory limitation on the rebate amounts drug manufacturers pay to state Medicaid programs and general uncertainty that pharmaceutical manufacturers have historically seen with government payors often submitting lagged claims many periods after the initial dispensing of a product to an end patient. There was additional new information that arose during June 2024 that suggested our liabilities for certain payor claims were successfully resolved, which resulted in the $12.6 million adjustment to the accrual for U.S. Medicaid rebates in June 2024. Additional changes in estimate assumptions surrounding U.S. Medicaid and other rebate obligations could materially impact our revenues and our results of operations in the future.

Stock-Based Compensation

All equity-based payments, including grants of stock options and restricted stock units (“RSUs”), are recognized at their estimated fair value at the date of grant, and compensation expense is recognized on a straight-line basis over the grantee’s requisite vesting period. For the purpose of valuing stock options granted to our employees, directors and executive officers, we use the Black-Scholes option pricing model. We also use the Black-Scholes model when determining additional compensation cost resulting from the modification to previously issued option grants. 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 term of our awards. The expected term of the options granted is in accordance with U.S. Securities and Exchange Commission (“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. 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 our election to utilize an alternative method for valuing stock options granted to employees, directors and executive officers, could potentially impact our stock-based compensation expense and our results of operations.

Deferred Tax Assets

Prior to December 31, 2024, we maintained a full valuation allowance against all of our net deferred tax assets, and as a result we have historically not recorded an income tax benefit in the accompanying consolidated financial statements despite continued losses through December 31, 2023. This valuation allowance reflected our assessment of whether it is more likely than not that we would 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, and we considered cumulative losses in recent years to be a significant type of negative evidence. As of December 31, 2024, we determined that it is more-likely-than-not that our federal and state deferred tax assets will be realized. As a result, we recorded a release of the valuation allowance associated with these deferred tax assets, which was due in part to achieving three years of cumulative taxable income and projected taxable income that is more than sufficient to realize our federal and state deferred tax assets, and we recorded a deferred income tax benefit in the amount of $84.3 million for the year ended December 31, 2024 (see Note 11 to the consolidated financial statements).

Year Ended December 31, 2024 Compared to Year Ended December 31, 2023

The following table presents a summary of the changes in our results of operations for the year ended December 31, 2024 compared to the year ended December 31, 2023:

	Year Ended December 31,		
(in thousands)	**2024**	**2023**	**Increase (Decrease)**
Revenues	$ 426,454	$ 258,215	$ 168,239
Cost of product revenue	206,901	169,273	37,628
Gross profit	219,553	88,942	130,611
Research and development expenses	1,813	3,300	(1,487)
Plasma center operating expenses	4,245	4,266	(21)
Amortization of intangibles	388	724	(336)
Selling, general and administrative expenses	74,124	59,020	15,104
Income from operations	138,983	21,632	117,351
Interest expense	(13,930)	(25,027)	11,097
Loss on extinguishment of debt	(1,243)	(26,174)	24,931
Other income, net	1,904	1,330	574
Income (loss) from before taxes	125,714	(28,239)	153,953
Income tax benefit	(71,959)	-	(71,959)
Net income (loss)	$ 197,673	$ (28,239)	$ 225,912
Adjusted EBITDA *	$ 164,612	$ 40,251	$ 124,361
Adjusted net income*	$ 119,218	$ 705	$ 118,513

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

Revenues

We recorded total revenues of $426.5 million for the year ended December 31, 2024, as compared to $258.2 million for the year ended December 31, 2023, an increase of $168.2 million, or 65%. Excluding the $12.6 million adjustment we recorded in the second quarter of 2024 to decrease our accrual for estimated U.S. Medicaid rebates (which had the effect of increasing net revenues by $12.6 million), revenue increased by approximately $155.6 million, or 60%. This increase is primarily related to increased sales of ASCENIV, as we continue to experience increased physician, payer and patient acceptance and utilization of this product, as well as sales increases for some of our other IG products. The revenue increase also includes an increase in sales of normal source plasma ("NSP") and hyperimmune Hepatitis B plasma by our Plasma Collection Centers business segment in the amount of $2.2 million.

Cost of Product Revenue and Gross Profit

Cost of product revenue was $206.9 million for the year ended December 31, 2024, as compared to $169.3 million for the year ended December 31, 2023. This increase is primarily attributable to volume-driven increases in product revenue costs related to our increased sales of IG products and plasma of $39.5 million and $3.1 million, respectively, partially offset by a reduction in other manufacturing costs, mainly unabsorbed manufacturing expenses, of $5.1 million.

For the year ended December 31, 2024, we had gross profit of $219.6 million, as compared to $88.9 million for the prior year, which represents a gross margin for fiscal 2024 of 51.5%, as compared to 34.4% for fiscal 2023. Excluding the $12.6 million adjustment we recorded in the second quarter of 2024 to reduce our accrual for estimated U.S. Medicaid rebates, our gross profit for the year ended December 31, 2024 was approximately $207.0 million, representing a gross margin of approximately 50.0%. The improvement in gross margin is mainly driven by a significantly more favorable mix of higher margin IG sales in 2024 as compared to 2023, along with the reduction in other manufacturing costs. We expect to see further shifts in our revenue mix toward higher margin IVIG products in fiscal 2025.

Research and Development Expenses

Research and development ("R&D") expenses totaled $1.8 million for the year ended December 31, 2024, as compared to $3.3 million for the year ended December 31, 2023. The decrease is primarily due to the absence of expenditures in 2024 related to the BIVIGAM post-marketing commitments, for which we incurred $1.7 million of expenses in 2023, partially offset by an increase in expenses associated with our ASCENIV pediatric study in the amount of $0.3 million.

Plasma Center Operating Expenses

Plasma center operating expenses, which primarily consists of compensation, benefits and travel for plasma center management and administrative staff, along with certain initial opening, marketing and start-up costs, were essentially unchanged at $4.2 million for the year ended December 31, 2024 as compared to approximately $4.3 million for the year ended December 31, 2023.

Amortization of Intangibles

Amortization expense mainly pertains to the amortization of intangible assets acquired in a 2017 acquisition transaction and was $0.4 million and $0.7 million for the years ended December 31, 2024 and 2023, respectively. The intangible assets acquired in 2017 became fully amortized in June of 2024.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses were $74.1 million for the year ended December 31, 2024, an increase of $15.1 million from the year ended December 31, 2023, and reflects an increase in stock-based compensation expense of $6.4 million in 2024, largely due to the higher valuation of grants awarded in 2024 and to additional compensation expense recognized for the modification of certain outstanding equity awards. The increase in SG&A also reflects increases in employee-related costs, including salaries and wages, benefits, relocation and recruiting, in the aggregate amount of $4.8 million, software maintenance expense of $1.2 million, consulting and professional fees of $0.9 million, audit and tax fees of $0.6 million, insurance expense of $0.6 million and temporary labor expense of $0.7 million. SG&A expenses as a percentage of net revenues decreased from 22.9% in fiscal 2023 to 17.4% in fiscal 2024.

Income from Operations

Our operating income was $139.0 million for the year ended December 31, 2024, as compared to $21.6 million for the year ended December 31, 2023. The $117.4 million increase in operating income was mainly due to the improved gross profit, driven by both the year-over-year revenue growth and the shift in revenue mix toward significantly higher margin IVIG products, partially offset by $13.3 million of higher total operating expenses. The higher gross profit also reflects the foregoing adjustment to our accrual for estimated U.S. Medicaid rebates which increased our revenues for the year ended December 31, 2024 by $12.6 million.

Interest Expense

Interest expense for the year ended December 31, 2024 was $13.9 million, as compared to $25.0 million for the year ended December 31, 2023. Prior to the refinancing of our senior debt on December 18, 2023 (see "Liquidity and Capital Resources"), our outstanding debt principal balance throughout 2023 ranged between $155.1 million and $158.6 million. The refinancing transaction reduced our debt principal to $135.0 million as of December 31, 2023, and we made additional principal payments on this indebtedness of $30.0 million on each of August 14, 2024 and December 19, 2024, reducing our debt principal balance to $75.0 million as of December 31, 2024. In addition, the stated interest rate on our debt during 2024 was approximately 10.1%, as compared to approximately 13.9% during 2023. We also incurred lower expense related to the amortization of debt discount in 2024 in the amount of $1.6 million. We expect our interest expense to continue to decline in 2025 due to the reduced debt principal balance and potential further repayments on our outstanding debt.

Loss on Extinguishment of Debt

As a result of the prepayment we made on our senior debt on December 19, 2024, we incurred a prepayment penalty in the amount of $0.45 million and recorded a partial write-down of unamortized debt discount of approximately $0.8 million, for a loss on this partial extinguishment of debt in the amount of $1.2 million. 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 Note 7 to the Consolidated Financial Statements).

Other Income, Net

Other income, net, for the year ended December 31, 2024 was $1.9 million, as compared to $1.3 million for the year ended December 31, 2023. The increase is mainly due to an increase in interest income of $0.5 million in 2024 resulting from higher average cash balances in 2024.

Income Tax Benefit

We recorded a total income tax benefit of $72.0 million for the year ended December 31, 2024, with no comparable amount for the year ended December 31, 2023. The provision for income taxes for fiscal 2024 includes a deferred tax benefit of $84.3 million related to the release of the valuation allowance against our net deferred tax assets, partially offset by current income tax expense of $12.3 million, which reflects federal and state income tax liabilities that are not fully sheltered by NOLs due to limitations from prior ownership changes and other limitations on net operating loss carryforwards under the Internal Revenue Code of 1986, as amended (see "Risk Factors - Our ability to use our net operating loss carryforwards ("NOLs") may be limited." appearing elsewhere in this report and Note 11 to the Consolidated Financial Statements). We expect that we will record income tax expense in 2025 and beyond as we expect to continue to generate additional taxable income for the foreseeable future.

Net Income/Loss

Our net income was $197.7 million for the year ended December 31, 2024, as compared to a net loss of $28.2 million for the year ended December 31, 2023, an improvement of $225.9 million. The increase was primarily due to the increase in operating income of $117.4 million, lower interest expense of $11.1 million discussed above, a reduced loss on the extinguishment of debt as compared to fiscal 2023 and the income tax benefit of $72.0 million. The foregoing change in estimate in our accrual for Medicaid rebates favorably impacted our net after-tax income for the year ended December 31, 2024 by approximately $11.4 million.

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,		
(in thousands)	2023	2022	Increase (Decrease)
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

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, largely driven by the year-over-year revenue growth and shift in revenue mix toward higher margin IVIG products, 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 of 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.

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, 2024, 2023 and 2022:

	Year Ended December 31,		
	2024	2023	2022
		(In thousands)	
Net income (loss)	$ 197,673	$ (28,239)	$ (65,904)
Depreciation	7,657	7,608	6,398
Amortization	388	724	715
Income tax benefit	(71,959)	-	-
Interest expense	13,930	25,027	19,279
EBITDA	147,689	5,120	(39,512)
Stock-based compensation	13,616	6,187	5,215
Loss on extinguishment of debt	1,243	26,174	6,670
Yield enhancement	2,064	-	-
IT systems disruption	-	2,770	-
Adjusted EBITDA	$ 164,612	$ 40,251	$ (27,627)

Adjusted EBITDA improved by $122.3 million for the year ended December 31, 2024 as compared to the year ended December 31, 2023, mainly due to the substantial increase in operating income in 2024 of $117.4 million. 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.

The following table presents the reconciliation of Net income (loss) to Adjusted net income (loss) for the years ended December 31, 2024, 2023 and 2022:

	Years Ended December 31,		
(in thousands)	**2024**	**2023**	**2022**
Net income (loss)	$ 197,673	$ (28,239)	$ (65,904)
Loss on extinguishment of debt	1,243	26,174	6,670
Deferred tax benefit	(84,280)	-	-
Yield enhancement	2,064	-	-
Stock-based compenstion modifications	2,518	-	-
IT systems disruption	-	2,770	-
Adjusted net income (loss)	$ 119,218	$ 705	$ (59,234)

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2024, we had working capital of $275.9 million, primarily consisting of $170.2 million of inventory, cash and cash equivalents of $103.1 million and $50.0 million of accounts receivable, partially offset by current liabilities of $55.5 million, as compared to working capital at December 31, 2023 of $207.2 million, primarily consisting of $172.9 million of inventory, cash and cash equivalents of $51.4 million and accounts receivable of $27.4 million, partially offset by current liabilities of $49.8 million. Although we have incurred an accumulated deficit of $308.6 million since inception, we had positive cash flow from operations for the years ended December 31, 2024 and 2023 of $118.7 million and $8.8 million for the years ended December 31, 2024 and 2023, respectively. Prior to fiscal 2024, we funded our operations over the previous 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, improvements, repairs and supplies;
- Conducting required post-marketing clinical trials for ASCENIV; and
- Continuous improvements and updates to our IT infrastructure, laboratory equipment and assays, and facilities and engineering equipment.

As we continue to onboard new staff and expand production at the Boca Facility, we may also decide to use cash on hand, in whole or in part, to purchase additional real estate to add redundancies, expand operations and prepare for future growth opportunities. 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, 2024, we had pre-tax income and GAAP net income of $125.7 million and $197.7 million, respectively. 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 2026. However, our current outlook with respect to cash flows and profitability may change based upon several factors, including the continued 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 2025, we may choose to raise additional capital. If we are unable to generate sufficient revenue to maintain positive cash flow throughout fiscal 2025 and elect 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 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 provided 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 in the year ended December 31, 2023, which is mainly comprised of the write-off of unamortized debt discount and the prepayment penalty.

On August 14, 2024, we repaid $30.0 million against the revolving credit facility and the outstanding balance on the revolving credit facility as of December 31, 2024 was $42.5 million. On December 19, 2024 we repaid $30.0 million against the term loan and the outstanding balance on the term loan as of December 31, 2024 was $32.5 million. In connection with the repayment against the term loan, we recognized a loss on extinguishment of debt in the approximate amount of $1.2 million, which is comprised of a prepayment penalty in the amount of $0.45 million and a partial write-off of unamortized discount attributable to the term loan in the amount of $0.8 million.

Borrowings under the term loan 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 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%. As of December 31, 2024, the interest rate on the term loan was approximately 10.9% and the interest rate on the revolving facility was approximately 8.3%, representing a weighted-average interest rate of approximately 9.4%.

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 $1.8 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 pay down an aggregate amount under the revolving facility that is greater than 50% of revolving facility commitment of $72.5 million, we will still be required to pay interest on 50% of this amount, 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 obligation has been accrued as a separate liability in our consolidated balance sheet as of December 31, 2024 and 2023 in the amount of $1.3 million and $1.7 million, respectively. 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, 2024 and 2023 was 10.81% and 11.39%, respectively. In connection with the prepayment of the term loan on December 19, 2024, we also paid a pro rata portion of the exit fee in the amount of $0.4 million.

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, 2024, 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, 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 our termination of the Hayfin Credit Agreement. 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.

Cash Flows

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

(in thousands)	Year Ended December 31, 2024	2023	2022
Net cash provided by (used in) operating activities	$ 118,672	$ 8,800	$ (59,508)
Net cash used in investing activities	(8,575)	(4,981)	(13,911)
Net cash (used in) provided by financing activities	(58,302)	(38,989)	108,852
Net change in cash and cash equivalents	51,795	(35,170)	35,433
Cash and cash equivalents - beginning of year	51,352	86,522	51,089
Cash and cash equivalents - end of year	$ 103,147	$ 51,352	$ 86,522

Net Cash Provided by (Used in) Operating Activities

Cash provided by operations for the year ended December 31, 2024 was $118.7 million, as compared to $8.8 million for the year ended December 31, 2023. The increase is mainly due to substantially higher net income. The improvement in cash flow from operations in 2023 as compared to the year ended December 31, 2022 was mainly due to the improvement in our operating results, driven by higher revenues and gross margins, and a lower increase in inventories. The following table illustrates the primary components of our cash flows from operations:

(in thousands)	Year Ended December 31, 2024	2023	2022
Net income (loss)	$ 197,673	$ (28,239)	$ (65,904)
Non-cash expenses, gains and losses	(60,462)	47,162	24,682
Changes in accounts receivable	(22,578)	(11,916)	13,072
Changes in inventories	2,671	(9,626)	(38,556)
Changes in accounts payable and accrued expenses	5,192	11,369	8,334
Other	(3,824)	50	(1,136)
Cash provided by (used in) operations	$ 118,672	$ 8,800	$ (59,508)

Net Cash Used in Investing Activities

Cash used in investing activities for the year ended December 31, 2024 was $8.6 million and is mainly comprised of equipment purchases and other capital expenditures at the Boca Facility. 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. While we do not have any firm commitments for material capital expenditures in 2025, we expect our total capital expenditures will be between $12.0 million and $18.0 million for fiscal 2025.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities for the year ended December 31, 2024 was $58.3 million and was primarily composed of an aggregate of $60.0 million of debt principal payments during the year. 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 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.

Effect of Inflation

Inflation impacted a number of facets of our business during the years ended December 31, 2024, 2023 and 2022 at each of our business segments. Disruptions in the global economy have impeded global supply chains, resulted in longer lead times and delays in procuring certain raw materials, and resulted in inflationary cost increases in certain raw materials, labor and transportation. We also experienced price increases for, among other items, 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 subside somewhat in 2025, however we cannot predict the extent to which future domestic and global economic conditions including, but not limited to, supply chain constraints or geopolitical conditions, including the continuing conflicts in Europe and in the Middle East and surrounding areas, could have a significant impact on our future results of operations. In addition, some of our third-party inventory purchase agreements provide for scheduled price increases that are tied to various consumer price indices, which have resulted in higher than historical percentage price increases and could result in higher source plasma and other raw material and supplies costs in 2025 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.

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, 2024, we had $75.0 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 $0.8 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, 2024. 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, 2024, 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 Firms

The effectiveness of our internal control over financial reporting as of December 31, 2024 has been audited by KPMG. KPMG is an independent registered public accounting firm, as stated in their reports which appear 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 ending December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

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 constitute a non-Rule 10b5-1 trading arrangement under the Exchange Act.

During the quarter ended December 31, 2024, none of our directors or executive officers adopted or terminated any such contract, instruction or written plans except for Adam Grossman, our President and CEO, who entered into a Rule 105b-1 trading plan with Fidelity Brokerage Services LLC on December 5, 2024 (the "Grossman Plan"). The Grossman Plan provides that Mr. Grossman may sell up to an aggregate of (i) 60,000 shares of our common stock and (ii) 150,000 shares of our common stock to be received upon the exercise of vested options granted to Mr. Grossman. The Grossman Plan is scheduled to terminate on December 31, 2025, subject to earlier termination upon the sale of all shares subject to the plan, upon termination by Mr. Grossman or the broker, or as otherwise provided in the plan.

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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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.

Our Insider Trading Policy governs transactions in our securities by our directors, officers and employees and is designed to promote compliance with applicable insider trading laws, rules and regulations. A copy of our Insider Trading Policy is filed with this Annual Report on Form 10-K as Exhibit 19.

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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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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Management's Annual Report on Internal Control Over Financial Reporting	F-2
Reports of Independent Registered Public Accounting Firm (PCAOB ID 185)	F-3
Report of Independent Registered Public Accounting Firm (PCAOB ID 596)	F-7
Consolidated Balance Sheets as of December 31, 2024 and 2023	F-8
Consolidated Statements of Operations for the years ended December 31, 2024, 2023 and 2022	F-9
Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2024, 2023 and 2022	F-10
Consolidated Statements of Cash Flows for the years ended December 31, 2024, 2023 and 2022	F-11
Notes to Consolidated Financial Statements	F-12

(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 herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 28, 2021).
3.2	Second 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 June 28, 2024).
3.3	Amended and Restated Certificate of Designation of Series A Junior Participating Preferred Stock of ADMA Biologics, Inc. (incorporated herein 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 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 herein by reference to Exhibit 4.13 to the Company's Annual Report on Form 10-K, filed with the SEC on March 24, 2022).
4.3	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 herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 2, 2023).
4.4	Description of Securities Registered under Section 12 of the Securities Exchange Act of 1934 (incorporated herein by reference to Exhibit 4.11 to the Company's Annual Report on Form 10-K, filed with the SEC on March 24, 2022).
10.1†	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).
10.2†	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 SEC on June 21, 2022).
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 herein 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†	Employment Agreement, dated April 1, 2024, by and between ADMA Biologics, Inc. and Kaitlin Kestenberg (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on April 2, 2024).
10.5†	Employment Agreement, dated as of July 24, 2024, by and between ADMA Biologics, Inc. and Brad Tade (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 26, 2024).
10.6†	Consulting Services Agreement, effective as of April 1, 2024, by and between ADMA Biologics, Inc. and Brian Lenz (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 28, 2024).
10.7++*	Amended and Restated Plasma Purchase Agreement, effective as of October 1, 2024, by and between Grifols Worldwide Operations Limited and ADMA BioManufacturing, LLC.
10.8++*	Plasma Purchase Agreement, effective as of August 6, 2024, by and between KEDPlasma LLC and ADMA BioManufacturing, LLC.
10.9+	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).

10.9.1+	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).
10.10	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).
10.10.1	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 13, 2020).
10.10.2	Amendment 4 to the Amended and Restated Agreement For Services Between ADMA BioManufacturing, LLC and Areth LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2022).
10.11*	Form of Indemnification Agreement.
10.12+	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).
10.12.1	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).
10.13	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).
10.14	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).
16.1	Letter, dated October 9, 2024, from CohnReznick LLP addressed to the Commission (incorporated herein by reference to Exhibit 16.1 to the Registrant's Current Report on Form 8-K filed with the Commission on October 9, 2024).
19.1*	The Company's Insider Trading Policy, effective September 2024.
21.1*	Subsidiaries of the Company.
23.1*	Consent of KPMG LLP.
23.2*	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 (incorporated herein by reference to Ex. 97 to the Company's Annual Report on Form 10-K filed with the Commission on February 28, 2024).
101*	The following materials from ADMA Biologics, Inc. Form 10-K for the year ended December 31, 2024, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at December 31, 2024 and December 31, 2023, (ii) Consolidated Statements of Operations for the years ended December 31, 2024, 2023 and 2022, (iii) Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2024, 2023 and 2022, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2024, 2023 and 2022; 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: March 18, 2025

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

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

Signature	Title	Date
/s/ Adam S. Grossman Adam S. Grossman	President and Chief Executive Officer (Principal Executive Officer) and Director	March 18, 2025
/s/ Brad Tade Brad Tade	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 18, 2025
/s/ Steven A. Elms Steven A. Elms	Chairman of the Board of Directors	March 18, 2025
/s/ Dr. Jerrold B. Grossman Dr. Jerrold B. Grossman	Vice Chairman of the Board of Directors	March 18, 2025
/s/ Alison Finger Alison Finger	Director	March 18, 2025
/s/ Lawrence P. Guiheen Lawrence P. Guiheen	Director	March 18, 2025
/s/ Young T. Kwon Young T. Kwon	Director	March 18, 2025
/s/ Eduardo Rene Salas Eduardo Rene Salas	Director	March 18, 2025

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, 2024. 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, 2024 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, 2024. 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

March 18, 2025

/s/ Brad Tade
Brad Tade
Chief Financial Officer

March 18, 2025



Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited ADMA Biologics, Inc. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2024, 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 Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheet of the Company as of December 31, 2024, the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the year ended December 31, 2024, and the related notes and financial statement schedule II - valuation and qualifying accounts(collectively, the consolidated financial statements), and our report dated March 18, 2025 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ KPMG LLP

Stamford, Connecticut
March 18, 2025



Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of ADMA Biologics, Inc. and subsidiaries (the Company) as of December 31, 2024, the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the period ended December 31, 2024, and the related notes and financial statement schedule II - valuation and qualified accounts (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 18, 2025 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audit 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 audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matter

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

Valuation of the U.S. Medicaid rebate accrual for immunoglobulin products

As disclosed in Note 2 to the consolidated financial statements, the Company recognizes immunoglobulin product revenue net of estimated rebates. The amount of these rebate are based on contractual agreements and historical experience. These estimated rebates include U.S. Medicaid rebates, which, the Company accrues for in the same period the product is sold, however, third-party reporting and payments of the rebate amount occur on a time lag. As of December 31, 2024, the Company had recorded $4.2 million of accrued rebates included in accrued expenses and other liabilities on the balance sheet, of which a portion related to Medicaid rebates.

We identified the estimate of rebate accruals for U.S. Medicaid claims as a critical audit matter. The evaluation of historical claims experience, current sales volumes and the claims processing time lag associated with U.S. Medicaid reporting rebate amounts involved subjective auditor judgement. The key assumptions made included the historical percentage of U.S. Medicaid rebates paid to gross sales and assumption that the historical patterns will be indicative of future patterns.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to the Company's process to estimate the U.S. Medicaid rebate accrual, including historical claims experience, current sales volumes and the claims time lag. We evaluated the U.S. Medicaid rebate accrual by (1) obtaining an understanding of the estimation methodology, (2) recalculating management's estimate of the accrual by utilizing current gross sales and the historical revenue and rebates paid data and(3) testing the appropriateness of the assumptions of using a certain number of months of historical data and that historical results are indicative of future expectations by reviewing the Company's historical trends.

/s/ KPMG LLP

We have served as the Company's auditor since 2024.

Stamford, Connecticut
March 18, 2025

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
ADMA Biologics, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of ADMA Biologics, Inc. and subsidiaries (the "Company") as of December 31, 2023, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two-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").

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 the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audit 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 audit 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.

/s/ CohnReznick LLP

We served as the Company's auditor from 2008 through November 7, 2024.

Parsippany, New Jersey

February 28, 2024, except for Note 11 and Note 13 as to which the date is March 18, 2025

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
Years Ended December 31, 2024 and 2023

	December 31, 2024	December 31, 2023
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 103,147	$ 51,352
Accounts receivable, net	49,999	27,421
Inventories	170,235	172,906
Prepaid expenses and other current assets	8,029	5,334
Total current assets	331,410	257,013
Property and equipment, net	54,707	53,835
Intangible assets, net	460	499
Goodwill	3,530	3,530
Deferred tax assets, net	84,280	-
Right-of-use assets	8,634	9,635
Deposits and other assets	5,657	4,670
TOTAL ASSETS	$ 488,678	$ 329,182
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 20,219	$ 15,660
Accrued expenses and other current liabilities	33,962	32,919
Current portion of deferred revenue	143	182
Current portion of lease obligations	1,218	1,045
Total current liabilities	55,542	49,806
Senior notes payable, net of discount	72,337	130,594
Deferred revenue, net of current portion	1,547	1,690
End of term fee	1,313	1,688
Lease obligations, net of current portion	8,561	9,779
Other non-current liabilities	360	419
TOTAL LIABILITIES	139,660	193,976
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, 236,620,545 and 226,063,032 shares issued and outstanding at December 31, 2024 and December 31, 2023	24	23
Additional paid-in capital	657,577	641,439
Accumulated deficit	(308,583)	(506,256)
TOTAL STOCKHOLDERS' EQUITY	349,018	135,206
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 488,678	$ 329,182

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,		
	2024	2023	2022
	(In thousands, except share and per share data)		
REVENUES	$ 426,454	$ 258,215	$ 154,080
Cost of product revenue	206,901	169,273	118,815
Gross profit	219,553	88,942	35,265
OPERATING EXPENSES:			
Research and development	1,813	3,300	3,614
Plasma center operating expenses	4,245	4,266	17,843
Amortization of intangible assets	388	724	715
Selling, general and administrative	74,124	59,020	52,458
Total operating expenses	80,570	67,310	74,630
INCOME (LOSS) FROM OPERATIONS	138,983	21,632	(39,365)
OTHER INCOME (EXPENSE):			
Interest income	2,097	1,617	45
Interest expense	(13,930)	(25,027)	(19,279)
Loss on extinguishment of debt	(1,243)	(26,174)	(6,670)
Other expense	(193)	(287)	(635)
Other expense, net	(13,269)	(49,871)	(26,539)
INCOME (LOSS) BEFORE INCOME TAXES	125,714	(28,239)	(65,904)
Income tax benefit	(71,959)	-	-
NET INCOME (LOSS)	$ 197,673	$ (28,239)	$ (65,904)
BASIC EARNINGS (LOSS) PER COMMON SHARE	$ 0.85	$ (0.13)	$ (0.33)
DILUTED EARNINGS (LOSS) PER COMMON SHARE	$ 0.81	$ (0.13)	$ (0.33)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:			
Basic	233,084,236	223,977,315	197,874,895
Diluted	243,342,466	223,977,315	197,874,895

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, 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	226,063,032	23	641,439	(506,256)	135,206
Stock-based compensation	-	-	13,616	-	13,616
Vesting of Restricted Stock Units, net of shares withheld for taxes	1,344,555	-	(4,971)	-	(4,971)
Exercise of stock options	1,988,066	-	7,494		7,494
Cashless exercise of warrants	7,224,892	1	(1)	-	-
Net income	-	-	-	197,673	197,673
Balance at December 31, 2024	236,620,545	$ 24	$ 657,577	$ (308,583)	$ 349,018

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,		
	2024	2023	2022
		(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$ 197,673	$ (28,239)	$ (65,904)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	8,045	8,332	7,113
Loss on disposal of fixed assets	106	182	427
Deferred income tax benefit	(84,280)	-	-
Interest paid in kind	-	3,836	2,998
Stock-based compensation	13,616	6,187	5,215
Amortization of debt discount	951	2,594	2,402
Loss on extinguishment of debt	1,243	26,174	6,670
Amortization of license revenue	(143)	(143)	(143)
Changes in operating assets and liabilities:			
Accounts receivable	(22,578)	(11,916)	13,072
Inventories	2,671	(9,626)	(38,556)
Prepaid expenses and other current assets	(2,695)	(239)	(756)
Deposits and other assets	15	1,080	122
Accounts payable	4,150	3,839	800
Accrued expenses	1,042	7,530	7,534
Other current and non-current liabilities	(1,144)	(791)	(502)
Net cash provided by (used in) operating activities	118,672	8,800	(59,508)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(8,226)	(4,771)	(13,911)
Acquisition of intangible assets	(349)	(210)	-
Net cash used in investing activities	(8,575)	(4,981)	(13,911)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Principal payments on notes payable	(60,000)	(158,584)	(100,000)
Proceeds from issuance of common stock, net of offering expenses	-	-	64,645
Prepayment penalties on repayment of debt	(450)	(11,140)	(2,000)
Proceeds from issuance of note payable	-	135,000	151,750
Taxes paid on vested Restricted Stock Units	(4,971)	(1,415)	(2,899)
Payments on finance lease obligations	-	(17)	(36)
Net proceeds from the exercise of stock options	7,494	1,104	175
Payment of end of term fee	(375)	(1,586)	-
Payment of deferred financing fees	-	(2,351)	(2,783)
Net cash (used in) provided by financing activities	(58,302)	(38,989)	108,852
Net increase (decrease) in cash and cash equivalents	51,795	(35,170)	35,433
Cash and cash equivalents - beginning of year	51,352	86,522	51,089
Cash and cash equivalents - end of year	$ 103,147	$ 51,352	$ 86,522

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.

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, 2024, 2023 and 2022, comprehensive income (loss) was equal to the net income (loss) amounts presented for the respective periods in the accompanying consolidated statements of operations. In addition, certain prior year balances have been reclassified to conform to the current presentation. Specifically, the disaggregation of some of the Company's accrued expenses and other current liabilities (see Note 6) and deferred tax assets and liabilities, as well as the rate reconciliation for U.S. federal income taxes (see Note 11), as of December 31, 2023 have been adjusted to conform to the presentation as of December 31, 2024.

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, assumptions used in the fair value of awards granted under the Company's equity incentive plans and the valuation allowance for the Company's deferred tax assets.

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The Company engaged a third-party specialist to assist in the evaluation of the Company's accrual for U.S. Medicaid rebates related to the sale of the Company's immunoglobulin products. As a result of this evaluation, the Company recognized a reduction in this accrual and a corresponding increase to net revenues of $12.6 million for the year ended December 31, 2024. The Company considered several qualitative factors when evaluating its rebate accrual, such as the absence of a statutory limitation on the rebate amounts drug manufacturers pay to state Medicaid programs and general uncertainty that pharmaceutical manufacturers have historically seen with government payors often submitting lagged claims many periods after the initial dispensing of a product to an end patient. There was additional new information that arose during June 2024 that suggested the Company's liabilities for certain payor claims were successfully resolved, which resulted in the $12.6 million adjustment to the accrual for U.S. Medicaid rebates in June 2024.

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 $0.2 million and $0.1 million at December 31, 2024 and 2023, respectively, 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.

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 or purchased from third parties, 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.

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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, 2024 and 2023 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, 2024, 2023 and 2022.

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 assessment as of October 1 of each year. The Company's annual goodwill impairment assessments as of October 1, 2024, 2023 and 2022 did not result in any impairment charges related to goodwill for the years ended December 31, 2024, 2023 and 2022.

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, 2024, 2023 and 2022, the Company determined that there was no impairment of its long-lived assets.

Revenue recognition

Revenues for the years ended December 31, 2024, 2023 and 2022 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 and the performance obligation is satisfied. 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.

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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.

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 and the performance obligation is satisfied, which generally occurs at the time of shipment from one of the Company's plasma collection facilities or from a third-party warehouse that is utilized by the Company. Product revenues are recognized at the time of delivery if the Company retains control of the product during shipment.

For all of the Company's product revenues, payment from the customer is typically due within 90 days of sale.

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 $2.7 million, $3.3 million and $2.2 million for the years ended December 31, 2024, 2023 and 2022, 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, which were awarded to two of the Company's executive officers in September of 2021 and vested during fiscal 2022, the Company would periodically assess the probability of vesting for each milestone-based award and adjust 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.

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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 2020 and for previous periods as it relates to the Company's net operating loss carryforwards.

Earnings (Loss) Per Share

Basic earnings (loss) per share is computed by dividing net income or 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 income or 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) and upon the vesting of restricted stock units ("RSUs"). Potentially dilutive common stock in the diluted net earnings (loss) per share computation is excluded to the extent that it would be anti-dilutive. For the year ended December 31, 2024, basic and diluted earnings per share are calculated as follows:

	Year Ended December 31, 2024
Net income available to common stockholders ($000's) (numerator)	$ 197,673
Weighted-average number of common shares (denominator)	233,084,236
Basic earnings per common shares	$ 0.85
Weighted-average number of common shares	233,084,236
Potential shares of common stock arising from outstanding stock options	4,150,584
Potential shares of common stock arising from outstanding warrants	3,085,640
Potential shares of common stock arising from unvested RSUs	3,022,006
Total shares - diluted (denominator)	243,342,466
Diluted earnings per common share	$ 0.81

For the year ended December 31, 2024, there were no shares with an anti-dilutive effect that needed to be excluded from the earnings per share computation. For the years ended December 31, 2023 and 2022, no potentially dilutive securities are included in the computation of diluted loss per share in the accompanying consolidated financial statements as the Company reported a net loss for these periods. For the years ended December 31, 2023 and 2022, 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
Stock Options	5,906,184	8,256,211
Restricted Stock Units	4,657,297	2,866,987
Warrants	12,502,906	13,525,148
Total	23,066,387	24,648,346

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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) also approximates fair value, based on a Level 3 classification under the fair value hierarchy, due to the variable interest rate on this debt.

Recent Accounting Pronouncements

In November of 2024 the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40)*. The amendments in this Update require disclosure, in the notes to the financial statements, of specified information about certain costs and expenses, including but not limited to, purchases of inventory, employee compensation and selling expense. This Update becomes effective for fiscal years beginning after December 15, 2026. The Company has yet to determine the impact this Update may have on the Company's 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 is currently evaluating the impact that this Update may have on the Company's consolidated financial statements.

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 became effective for fiscal years beginning after December 15, 2023 (see Note 13). Adoption of this Update did not have a material impact on the Company's consolidated financial statements.

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

3. INVENTORIES

The following table provides the components of inventories:

	December 31, 2024	December 31, 2023
	(In thousands)	
Raw materials	$ 60,473	$ 52,999
Work-in-process	61,641	49,621
Finished goods	48,121	70,286
Total inventories	$ 170,235	$ 172,906

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.

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, 2024 and 2023 is summarized as follows:

	December 31, 2024	December 31, 2023
	(In thousands)	
Manufacturing and laboratory equipment	$ 21,305	$ 21,093
Office equipment and computer software	5,772	6,062
Furniture and fixtures	5,840	5,776
Construction in process	8,149	2,273
Leasehold improvements	21,066	20,811
Land	4,339	4,339
Buildings and building improvements	21,788	20,218
	88,259	80,572
Less: Accumulated depreciation	(33,552)	(26,737)
Total property and equipment, net	$ 54,707	$ 53,835

The Company recorded depreciation expense on property and equipment of $7.7 million, $7.6 million and $6.4 million for the years ended December 31, 2024, 2023 and 2022, respectively.

5. INTANGIBLE ASSETS

Intangible assets at December 31, 2024 and 2023 consist of the following:

	December 31, 2024			December 31, 2023		
	(In thousands)					
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Trademark and other intangible rights related to Nabi-HB	$ 4,100	$ 4,100	$ -	$ 4,100	$ 3,856	$ 244
Internally developed software	559	99	460	210	9	201
Rights to intermediates	907	907	-	907	853	54
	$ 5,566	$ 5,106	$ 460	$ 5,217	$ 4,718	$ 499

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 as well as the intangible rights to Nabi-HB, which were amortized over a period of seven years. As of December 31, 2024, the Company's intangible assets are comprised of several internally developed data intelligence and analytics programs at a cost of approximately $0.6 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, 2024, 2023 and 2022 was $0.4 million, $0.7 million and $0.7 million, respectively. Estimated aggregate future aggregate amortization expense is expected to be as follows (in thousands):

2025	$ 140
2026	$ 140
2027	$ 130
2028	$ 50

6. ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other current liabilities at December 31, 2024 and 2023 are as follows:

	December 31, 2024	December 31, 2023
	(In thousands)	
Accrued rebates	$ 4,155	$ 16,608
Accrued distribution fees	11,565	5,954
Accrued incentives	5,892	4,961
Accrued interest	2,857	546
Accrued testing	827	282
Accrued payroll and other compensation	3,332	2,203
Income taxes payable	3,481	-
Other	1,853	2,365
Total accrued expenses and other current liabilities	$ 33,962	$ 32,919

7. NOTES PAYABLE

Senior Notes Payable

A summary of outstanding senior notes payable is as follows:

	December 31, 2024	December 31, 2023
	(In thousands)	
Term loan	$ 32,500	$ 62,500
Revolving credit facility	42,500	72,500
Less:		
Debt discount	(2,663)	(4,406)
Senior notes payable	$ 72,337	$ 130,594

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 provided 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 for the year ended December 31, 2023 in the amount of $26.2 million, which is mainly comprised of the write-off of unamortized debt discount and the prepayment penalty.

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On August 14, 2024, the Company repaid $30.0 million against the revolving credit facility and the outstanding balance on the revolving credit facility as of December 31, 2024 was $42.5 million, with an additional $30.0 million of availability through the Ares Maturity Date. The Company is required to pay an unused commitment fee of 0.5% per annum for this availability.

On December 19, 2024 the Company repaid $30.0 million against the term loan and the outstanding balance on the term loan as of December 31, 2024 was $32.5 million. In connection with the repayment against the term loan, the Company recognized a loss on extinguishment of debt in the approximate amount of $1.2 million, which is comprised of a prepayment penalty in the amount of $0.5 million and a partial write-off of unamortized discount attributable to the term loan in the amount of $0.8 million.

Borrowings under the term loan 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%. 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%. As of December 31, 2024 and December 31, 2023, the interest rate on the term loan was approximately 10.85% and 11.88%, respectively, and the interest rate on the revolving facility was approximately 8.34% and 9.13%, respectively.

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. After giving effect to the principal payments made during the year ended December 31, 2024, the Company is required to make quarterly interest payments to Ares of approximately $1.8 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 pays down an aggregate amount under the Revolving Facility that is greater than 50% of the $72.5 million commitment amount, the Company will still be required to pay interest on 50% of this amount, 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 obligation was 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 was 10.81% and 11.39% as of December 31, 2024 and 2023, respectively. 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. In connection with the prepayment of the term loan on December 19, 2024, the Company also paid a pro rata portion of the exit fee in the amount of $0.4 million, and the balance of the exit fee liability as of December 31, 2024 is $1.3 million.

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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 $15.0 million 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, 2024 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, 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.

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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 to 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.

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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, 2024 and 2023.

Common Stock

As of December 31, 2024 and 2023, the Company was authorized to issue 300,000,000 shares of its common stock, $0.0001 par value per share, and 236,620,545 and 226,063,032 shares of common stock were outstanding as of December 31, 2024 and 2023, respectively. After giving effect to shares reserved for the issuance of warrants and for awards issued under the Company's equity incentive plans, 36,093,118 shares of common stock were available for issuance as of December 31, 2024.

During the years ended December 31, 2024, 2023 and 2022, outstanding stock options aggregating to 1,988,066, 1,444,533 and 68,679 shares, respectively, of common stock were exercised, and the Company received net proceeds from the exercises of approximately $7.5 million, $1.1 million and $0.2 million, respectively.

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.

Warrants

During the year ended December 31, 2024, several of the Company's former noteholders exercised an aggregate of 11,308,702 warrants in cashless exercise transactions resulting in the Company issuing 7,224,892 shares of its common stock. Also during the year ended December 31, 2024, warrants to purchase 227,650 shares of common stock that had been issued to former noteholders of the Company expired in accordance with their terms.

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.

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At December 31, 2024 and 2023, the Company had outstanding warrants to purchase an aggregate of 966,554 and 12,502,906 shares, respectively, of common stock, with a weighted average exercise price of $1.98 and $2.32 per share, respectively, and expiration dates ranging between March 2029 and May 2030. The following table summarizes information about warrants outstanding as of December 31, 2024, 2023 and 2022:

	Shares	Weighted Average Exercise Price
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
Expired	(227,650)	$ 4.21
Granted	-	$ -
Exercised	(11,308,702)	$ 2.31
Warrants outstanding at December 31, 2024	966,554	$ 1.98

Equity Incentive Plans

On June 21, 2022, the Company's stockholders approved the ADMA Biologics, Inc. 2022 Compensation Plan (the "2022 Equity Plan"), which replaced the Company's Amended and Restated 2014 Omnibus Incentive Compensation Plan (the "2014 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 Company's Board of Directors (the "Board") or a Committee of the Board (the "Committee") to grant awards to grantees 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. Shares issued in connection with the exercise of stock options or the vesting of RSUs are newly issued shares.

For the years ended December 31, 2024, 2023 and 2022, the Company granted options to purchase an aggregate of 1,531,635, 1,826,380 and 1,194,032 shares, respectively, of common stock to employees and directors under the 2022 Equity Plan and 2014 Plan. During the year ended December 31, 2024, options to purchase 2,020,142 shares of common stock were exercised, for which 32,076 shares were withheld to cover the aggregate exercise prices and payroll taxes, and the Company received aggregate net exercise proceeds of $7.5 million. 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 all options granted is in accordance with Staff Accounting Bulletins 107 and 110, which is based on the average between vesting terms and contractual terms as the Company had a limited history of option exercises prior to the middle of fiscal 2023. 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, 2024, 2023 and 2022, 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.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
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The grant date fair values of stock options awarded during the years ended December 31, 2024, 2023 and 2022 were determined using the Black-Scholes option pricing model with the following assumptions:

	Years Ended		
	December 31, 2024	December 31, 2023	December 31, 2022
Expected term	5.5-6.3 years	5.5-6.3 years	5.5-6.3 years
Volatility	66%	68%	68%
Dividend yield	0.0	0.0	0.0
Risk-free interest rate	4.16-4.39%	4.20-4.62%	1.72-1.73%

The following table summarizes information about stock options outstanding as of December 31, 2024, 2023 and 2022:

	Shares	Weighted Average Exercise Price
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
Forfeited	(30,094)	$ 3.36
Expired	(246,067)	$ 7.01
Granted	1,531,635	$ 6.40
Exercised	(2,020,142)	$ 3.90
Options outstanding, vested and expected to vest at December 31, 2024	5,141,516	$ 3.90
Options exercisable	2,657,932	$ 3.03

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
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As of December 31, 2024, the Company had $6.7 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 2.8 years. The weighted average remaining contractual term of stock options outstanding and expected to vest at December 31, 2024 is 7.1 years. The weighted average remaining contractual term of stock options exercisable at December 31, 2024 is 5.7 years. The following table summarizes additional information regarding outstanding and exercisable options under the stock option plans at December 31, 2024:

	Stock Options Outstanding				Stock Options Exercisable			
Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value ($000's)	Options Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value ($000's)
$1.10 - $1.67	981,093	6.8	$ 1.60	$ 15,252	676,542	6.6	$ 1.58	$ 10,532
$1.73 - $2.60	629,655	5.7	$ 2.32	9,336	585,771	5.6	$ 2.33	8,683
$2.67 - $4.01	1,809,746	6.6	$ 3.41	24,868	1,012,271	5.4	$ 3.46	13,863
$4.09 - $6.14	1,264,083	8.1	$ 5.35	14,913	361,848	5.4	$ 5.23	4,312
$6.54 - $9.81	307,828	9.0	$ 6.60	3,248	7,500	0.6	$ 8.98	61
$10.80 - $17.49	149,111	8.7	$ 8.74	500	14,000	0.1	$ 10.80	89
	5,141,516	7.1	$ 3.90	$ 68,117	2,657,932	5.7	$ 3.03	$ 37,540

During the years ended December 31, 2024, 2023 and 2022, the Company granted RSUs representing an aggregate of 3,278,688, 3,389,760 and 1,174,266 shares, respectively, to certain employees and consultants of the Company and to members of the Board. The RSUs generally vest annually over a period of four years for employees and semi-annually over a period of one year for directors.

During the years ended December 31, 2024, 2023 and 2022, 1,886,463, 1,199,445 and 2,727,412 shares, respectively, vested in connection with grants of RSUs. With respect to RSUs vested during the year ended December 31, 2024, 541,908 shares valued at approximately $5.0 million were withheld were withheld to cover employees' tax liabilities. 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. All of these shares have been retired by the Company or were otherwise no longer outstanding as of December 31, 2024. 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, 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	4,657,297	$ 2.81
Granted	3,278,688	$ 7.44
Vested	(1,886,463)	$ 2.50
Forfeited	(303,532)	$ 3.92
Balance at December 31, 2024	5,745,990	$ 5.50

As of December 31, 2024, the Company had $25.3 million of unrecognized compensation expense related to unvested RSUs granted under the Company's equity incentive plans, which is expected to be recognized over a weighted-average period of 3.1 years.

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During the year ended December 31, 2024, three of the Company's employees and one of the Company's non-employee directors received modifications to their outstanding stock option and RSU awards in connection with their departure from the Company or transition from an employee to a consulting role (see Note 9). The modifications allowed, among other things, the former employees to continue to participate in the Company's equity incentive plans with respect to certain of their outstanding awards when they would otherwise not be eligible to do so. In connection with these modifications, the Company recognized an aggregate of $2.5 million of additional compensation expense in the year ended December 31, 2024. Total stock-based compensation expense for all awards granted under the Company's equity incentive plans for the years ended December 31, 2024, 2023 and 2022 was as follows (in thousands):

	Year Ended December 31,		
(in thousands)	2024	2023	2022
Research and development	$ 98	$ 40	$ 19
Plasma center operating expenses	184	146	82
Selling, general and administrative	11,720	5,331	4,717
Cost of product revenue	1,614	670	397
Total stock-based compensation expense	$ 13,616	$ 6,187	$ 5,215

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, 2024, 2023 and 2022 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, 2024, 2023 and 2022.

During the years ended December 31, 2024, 2023 and 2022, the Company purchased certain specialized equipment and repair services used for the collection and processing of source plasma from Genesis BPS and its affiliates ("Genesis") in the amount of $0.2 million, $0.4 million and $0.2 million, respectively. Genesis is owned by Dr. Grossman and Adam Grossman.

On November 19, 2024, the Company entered into an agreement with Bryant Fong whereby the Company agreed, in conjunction with Mr. Fong's resignation from the Board, to immediately vest all of Mr. Fong's 12,020 unvested RSUs. The agreement also extended the post-termination exercise period for his vested stock options from 90 days to two years (or earlier, if such options' 10-year expiration date occurs sooner than November 19, 2026). All of Mr. Fong's unvested stock options were forfeited in accordance with the terms of the 2022 Equity Plan. In connection with this modification of Mr. Fong's equity awards, the Company recorded additional compensation expense of $0.3 million (see Note 8) in the year ended December 31, 2024.

On April 1, 2024, the Company entered into a consulting agreement with Brian Lenz, the Company's former Executive Vice President, Chief Financial Officer and General Manager, ADMA BioCenters, whereby Mr. Lenz's outstanding equity awards were modified in connection with his transition to a consulting role. Under the terms of the consulting agreement, Mr. Lenz remained eligible to participate in the Company's equity compensation plans with respect to continued vesting of the subject awards as set forth in the agreement. In addition, the post-termination exercise period for Mr. Lenz's vested stock options was extended from 90 days to two years from the date of the consulting agreement (or earlier, if such options' 10-year expiration date occurs sooner than March 31, 2026). In connection with this modification, the Company recorded $1.6 million of additional compensation expense for the year ended December 31, 2024.

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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) Mr. Lenz purchased 6,993 shares of common stock, all at the public offering price of $2.86 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 statement 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. During each of the years ended December 31, 2024 and 2023, the Company's cybersecurity insurer paid the Company an aggregate of $0.2 million for approved restoration-related costs. During the first quarter of 2025, the Company's cybersecurity insurer paid the Company $0.4 million in business interruption loss coverage.

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 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 high-titer plasma from any number of wholly-owned ADMA plasma collection facilities and (ii) allow the Company to purchase its raw material 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. 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. Effective October 1, 2024, the Company entered into an Amended and Restated Plasma Purchase Agreement with Grifols (the "A&R Grifols Agreement") with a term expiring in September 2039, after which it may be renewed for two additional multi-year periods if agreed to by the parties. Pursuant to the A&R Grifols Agreement, Grifols supplies, on a non-exclusive basis, to ADMA BioManufacturing a minimum of 35,000 liters of RSV plasma annually to be used in the manufacture of ASCENIV, with an escalating price per liter depending on the volume supplied in a given 12-month period, with a minimum annual price increase every 12 months. Additionally, Grifols will be entitled to receive a fixed bonus payment in the event that a specified liter amount of high-titer plasma is supplied to the Company in any 12-month period during the term of the A&R Grifols Agreement.

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Effective August 6, 2024, the Company entered into a Plasma Purchase Agreement with KEDPlasma LLC ("KEDPlasma") with a term expiring in July 2031, after which it may be renewed for an additional five-year period if agreed to by the parties (the "KEDPlasma Agreement"). Pursuant to the KEDPlasma Agreement, KEDPlasma supplies, on a non-exclusive basis, to ADMA BioManufacturing a minimum of 35,000 liters of RSV plasma annually commencing with the 12-month period ending July 31, 2026, with an escalating price per liter depending on the volume supplied in a given 12-month period. The price per liter of high-titer plasma supplied pursuant to the KEDPlasma Agreement is also scheduled to increase on an annual basis. Additionally, KEDPlasma will be entitled to receive a fixed bonus payment in the event that a specified liter amount of RSV plasma is supplied to the Company in any 12-month period during the term of the KEDPlasma Agreement.

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 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 which patient enrollment has been successfully completed. For the years ended December 31, 2024, 2023 and 2022, the Company incurred expenses related to this study in the amount of $1.2 million, $1.0 million and $0.5 million, respectively. The Company expects to incur expenses of approximately $1.0 million to complete this study, which is required to be completed by June of 2026.

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. The Company did not incur any expenses related to this commitment for the year ended December 31, 2024. For the years ended December 31, 2023 and 2022, the Company incurred expenses related to these studies of $1.7 million and $2.2 million, respectively.

Other Commitments

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company's maximum exposure under these arrangements is unknown as of December 31, 2024. The Company does not anticipate recognizing any significant losses relating to these arrangements.

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11. INCOME TAXES

The components of the Company's income tax expense (benefit) are as follows:

	Year Ended December 31, (In thousands)		
	2024	2023	2022
Current:			
Federal	$ 10,434	$ -	$ -
State	1,887	-	-
Total current	12,321	-	-
Deferred:			
Federal	(72,858)	-	-
State	(11,422)	-	-
Total deferred	(84,280)	-	-
Total benefit from income taxes	$ (71,959)	$ -	$ -

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

	Year Ended December 31, (In thousands)		
	2024	2023	2022
Tax provision (benefit) at U.S. federal statutory rate	$ 26,400	$ (5,930)	$ (13,840)
State taxes, net of federal benefit	(9,931)	(763)	(1,773)
Non-deductible executive compensation	4,340	983	862
Excess tax benefits related to stock-based compensation	(5,661)	-	-
Change in valuation allowance	(87,969)	4,696	15,117
Other	862	1,014	(366)
Benefit for income taxes	$ (71,959)	$ -	$ -

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
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The significant components of the Company's deferred tax assets are as follows:

	Year Ended December 31,	
	2024	**2023**
Deferred tax assets:	*(in thousands)*	
Federal and state net operating loss carryforwards	$ 65,615	$ 76,645
Interest expense limitation carryforwards	13,604	21,165
Inventory	3,911	2,937
Stock-based compensation	2,523	1,795
Lease obligations	2,549	2,330
Accrued expenses and other	5,779	5,831
Total gross deferred tax assets	93,981	110,703
Less: valuation allowance for deferred tax assets	-	(101,422)
Total deferred tax assets, net of valuation allowance	93,981	9,281
Deferred tax liabilities:		
Depreciation of property and equipment	(6,166)	(6,837)
Right-of-use assets	(2,247)	(2,077)
Other deferred tax liabilities	(1,288)	(367)
Total deferred tax liabilities	(9,701)	(9,281)
Net deferred tax assets	$ 84,280	$ -

As of December 31, 2024, the Company has federal and state (post-apportioned basis) net operating losses ("NOLs") of $265.6 million and $204.0 million, respectively. Approximately $33.4 million and $62.0 million of the foregoing Federal and state NOLs, respectively, will expire at various dates from 2029 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. The annual amount of Federal NOLs that expire each year is as follows (in thousands):

Expiration Date	Remaining Available
2031	$ 2,409
2032	7,430
2033	11,295
2034	1,025
2035	1,025
2036	1,025
2037	9,157
Indefinite	232,240
Total	$ 265,606

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.

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As of December 31, 2024, the Company believes it is more-likely-than-not that the Company's federal and state deferred tax assets will be realized. The Company recorded a release of its valuation allowance associated with federal and state deferred tax assets which was due in part to achieving three years of cumulative taxable income and projected taxable income that is more than adequate to realize the Company's federal and state deferred tax assets. As a result, the Company reversed the federal and state valuation allowance recorded as of December 31, 2023 of $88.0 million and $13.4 million, respectively, resulting in a tax benefit to the income tax provision for the year ended December 31, 2024.

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, 2024 and 2023 and does not anticipate a significant change in unrecognized tax benefits during the next 12 months.

The Company files income tax returns in the U.S. federal and various state jurisdictions. All net operating losses and tax credits generated to date are subject to adjustment for U.S. federal and state income tax purposes. The Company's income tax returns are open to examination for tax years 2007 through 2023.

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. Upon adoption of ASU No. 2016-02, *Leases (Topic 842)* effective January 1, 2019, the Company elected the package of practical expedients, which permits the Company to not reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. In addition, the Company elected the short-term lease recognition exemption for all leases that qualify,

The Company determines if an arrangement is an operating lease or a financing 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-of-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 estimated incremental borrowing rate as of the lease commencement date. There were no new material leases entered into during the year ended December 31, 2024. For the lease liabilities recognized during the years ended December 31, 2023 and 2022, the Company used discount rates of 13% to 16%, representing a weighted average discount rate of 13.02%, 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, 2024, 2023 and 2022 was $2.4 million, $2.4 million and $2.1 million, respectively. Aggregate cash paid on these leases for the years ended December 31, 2024, 2023 and 2022 was $2.4 million, $2.4 million and $1.8 million, respectively.

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During the year ended December 31, 2023, the Company recognized one additional right-of-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-of-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). The Company has aggregate lease liabilities of $9.8 million and $10.8 million as of December 31, 2024 and 2023, 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 6.8 years. Scheduled payments under the Company's lease obligations are as follows (in thousands):

Year ended December 31, 2025	2,421
2026	2,157
2027	2,041
2028	2,088
2029	2,109
Thereafter	4,041
Total payments	14,857
Less: imputed interest	(5,078)
Current portion	(1,218)
Balance at December 31, 2024	$ 8,561

13. SEGMENTS

The Company is engaged in the manufacture, marketing and development of specialty plasma-derived biologics. The Company's ADMA BioManufacturing operating segment reflects the Company's immunoglobulin manufacturing, commercial and development operations in Boca Raton, FL. The Plasma Collection Centers operating segment consists of ten plasma collection facilities located throughout the United States, all of which are operational, collecting plasma and currently holding FDA licenses. The Company defines its operating 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 Corporate information included in the reconciliations below generally consists of certain unallocated general and administrative overhead expenses and interest expense on the Company's senior debt (see Note 7). The Company's CODM is its President and Chief Executive Officer. For the Company's two operating segments, the CODM uses income/loss before taxes as the measure of segment profit to determine the allocation of resources for each segment. Transactions between the two operating segments consist solely of the transfer of raw material plasma inventory at cost from the Plasma Collection Centers segment to the ADMA BioManufacturing segment with no markup or intercompany profit. Income tax benefit/expense is recorded at the Corporate entity and is not allocated to the operating segments. Summarized financial information concerning reportable segments is shown in the following tables:

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
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Year Ended December 31, 2024

(in thousands)	ADMA BioManufacturing	Plasma Collection Centers	Total
Revenues	$ 415,806	$ 10,505	$ 426,311
Cost of product revenue	195,605	11,296	206,901
Research and development	1,813	-	1,813
Plasma center operating expenses	-	4,245	4,245
Selling, marketing and distribution	18,683	-	18,683
Depreciation and amortization expense	4,827	3,218	8,045
General and administrative expense	26,001	-	26,001
Other expense, net	(178)	(5)	(183)
Income (loss) before taxes	173,138	(5,041)	168,097
Expenditures for additions to long-lived assets	8,352	223	8,575
Total assets	289,297	30,477	319,774
Reconciliation of revenues:			
Segment revenue			$ 426,311
License revenue (see Note 2 - Revenue Recognition)			143
Consolidated revenues			$ 426,454
Reconciliation of selling, general and administrative expense:			
Segment selling, marketing and distribution expense			$ 18,683
Segment general and administrative expense			26,001
Corporate general and administrative expense (a)			29,440
Consolidated selling, general and administrative expense			$ 74,124
Reconciliation of income (loss) before taxes:			
Segment income before taxes			$ 168,097
License revenue			143
Unallocated interest expense, primarily related to interest on senior debt (see Note 7)			(13,930)
Loss on extinguishment of debt (see Note 7)			(1,243)
Unallocated interest income			2,087
Corporate general and administrative expense (a)			(29,440)
Consolidated income before taxes			$ 125,714
Reconciliation of total assets:			
Total segment assets			$ 319,774
Corporate (b)			168,904
Consolidated total assets			$ 488,678

(a) - Primarily includes compensation expense, including stock-based compensation expense, for certain executive officers and consultants, insurance, legal and investor relations expenses and accounting and tax fees that are not allocated to the Company's operating segments.

(b) - Primarily consists of cash and deferred tax assets.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Year Ended December 31, 2023

(in thousands)	ADMA BioManufacturing	Plasma Collection Centers	Total
Revenues	$ 249,738	$ 8,334	$ 258,072
Cost of product revenue	161,157	8,116	169,273
Research and development	3,300	-	3,300
Plasma center operating expenses	-	4,266	4,266
Selling, marketing and distribution	18,407	-	18,407
Depreciation and amortization expense	5,156	3,176	8,332
General and administrative expense	18,625	-	18,625
Income (loss) before taxes	47,267	(4,049)	43,218
Expenditures for additions to long-lived assets	2,952	1,819	4,771
Total assets	246,719	34,733	281,452
Reconciliation of revenues:			
Segment revenue			$ 258,072
License revenue (see Note 2 - Revenue Recognition)			143
Consolidated revenues			$ 258,215
Reconciliation of selling, general and administrative expense:			
Segment selling, marketing and distribution expense			$ 18,407
Segment general and administrative expense			18,625
Corporate general and administrative expense (a)			21,988
Consolidated selling, general and administrative expense			$ 59,020
Reconciliation of income (loss) before taxes:			
Segment income before taxes			$ 43,218
License revenue			143
Unallocated interest expense, primaril related to interest on senior debt (see Note 7)			(25,027)
Loss on extinguishment of debt (see Note 7)			(26,174)
Unallocated interest income			1,589
Corporate general and administrative expense (a)			(21,988)
Consolidated income before taxes			$ (28,239)
Reconciliation of total assets:			
Total segment assets			$ 281,452
Corporate (b)			47,730
Consolidated total assets			$ 329,182

(a) - Primarily includes compensation expense, including stock-based compensation expense, for certain executive officers and consultants, insurance, legal and investor relations expenses and accounting and tax fees that are not allocated to the Company's operating segments.

(b) - Primarily consists of cash.

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Year Ended December 31, 2022

(in thousands)	ADMA BioManufacturing	Plasma Collection Centers	Total
Revenues	$ 144,070	$ 9,867	$ 153,937
Cost of product revenue	108,882	9,933	118,815
Research and development	3,614	-	3,614
Plasma center operating expenses	-	17,843	17,843
Selling, marketing and distribution	13,667	-	13,667
Depreciation and amortization expense	4,709	2,404	7,113
General and administrative expense	16,312	-	16,312
Income (loss) before taxes	374	(17,911)	(17,537)
Expenditures for additions to long-lived assets	5,247	8,664	13,911
Total assets	238,159	37,071	275,230
Reconciliation of revenues:			
Segment revenue			$ 153,937
License revenue (see Note 2 - Revenue Recognition)			143
Consolidated revenues			$ 154,080
Reconciliation of selling, general and administrative expense:			
Segment selling, marketing and distribution expense			$ 13,667
Segment general and administrative expense			16,312
Corporate general and administrative expense (a)			22,479
Consolidated selling, general and administrative expense			$ 52,458
Reconciliation of income (loss) before taxes:			
Segment income before taxes			$ (17,537)
License revenue			143
Unallocated interest expense, primaril related to interest on senior debt (see Note 7)			(19,276)
Loss on extinguishment of debt (see Note 7)			(6,670)
Other expense			(85)
Corporate general and administrative expense (a)			(22,479)
Consolidated income before taxes			$ (65,904)
Reconciliation of total assets:			
Total segment assets			$ 275,230
Corporate (b)			73,231
Consolidated total assets			$ 348,461

(a) - Primarily includes compensation expense, including stock-based compensation expense, for certain executive officers and consultants, insurance, legal and investor relations expenses and accounting and tax fees that are not allocated to the Company's operating segments.

(b) - Primarily consists of cash.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
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Net revenues according to geographic area, based on the location of where the product is shipped, are as follows:

	Year Ended December 31, 2024				
	ADMA BioManufacturing	Plasma Centers	Total Segment Revenue	License Revenue	Consolidated Revenue
United States	$ 400,336	$ 9,669	$ 410,005	$ 143	$ 410,148
International	15,470	836	16,306	-	16,306
Total revenues	$ 415,806	$ 10,505	$ 426,311	$ 143	$ 426,454

	Year Ended December 31, 2023				
	ADMA BioManufacturing	Plasma Centers	Total Segment Revenue	License Revenue	Consolidated Revenue
United States	$ 237,454	$ 7,284	$ 244,738	$ 143	$ 244,881
International	12,284	1,050	13,334	-	13,334
Total revenues	$ 249,738	$ 8,334	$ 258,072	$ 143	$ 258,215

	Year Ended December 31, 2022				
	ADMA BioManufacturing	Plasma Centers	Total Segment Revenue	License Revenue	Consolidated Revenue
United States	$ 136,827	$ 9,457	$ 146,284	$ 143	$ 146,427
International	7,243	410	7,653	-	7,653
Total revenues	$ 144,070	$ 9,867	$ 153,937	$ 143	$ 154,080

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 $1.5 million, $1.3 million and $1.3 million of related compensation expense for the years ended December 31, 2024, 2023 and 2022, respectively.

15. SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Supplemental cash flow information for the years ended December 31, 2024, 2023 and 2022 is as follows:

	2024	2023	2022
		(In thousands)	
SUPPLEMENTAL CASH FLOW INFORMATION:			
Cash paid for interest	$ 10,668	$ 18,051	$ 13,880
Cash paid for income taxes	$ 9,392	$ -	$ -
Noncash Financing and Investing Activities:			
Equipment acquired reflected in accounts payable and accrued liabilities	$ 725	$ 86	$ 1,495
Right-to-use assets in exchange for lease obligations	$ -	$ 130	$ 4,048
Warrants issued in connection with notes payable	$ -	$ 5,595	$ 9,570

See Note 8 and the Consolidated Statement of Stockholders' Equity for cashless exercise activity related to the Company's outstanding warrants.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
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16. CONCENTRATIONS

Financial instruments that potentially subject the Company to concentrations of credit risk consist of accounts receivable. At December 31, 2024, three customers accounted for approximately 91% of the Company's consolidated accounts receivable. At December 31, 2023, five customers accounted for approximately 98% of the Company's consolidated accounts receivable.

For the years ended December 31, 2024 and 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. Revenues for both of these customers are attributable to the ADMA BioManufacturing business segment. There were no customers attributable to the Plasma Collections Center whose revenues exceeded 10% of the Company's consolidated revenues.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Schedule II – Valuation and Qualifying Accounts
Years ended December 31, 2024, 2023 and 2022

(in thousands)	Balance at beginning of year	Additions: Charged to costs and expenses	Additions: Other	Deductions	Balance at end of year
Year ended December 31, 2024					
Accrued rebates	$ 16,608	$ 8,514	$ (12,618)	$ 8,349	$ 4,155
Inventory valuation allowance	$ 2,992	$ 9,338	$ 118	$ 7,287	$ 5,161
Deferred tax asset valuation allowance	$ 101,421	$ (84,280)	$ -	$ 17,141	$ -
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