UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2024

OR

☐ TRANSITION REPORT PURSUANT TO 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)

(201) 478-5552
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ADMA	Nasdaq Global Market

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 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.

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

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

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

As of November 1, 2024, there were 236,390,253 shares of the issuer's common stock outstanding.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

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

Special Note Regarding Forward-Looking Statements

Some of the information in this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. These statements include, among others, statements about:

- our ability to manufacture ASCENIV and BIVIGAM on a commercial scale and further commercialize these products as a result of their approval by the U.S. Food and Drug Administration (the "FDA") in 2019;
- our plans to develop, manufacture, market, launch and expand our commercial infrastructure and commercialize our current and future products and the success of such efforts;
- the safety, efficacy and expected timing of and our ability to obtain and maintain regulatory approvals for our current products and product candidates, and the labeling or nature of any such approvals;
- the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals for our product candidates;
- our dependence upon our third-party customers, 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 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 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 conflict in Europe or the evolving conflict in the Middle East and surrounding areas.

These statements may be found under the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this Quarterly Report on Form 10-Q. Forward-looking statements may be identified by the use of terms such as "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," or "should" or the negative thereof or other variations thereof or comparable terminology. Our actual results could differ materially from those contained in the forward-looking statements due to the factors described in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 and in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2024. Any forward-looking statement included or incorporated by reference in this Quarterly Report on Form 10-Q reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions related to our operations, industry and future growth. These forward-looking statements speak only as of the dates such statements are made and we undertake no obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, unless otherwise required by the federal securities laws.

PART I
FINANCIAL INFORMATION

Item 1. Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2024	December 31, 2023
	(Unaudited)	
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 86,707	$ 51,352
Accounts receivable, net	50,140	27,421
Inventories	171,801	172,906
Prepaid expenses and other current assets	9,545	5,334
Total current assets	318,193	257,013
Property and equipment, net	53,694	53,835
Intangible assets, net	485	499
Goodwill	3,530	3,530
Right-to-use assets	8,897	9,635
Deposits and other assets	5,819	4,670
TOTAL ASSETS	$ 390,618	$ 329,182
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 16,020	$ 15,660
Accrued expenses and other current liabilities	27,535	32,919
Current portion of deferred revenue	143	182
Current portion of lease obligations	1,193	1,045
Total current liabilities	44,891	49,806
Senior notes payable, net of discount	101,326	130,594
Deferred revenue, net of current portion	1,583	1,690
End of term fee	1,688	1,688
Lease obligations, net of current portion	8,865	9,779
Other non-current liabilities	375	419
TOTAL LIABILITIES	158,728	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, 236,378,607 and 226,063,032 shares issued and outstanding at September 30, 2024 and December 31, 2023	24	23
Additional paid-in capital	652,345	641,439
Accumulated deficit	(420,479)	(506,256)
TOTAL STOCKHOLDERS' EQUITY	231,890	135,206
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 390,618	$ 329,182

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months ended September 30,		Nine Months ended September 30,	
	2024	2023	2024	2023
	(In thousands, except share and per share data)			
REVENUES	$ 119,839	$ 67,275	$ 308,905	$ 184,311
Cost of product revenue	60,180	42,622	152,685	126,455
Gross profit	59,659	24,653	156,220	57,856
OPERATING EXPENSES:				
Research and development	412	596	1,422	2,854
Plasma center operating expenses	1,021	467	2,968	3,581
Amortization of intangible assets	28	179	363	537
Selling, general and administrative	18,560	14,726	50,807	43,485
Total operating expenses	20,021	15,968	55,560	50,457
INCOME FROM OPERATIONS	39,638	8,685	100,660	7,399
OTHER INCOME (EXPENSE):				
Interest income	666	423	1,499	1,005
Interest expense	(3,499)	(6,398)	(11,051)	(18,812)
Other expense	(56)	(145)	(107)	(186)
Other expense, net	(2,889)	(6,120)	(9,659)	(17,993)
INCOME (LOSS) BEFORE INCOME TAXES	36,749	2,565	91,001	(10,594)
Provision for income taxes	840	-	5,224	-
NET INCOME (LOSS)	$ 35,909	$ 2,565	$ 85,777	$ (10,594)
BASIC EARNINGS (LOSS) PER COMMON SHARE	$ 0.15	$ 0.01	$ 0.37	$ (0.05)
DILUTED EARNINGS (LOSS) PER COMMON SHARE	$ 0.15	$ 0.01	$ 0.35	$ (0.05)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic	234,571,376	225,276,980	231,959,579	223,306,331
Diluted	244,804,065	233,761,262	241,772,162	223,306,331

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (Unaudited)

(In thousands, except share data)

For the Three and Nine Months Ended September 30, 2024

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2023	226,063,032	$ 23	$ 641,439	$ (506,256)	$ 135,206
Stock-based compensation	-	-	2,141	-	2,141
Cashless exercise of warrants	4,545,503	-	-	-	-
Vesting of Restricted Stock Units, net of shares withheld for taxes	774,889	-	(2,476)	-	(2,476)
Exercise of stock options	386,341	-	1,029	-	1,029
Net income	-	-	-	17,806	17,806
Balance at March 31, 2024	231,769,765	23	642,133	(488,450)	153,706
Stock-based compensation	-	-	2,863	-	2,863
Cashless exercise of warrants	937,507	-	-	-	-
Vesting of Restricted Stock Units, net of shares withheld for taxes	171,408	-	(693)	-	(693)
Exercise of stock options	148,056	-	331	-	331
Net income	-	-	-	32,062	32,062
Balance at June 30, 2024	233,026,736	23	644,634	(456,388)	188,269
Stock-based compensation	-	-	3,179	-	3,179
Cashless exercise of warrants	1,741,882	1	(1)	-	-
Vesting of Restricted Stock Units, net of shares withheld for taxes	250,107	-	(1,158)	-	(1,158)
Exercise of stock options	1,359,882	-	5,691	-	5,691
Net income	-	-	-	35,909	35,909
Balance at September 30, 2024	236,378,607	$ 24	$ 652,345	$ (420,479)	$ 231,890

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (Unaudited)

(In thousands, except share data)

For the Three and Nine Months Ended September 30, 2023

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2022	221,816,930	$ 22	$ 629,969	$ (478,017)	$ 151,974
Stock-based compensation	-	-	1,110	-	1,110
Vesting of Restricted Stock Units, net of shares withheld for taxes	443,215	-	(640)	-	(640)
Exercise of stock options	2,443	-	-	-	-
Net loss	-	-	-	(6,789)	(6,789)
Balance at March 31, 2023	222,262,588	22	630,439	(484,806)	145,655
Stock-based compensation	-	-	1,637	-	1,637
Vesting of Restricted Stock Units, net of shares withheld for taxes	117,484	-	(225)	-	(225)
Warrants issued in connection with note payable	-	-	5,594	-	5,594
Cashless exercise of warrants	1,967,847	-	-	-	-
Exercise of stock options	178,829	-	472	-	472
Net loss	-	-	-	(6,371)	(6,371)
Balance at June 30, 2023	224,526,748	22	637,917	(491,177)	146,762
Stock-based compensation	-	-	1,695	-	1,695
Vesting of Restricted Stock Units, net of shares withheld for taxes	171,295	-	(209)	-	(209)
Exercise of stock options	1,260,041	1	623		624
Net income	-	-	-	2,565	2,565
Balance at September 30, 2023	225,958,084	$ 23	$ 640,026	$ (488,612)	$ 151,437

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2024	**2023**
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 85,777	$ (10,594)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	6,101	6,223
Loss on disposal of fixed assets	32	111
Interest paid in kind	-	2,959
Stock-based compensation	8,183	4,442
Amortization of debt discount	732	1,896
Amortization of license revenue	(107)	(107)
Changes in operating assets and liabilities:		
Accounts receivable	(22,719)	(15,814)
Inventories	1,105	164
Prepaid expenses and other current assets	(4,211)	(12)
Deposits and other assets	(411)	(1,221)
Accounts payable	208	(1,155)
Accrued expenses	(5,384)	4,872
Other current and non-current liabilities	(850)	(561)
Net cash provided by (used in) operating activities	68,456	(8,797)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(5,469)	(3,574)
Acquisition of intangible assets	(356)	-
Net cash used in investing activities	(5,825)	(3,574)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Taxes paid on vested Restricted Stock Units	(4,327)	(1,074)
Repayment of notes payable	(30,000)	-
Payments on finance lease obligations	-	(16)
Net proceeds from the exercise of stock options	7,051	1,096
Net cash used in financing activities	(27,276)	6
Net increase (decrease) in cash and cash equivalents	35,355	(12,365)
Cash and cash equivalents - beginning of period	51,352	86,522
Cash and cash equivalents - end of period	$ 86,707	$ 74,157

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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 United States, all of which hold an approved license with the FDA.

The Company has three FDA-approved products, all of which are currently marketed and commercially available: (i) ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), an intravenous immune globulin ("IVIG") product indicated for the treatment of Primary Humoral Immunodeficiency ("PI"), also known as Primary Immunodeficiency Disease ("PIDD") or Inborn Errors of Immunity, for which the Company received FDA approval on April 1, 2019 and commenced first commercial sales in October 2019; (ii) BIVIGAM (Immune Globulin Intravenous, Human), an IVIG product indicated for the treatment of PI, and for which the Company received FDA approval on May 9, 2019 and commenced commercial sales in August 2019; and (iii) Nabi-HB (Hepatitis B Immune Globulin, Human), which is indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen ("HBsAg") and other listed exposures to Hepatitis B. In addition to its commercially available immunoglobulin products, the Company generates revenues from the sale of intermediate by-products that result from the immunoglobulin production process and from time to time provides contract manufacturing and laboratory services for certain clients. The Company seeks to develop a pipeline of plasma-derived therapeutics, and its products and product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients with or at risk for certain infectious diseases.

As of September 30, 2024, the Company had working capital of $273.3 million, including $86.7 million of cash and cash equivalents, $50.1 million of accounts receivable and $171.8 million of inventories, partially offset by $44.9 million of current liabilities. Based upon the Company's current projected revenue and expenditures, including capital expenditures and continued implementation of the Company's commercialization and expansion activities, the Company's management currently believes that its cash, cash equivalents and accounts receivable, along with its projected future operating cash flow, will be sufficient to fund ADMA's operations, as currently conducted, through the end of the fourth quarter of fiscal 2025 and beyond. However, the Company's current outlook on cash flows and profitability may change based upon several factors, including the success of the Company's commercial sales of its products, whether or not the assumptions underlying the Company's projected revenues and expenses are correct and the continued acceptability of ADMA's immune globulin products by physicians, patients and payers. The Company is subject to risks common to companies in the biotechnology and pharmaceutical manufacturing industries including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, inflationary pressures, supply chain constraints, protection of proprietary technology, and compliance with FDA and other governmental regulations and approval requirements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information. 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").

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on February 28, 2024. The accompanying consolidated balance sheet as of December 31, 2023 was derived from the audited financial statements as of and for the year ended December 31, 2023. These condensed consolidated interim financial statements have been prepared in accordance with the instructions to Form 10-Q, Article 10 of Regulation S-X and ASC 270, *Interim Financial Statements*, and therefore omit or condense certain footnotes and other information normally included in annual consolidated financial statements prepared in accordance with U.S. GAAP. All intercompany balances and transactions have been eliminated in consolidation. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements), as well as material non-recurring costs, gains and losses applicable to the interim period, that are considered necessary to present fairly the Company's financial position as of September 30, 2024, its results of operations and changes in stockholders' equity for the three and nine months ended September 30, 2024 and 2023 and cash flows for the nine months ended September 30, 2024 and 2023.

During the three and nine months ended September 30, 2024 and 2023, comprehensive income/loss was equal to the net income/loss amounts presented for the respective periods in the accompanying condensed consolidated statements of operations. Operating results for interim periods are not necessarily indicative of the results that may be expected for the full fiscal year.

Use of Estimates

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

During the second quarter of 2024, 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 nine months ended September 30, 2024. This change in estimate was applied on a prospective basis as of June 30, 2024 and increased income from operations and net income for the nine months ended September 30, 2024 by approximately $12.6 million and $11.9 million, respectively, and increased basic and diluted earnings per share by $0.05. Because there was little to no historical data to rely upon at the time BIVIGAM and ASCENIV were launched, the Company had considered several qualitative factors when evaluating the initial rate to accrue for rebates, 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. The Company additionally considered that estimates may change over the lifetime of these products due to changes in utilization and payor mixes. There was additional new information that arose during the three months ended June 30, 2024 that suggested the need to reevaluate the underlying assumption of historical payer mix for BIVIGAM and ASCENIV, which resulted in the $12.6 million adjustment to the accrual for U.S. Medicaid rebates at June 30, 2024.

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 credit facility (see Note 7) approximates fair value due to the variable interest rate on this debt.

Accounts Receivable

Accounts receivable is reported at realizable value, net of allowances for contractual credits and credit losses in the amount of $0.2 million and $0.1 million at September 30, 2024 and December 31, 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, payment history and associated credit risk of customers are performed on an ongoing basis. Based on these evaluations, the Company has concluded that its credit risk is minimal. At September 30, 2024, four customers accounted for an aggregate of approximately 91% of the Company's total accounts receivable, and at December 31, 2023, five customers accounted for approximately 98% of the Company's total accounts receivable.

Inventories

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

Inventories, including plasma intended for resale and plasma intended for internal use in the Company's manufacturing, commercialization or research and development activities, are carried at the lower of cost or net realizable value determined by the first-in, first-out method. Net realizable value is generally determined based upon the consideration the Company expects to receive when the inventory is sold, less costs to deliver the inventory to the recipient. The estimates for net realizable value of inventory are based on contractual terms or upon historical experience and certain other assumptions, and the Company believes that such assumptions are reasonable. Inventory is periodically reviewed to ensure that its carrying value does not exceed its net realizable value, and adjustments are recorded to write down such inventory, with a corresponding charge to cost of product revenue, when the carrying value or historical cost exceeds its estimated net realizable value.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill at September 30, 2024 and December 31, 2023 was $3.5 million. All of the Company's goodwill is attributable to its ADMA BioManufacturing business segment.

Goodwill is not amortized but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. The Company has the option to perform a qualitative assessment of goodwill to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill and other intangible assets. If the Company concludes that this is the case, then it must perform a goodwill impairment test by comparing the fair value of the reporting unit to its carrying value. An impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value, not to exceed the total amount of goodwill allocated to that reporting unit. The Company performs its annual goodwill impairment test as of October 1 of each year. The Company did not record any impairment charges related to goodwill for the three and nine months ended September 30, 2024 and 2023.

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 three and nine months ended September 30, 2024 and 2023, the Company did not identify any impairment indicators for its long-lived assets, and as a result no impairment charges were recorded.

Revenue Recognition

Revenues for the three and nine months ended September 30, 2024 and 2023 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 through the Company's Plasma Collection Centers business segment, (iii) contract manufacturing and laboratory services revenue, (iv) revenues from the sale of intermediate by-products; and (v) license and other revenues primarily attributable to the out-licensing of ASCENIV to Biotest AG ("Biotest") in 2012 to market and sell this product in Europe and selected countries in North Africa and the Middle East. Biotest has provided the Company with certain services and financial payments in accordance with the related Biotest license agreement and is obligated to pay the Company certain amounts in the future if certain milestones are achieved. Deferred revenue is amortized into income over the term of the Biotest license, representing a period of approximately 22 years.

Product revenue is recognized when the customer is deemed to have control over the product. Control is determined based on when the product is shipped or delivered, depending on the sales terms, 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 historical experience and certain other assumptions, and while the Company believes that such estimates are reasonable, they are subject to change based on future experience and other factors. During the second quarter of 2024, 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 nine months ended September 30, 2024, substantially all of which was related to the sale of ASCENIV and BIVIGAM. This change in estimate was applied on a prospective basis as of June 30, 2024 and increased income from operations and net income by approximately $12.6 million and $11.9 million, respectively, and increased basic and diluted earnings per share by $0.05 for the nine months ending September 30, 2024. Because there was little to no historical data to rely upon at the time BIVIGAM and ASCENIV were launched, the Company had considered several qualitative factors when evaluating the initial rate to accrue for rebates, 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. The Company additionally considered that estimates may change over the lifetime of these products due to changes in utilization and payor mixes. There was additional new information that arose during the three months ended June 30, 2024 that suggested the need to reevaluate the underlying assumption of historical payer mix for BIVIGAM and ASCENIV, which resulted in the $12.6 million adjustment to the accrual for U.S. Medicaid rebates at June 30, 2024.

For revenues associated with contract manufacturing and the sale of intermediates, control transfers to the customer and the performance obligation is satisfied when the customer takes possession of the product from the Boca Facility or from a third-party warehouse that is utilized by the Company.

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

For the nine months ended September 30, 2024 and 2023, two customers represented an aggregate of approximately 71% of the Company's consolidated revenues.

Cost of Product Revenue

Cost of product revenue includes costs associated with the manufacture of the Company's FDA-approved products, intermediates and 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 or processes in development, the expenses are classified as research and development expenses.

Earnings/Loss Per Common Share

Basic earnings/loss per common share is computed by dividing net earnings/loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings/loss per common share is calculated by dividing net earnings/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, as well as restricted stock units ("RSUs"), using the treasury stock method. Potentially dilutive common stock is excluded from the diluted earnings/loss per common share computation to the extent that it would be anti-dilutive. For the three and nine months ended September 30, 2024 and the three months ended September 30, 2023, basic and diluted earnings per share is calculated as follows:

	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024
Net income available to common stockholders ($000's) (numerator)	$ 35,909	$ 2,565	$ 85,777
Weighted-average number of common shares (denominator)	234,571,376	225,276,980	231,959,579
Basic earnings per common shares	$ 0.15	$ 0.01	$ 0.37
Weighted-average number of common shares	234,571,376	225,276,980	231,959,579
Potential shares of common stock arising from outstanding stock options, warrants and unvested RSUs	10,232,689	8,484,282	9,812,583
Total shares - diluted (denominator)	244,804,065	233,761,262	241,772,162
Diluted earnings per common share	$ 0.15	$ 0.01	$ 0.35

For the three and nine months ended September 30, 2024 and the three months ended September 30, 2023, there were no shares with an anti-dilutive effect that needed to be excluded from the earnings per share computation. For the nine months ended September 30, 2023 no potentially dilutive securities were included in the computation of diluted loss per share in the accompanying condensed consolidated financial statements as the Company reported a net loss for this period. For the nine months ended September 30, 2023, the following securities were excluded from the calculation of diluted loss per common share because of their anti-dilutive effects:

Stock Options	5,841,241
Restricted Stock Units	4,877,482
Warrants	12,502,906
	23,221,629

Stock-Based Compensation

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

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or its tax returns. Under this method, deferred tax assets and liabilities are recognized for the temporary differences between the tax bases of assets and liabilities and their respective financial reporting amounts at enacted tax rates in effect for the years in which the temporary differences are expected to reverse. The Company records a valuation allowance on its deferred tax assets if it is more likely than not that the Company will not generate sufficient taxable income to utilize its deferred tax assets. 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.

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. Tax benefits are recognized for an uncertain tax position when, in management's judgment, it is more likely than not that the position will be sustained upon examination by a taxing authority. For a tax position that meets the more-likely-than-not recognition threshold, the tax benefit is measured as the largest amount that is judged to have a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority. The liability associated with unrecognized tax benefits is adjusted periodically due to changing circumstances and when new information becomes available. Such adjustments are recognized entirely in the period in which they are identified. Derecognition of a tax benefit previously recognized could result in the Company recording a tax liability that would reduce net assets. Based on its analysis, the Company has determined that it has not incurred any material liability for uncertain tax positions as of September 30, 2024 and December 31, 2023, and during the three and nine months ended September 30, 2024 and 2023 the Company recognized no adjustments for uncertain tax positions.

Recent Accounting Pronouncements

In November of 2023 the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures.* The amendments in this ASU 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 an operating segment or the method for determining reportable segments. This update becomes effective for fiscal years beginning after December 15, 2023 and for interim periods beginning after December 15, 2024. The Company does not expect this ASU to have a material impact on the Company's consolidated financial statements, except that its adoption will likely lead to disclosures of additional significant segment expenses.

3. INVENTORIES

The following table provides the components of inventories:

	September 30, 2024	December 31, 2023
	(In thousands)	
Raw materials	$ 55,246	$ 52,999
Work-in-process	53,482	49,621
Finished goods	63,073	70,286
Total inventories	$ 171,801	$ 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 goods expected to be available for sale or otherwise have alternative uses that provide a probable future benefit.

Work-in-process inventory primarily consists of bulk drug substance and unlabeled filled vials of the Company's immunoglobulin products.

Finished goods inventory is comprised of immunoglobulin product inventory and related intermediates that are available for commercial sale, as well as plasma collected at the Company's plasma collection centers that is expected to be sold to third-party customers.

4. INTANGIBLE ASSETS

Intangible assets at September 30, 2024 and December 31, 2023 consist of the following:

	September 30, 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	74	485	210	9	201
Rights to intermediates	907	907	-	907	853	54
	$ 5,566	$ 5,081	$ 485	$ 5,217	$ 4,718	$ 499

During the nine months ended September 30, 2024, the Company continued to develop its data intelligence and analytics programs at a cost of approximately $0.4 million, and such costs are amortized over a period of three to five years upon the projects' completion and placement into service. Amortization expense related to the Company's intangible assets was $28,000 and $0.2 million for the three months ended September 30, 2024 and 2023, respectively, and $0.4 million and $0.5 million for the nine months ended September 30, 2024 and 2023, respectively. Estimated future aggregate amortization expense is expected to be as follows (in thousands):

2024	$ 25
2025	140
2026	140
2027	130
2028	50

5. PROPERTY AND EQUIPMENT

Property and equipment and related accumulated depreciation are summarized as follows:

	September 30, 2024	December 31, 2023
	(In thousands)	
Manufacturing and laboratory equipment	$ 21,240	$ 21,093
Office equipment and computer software	6,441	6,062
Furniture and fixtures	5,777	5,776
Construction in process	5,881	2,273
Leasehold improvements	21,051	20,811
Land	4,339	4,339
Buildings and building improvements	21,416	20,218
	86,145	80,572
Less: Accumulated depreciation	(32,451)	(26,737)
Total property and equipment, net	$ 53,694	$ 53,835

Property and equipment 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 were assigned a useful life of 30 years. Property and equipment other than land and buildings have useful lives ranging from three to 10 years. Leasehold improvements are amortized over the lesser of the lease term or their estimated useful lives.

The Company recorded depreciation expense on property and equipment for the three months ended September 30, 2024 and 2023 of $1.9 million and for the nine months ended September 30, 2024 and 2023 of $5.7 million.

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities at September 30, 2024 and December 31, 2023 are as follows:

	September 30, 2024	December 31, 2023
	(In thousands)	
Accrued rebates	$ 4,733	$ 16,608
Accrued distribution fees	9,780	5,954
Accrued incentives	3,670	4,961
Accrued interest	3,448	546
Accrued testing	579	282
Accrued payroll and other compensation	2,010	2,203
Other	3,315	2,365
Total accrued expenses and other current liabilities	$ 27,535	$ 32,919

7. DEBT

A summary of outstanding senior notes payable is as follows:

	September 30, 2024	December 31, 2023
	(In thousands)	
Term loan	$ 62,500	$ 62,500
Revolving credit facility	42,500	72,500
Less:		
Debt discount	(3,674)	(4,406)
Senior notes payable	$ 101,326	$ 130,594

On December 18, 2023 (the "Ares Closing Date"), the Company and all of its subsidiaries entered into a credit agreement (the "Ares Credit Agreement") with Ares Capital Corporation and certain credit funds affiliated with Ares Capital Corporation (collectively, "Ares"). The Ares Credit Agreement provides for a total of $135.0 million in senior secured credit facilities (the "Ares Credit Facility") consisting of (i) a term loan in the aggregate principal amount of $62.5 million and (ii) a revolving credit facility in the aggregate principal amount of $72.5 million (collectively, the "Ares Loans"), both of which were fully drawn on the Ares Closing Date. The Ares Credit Facility has a maturity date of December 20, 2027 (the "Ares Maturity Date"). On the Ares Closing Date, the Company used the proceeds from the Ares Loans, along with a portion of its existing cash on hand, to terminate and pay in full all of the outstanding obligations under the Company's previous senior credit facility (the "Hayfin Credit Facility") with Hayfin Services LLP ("Hayfin") including the outstanding principal in the amount of $158.6 million. 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 September 30, 2024 was $42.5 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"). As of September 30, 2024 and December 31, 2023, the interest rate on the term loan was approximately 11.36% and 11.88%, respectively, and the interest rate on the revolving facility was approximately 9.08% 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, and the Company is required to make quarterly interest payments to Ares of approximately $2.8 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 prepays an amount under the revolving credit facility that is greater than 50% of the original $72.5 million outstanding balance (of which $30.0 million, or 41.4%, has been repaid to date), the Company will still be required to pay interest on 50% of this balance, or $36.3 million, through the term of the Ares Credit Facility. The Company may prepay the outstanding principal on the term loan, together with any accrued but unpaid interest on the prepaid principal amount, at any time and from time to time upon three business days' prior written notice, subject to the payment to Ares of a prepayment premium equal to (i) the present value as of such date of all remaining required interest payments on the principal amount being repaid plus 1.5% of the prepaid principal amount, if prepaid on or prior to the first anniversary of the Ares Closing Date, (ii) 1.5% of the prepaid principal amount, if prepaid after the first anniversary of the Ares Closing Date and on or prior to the second anniversary of the Ares Closing Date, or (iii) 1.0% of the prepaid principal amount, if prepaid on or prior to the third anniversary of the Ares Closing Date.

In connection with the closing of the Ares Credit Facility, the Company incurred fees and expenses related to the transaction of $2.8 million, including a $1.7 million original discount payable to Ares, all of which was deducted from the Ares loan proceeds. In addition, the Company is also required to pay Ares an exit fee of $1.7 million upon the earlier of any prepayment date or the Ares Maturity Date, and this amount has been accrued as a separate liability in the Company's consolidated balance sheets as of September 30, 2024 and December 31, 2023. As a result, the Company recognized an aggregate debt discount of $4.4 million as of the Ares Closing Date, and the weighted-average effective interest rate on the Ares Loans as of September 30, 2024 and December 31, 2023 was 11.73% and 11.39%, 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.

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 September 30, 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.

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 September 30, 2024 and December 31, 2023.

Common Stock

As of September 30, 2024 and December 31, 2023, the Company was authorized to issue 300,000,000 shares of its common stock, $0.0001 par value per share, and 236,378,607 and 226,063,032 shares of common stock were outstanding as of September 30, 2024 and December 31, 2023, respectively. After giving effect to the 27,759,065 shares reserved for outstanding warrants and awards issued or reserved for future issuance under the Company's equity incentive plans, as of September 30, 2024 there were 35,862,328 shares of common stock available for issuance.

Warrants

On January 10, 2024, a former noteholder of the Company exercised a warrant to purchase 4 million shares of the Company's common stock on a cashless basis and the Company issued 1,977,514 shares of common stock to this noteholder. On March 8, 2024 Hayfin and its affiliates exercised warrants to purchase an aggregate of 3,388,681 shares of the Company's common stock on a cashless basis and the Company issued 2,482,205 shares of common stock to Hayfin and its affiliates. On March 14, 2024 an entity associated with another former noteholder of the Company exercised a warrant to purchase 169,651 shares of the Company's common stock on a cashless basis and the Company issued 85,784 shares of common stock to this entity. On May 9, 2024 Hayfin and its affiliates exercised warrants to purchase an aggregate of 1,787,424 shares of the Company's common stock on a cashless basis and the Company issued 937,507 shares of common stock to Hayfin and its affiliates. On August 15, 2024 Hayfin and its affiliates exercised warrants to purchase an aggregate of 1,962,946 shares of the Company's common stock on a cashless basis and the Company issued an aggregate of 1,741,882 shares of common stock to Hayfin and its affiliates.

On February 24, 2024 a warrant to purchase 34,800 shares of the Company's common stock held by a former noteholder of the Company expired in accordance with its terms. At September 30, 2024 and December 31, 2023, the Company had outstanding warrants to purchase an aggregate of 1,159,404 and 12,502,906 shares of common stock, respectively, with weighted-average exercise prices of $2.26 and $2.32 per share, respectively, with expiration dates ranging between October 2024 and May 2030. The following table summarizes the changes in warrants outstanding for the nine months ended September 30, 2024:

	Shares	Weighted Average Exercise Price
Warrants outstanding at December 31, 2023	12,502,906	$ 2.32
Expired	(34,800)	$ 7.50
Granted	-	$ -
Exercised	(11,308,702)	$ 2.31
Warrants outstanding at September 30, 2024	1,159,404	$ 2.26

Equity Incentive Plans

The fair value of stock options granted under the Company's equity incentive plans was determined on the date of grant using the Black-Scholes option valuation model. The Black-Scholes model was developed for use in estimating the fair value of publicly traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of certain subjective assumptions including the expected stock price volatility. The stock options granted to employees and directors have characteristics significantly different from those of traded options, and changes in the subjective input assumptions can materially affect the fair value estimate. The following assumptions were used to determine the fair value of options granted during the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,	
	2024	2023
Expected term	5.5 - 6.3 years	5.5 - 6.3 years
Volatility	66%	68%
Dividend yield	0.0	0.0
Risk-free interest rate	4.16-4.34%	4.20-4.24%

During the nine months ended September 30, 2024 and 2023, the Company granted options to purchase an aggregate of 1,511,624 and 1,727,510 shares of common stock, respectively, to its directors and employees. The weighted-average remaining contractual life of stock options outstanding and expected to vest at September 30, 2024 is 7.5 years. The weighted-average remaining contractual life of stock options exercisable at September 30, 2024 is 6.2 years. During the nine months ended September 30, 2024, options to purchase an aggregate of 1,925,498 shares of common stock were exercised, which included certain exercise transactions for which an aggregate of 31,219 shares were withheld to cover the exercise price and income tax liabilities, and the Company received aggregate net exercise proceeds of $7.1 million.

A summary of the Company's option activity under the Company's equity incentive plans and related information is as follows:

	Shares	Weighted Average Exercise Price
Options outstanding, vested and expected to vest at December 31, 2023	5,906,184	$ 3.38
Forfeited	(15,723)	$ 1.94
Expired	(221,067)	$ 7.34
Granted	1,511,624	$ 6.25
Exercised	(1,925,498)	$ 3.85
Options outstanding, vested and expected to vest at September 30, 2024	5,255,520	$ 3.87
Options exercisable	2,509,884	$ 3.10

As of September 30, 2024, the Company had $7.4 million of unrecognized compensation expense related to options granted under the Company's equity incentive plans, which is expected to be recognized over a weighted-average period of 2.9 years.

During the nine months ended September 30, 2024 and 2023, the Company granted RSUs representing an aggregate of 3,227,188 and 3,345,760 shares, respectively, to certain employees of the Company and to members of its Board of Directors. These 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 nine months ended September 30, 2024, an aggregate of 1,701,229 shares of common stock vested in connection with grants of RSUs. With respect to these vested RSUs, 504,825 shares valued at approximately $4.3 million were withheld by the Company to cover employees' tax liabilities. These shares were no longer outstanding as of September 30, 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, 2023	4,657,297	$ 2.81
Granted	3,227,188	$ 7.25
Vested	(1,701,229)	$ 2.59
Forfeited	(211,688)	$ 3.57
Balance at September 30, 2024	5,971,568	$ 5.25

As of September 30, 2024, the Company had $27.4 million of unrecognized compensation expense related to unvested RSUs granted under the Company's equity incentive plans, which is expected to be recognized over a weighted-average period of 3.2 years.

Total stock-based compensation expense for all awards granted under the Company's equity incentive plans for the three and nine months ended September 30, 2024 and 2023 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2024	2023	2024	2023
Research and development	$ 24	$ 12	$ 65	$ 27
Plasma center operating expenses	44	41	131	104
Selling, general and administrative	2,714	1,451	6,960	3,839
Cost of product revenue	397	191	1,027	472
Total stock-based compensation expense	$ 3,179	$ 1,695	$ 8,183	$ 4,442

9. RELATED PARTY TRANSACTIONS

The Company leases office space 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 through December 31, 2026. Rent expense for the nine months ended September 30, 2024 and 2023 amounted to $90,000. Areth is a company controlled by Dr. Jerrold B. Grossman, the Vice Chairman of the Company's Board of Directors, and Adam S. Grossman, the Company's President and Chief Executive Officer. The Company also reimburses Areth for office and building-related (common area) expenses, equipment and certain other operational expenses, which were not material to the condensed consolidated financial statements for the nine months ended September 30, 2024 and 2023.

During the nine months ended September 30, 2024 and 2023, the Company purchased certain specialized medical equipment and services primarily related to the Company's plasma collection centers, as well as personal protective equipment, from Genesis BPS and its affiliates ("Genesis"), aggregating to $0.2 million and $0.4 million, respectively. Genesis is owned by Dr. Grossman and Mr. Grossman.

During the three and nine months ended September 30, 2024, two of the Company's executive officers exercised options to purchase an aggregate of 650,395 shares of common stock, for which the Company received net proceeds of $3.0 million (see Note 8). During the three and nine months ended September 30, 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.

10. COMMITMENTS AND CONTINGENCIES

General Legal Matters

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

Vendor Commitments

Pursuant to the terms of a plasma purchase agreement dated as of November 17, 2011 (the "2011 Plasma Purchase Agreement"), the Company agreed to purchase from its former contract manufacturer an annual minimum volume of source plasma containing antibodies to RSV to be used in the manufacture of ASCENIV. The Company must purchase a to-be-determined and agreed upon annual minimum volume from the counterparty, and under the original 2011 Plasma Purchase Agreement the Company was permitted to also collect high-titer RSV plasma from up to five wholly-owned ADMA plasma collection facilities. During 2015, the Company amended the 2011 Plasma Purchase Agreement to (i) allow the Company to collect its raw material RSV high-titer plasma from any number of wholly-owned ADMA plasma collection facilities and (ii) allow the Company to purchase its raw material RSV high-titer plasma from other third-party collection organizations, in each case, provided that the annual minimum volumes from the Company's former contract manufacturer were met, thus allowing the Company to expand its reach for raw material supply as it executes its commercialization plans for ASCENIV. Unless terminated earlier, the 2011 Plasma Purchase Agreement expires in June 2027, after which it may be renewed for two additional five-year periods if agreed to by the parties. On December 10, 2018, the Company's former contract manufacturer assigned its rights and obligations under the 2011 Plasma Purchase Agreement to Grifols Worldwide Operations Limited ("Grifols") as its successor-in-interest, effective January 1, 2019.

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

Post-Marketing Commitments

In connection with the FDA's approval of ASCENIV on April 1, 2019, the Company is required to perform a pediatric study to evaluate the safety and efficacy of ASCENIV in children and adolescents. For the nine months ended September 30, 2024 and 2023, the Company incurred expenses related to this study in the approximate amount of $1.0 million and $0.6 million, respectively. The Company expects to incur expenses of approximately $0.5 million to complete this study, which is required to be completed by June of 2026.

Employment Contracts

The Company previously entered into employment agreements with Mr. Grossman and with Brian Lenz, the Company's former Executive Vice President, Chief Financial Officer and General Manager, ADMA BioCenters. Effective as of April 1, 2024, Mr. Lenz transitioned to a non-employee consulting role and entered into a consulting agreement with the Company. On April 1, 2024, the Company entered into an employment agreement with Kaitlin Kestenberg, who was promoted to Chief Operating Officer and Senior Vice President, Compliance. On July 24, 2024, the Company entered into an employment agreement with Brad Tade, who was appointed Chief Financial Officer and Treasurer of the Company.

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 executive 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 September 30, 2024. The Company does not anticipate recognizing any significant losses relating to these arrangements.

11. 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 hold 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. While not considered an operating segment, the Corporate information included in the tables below 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. Summarized financial information concerning reportable segments is shown in the following tables:

Three Months Ended September 30, 2024

(in thousands)	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 113,088	$ 6,715	$ 36	$ 119,839
Cost of product revenue	52,731	7,449	-	60,180
Income (loss) from operations	48,347	(1,755)	(6,954)	39,638
Interest and other expense, net	(54)	-	(2,835)	(2,889)
Income (loss) before taxes	48,293	(1,755)	(9,789)	36,749
Depreciation and amortization expense	1,138	802	-	1,940
Total assets	266,456	33,191	90,971	390,618

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Three Months Ended September 30, 2023

(in thousands)	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 66,567	$ 672	$ 36	$ 67,275
Cost of product revenue	41,734	888	-	42,622
Income (loss) from operations	15,017	(683)	(5,649)	8,685
Interest and other (expense) income, net	(141)	-	(5,979)	(6,120)
Income (loss) before taxes	14,876	(683)	(11,628)	2,565
Depreciation and amortization expense	1,282	811	-	2,093
Total assets	262,554	35,622	50,821	348,997

Nine Months Ended September 30, 2024

(in thousands)	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 299,385	$ 9,413	$ 107	$ 308,905
Cost of product revenue	142,193	10,492	-	152,685
Income (loss) from operations	123,756	(4,047)	(19,049)	100,660
Interest and other expense, net	(95)	(4)	(9,560)	(9,659)
Income (loss) before taxes	123,661	(4,051)	(28,609)	91,001
Capital expenditures	5,364	105	-	5,469
Depreciation and amortization expense	3,686	2,415	-	6,101

Nine Months Ended September 30, 2023

(in thousands)	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 175,905	$ 8,299	$ 107	$ 184,311
Cost of product revenue	118,708	7,747	-	126,455
Income (loss) from operations	26,577	(3,029)	(16,149)	7,399
Interest and other expense, net	(170)	-	(17,823)	(17,993)
Income (loss) before taxes	26,407	(3,029)	(33,972)	(10,594)
Capital expenditures	1,768	1,806	-	3,574
Depreciation and amortization expense	3,857	2,366	-	6,223

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2024	2023	2024	2023
United States	$ 114,748	$ 64,618	$ 295,465	$ 173,920
International	5,091	2,657	13,440	10,391
Total revenues	$ 119,839	$ 67,275	$ 308,905	$ 184,311

12. LEASE OBLIGATIONS

The Company leases certain properties and equipment for its ADMA BioCenters and ADMA BioManufacturing subsidiaries, which leases provide the right to use the underlying assets and require lease payments through the respective lease terms which expire at various dates through 2033. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

The Company determines if an arrangement is an operating lease at inception. Leases with an initial term of 12 months or less are not recorded on the balance sheet. All other leases are recorded on the balance sheet with assets representing the right to use the underlying asset for the lease term and lease liabilities representing the obligation to make lease payments arising from the lease. Right-to-use assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term and include options to extend or terminate the lease when they are reasonably certain to be exercised. The present value of the lease payments is determined using the Company's incremental borrowing rate. The Company's lease expense is recognized on a straight-line basis over the lease term and is reflected in Plasma center operating expenses and Selling, general and administrative expenses. Aggregate lease expense for the Company's leases for the three months ended September 30, 2024 and 2023 was approximately $0.6 million, and aggregate lease expense for the nine months ended September 30, 2024 and 2023 was approximately $1.8 million. Cash paid for the Company's leases for the three months ended September 30, 2024 and 2023 was also approximately $0.6 million, and cash paid for the nine months ended September 30, 2024 and 2023 was approximately $1.8 million.

The Company has aggregate lease liabilities of $10.1 million and $10.8 million as of September 30, 2024 and December 31, 2023, respectively, which are comprised primarily of the leases for the Company's plasma collection centers and a warehouse lease for raw material storage related to the Company's immunoglobulin manufacturing operations. The Company's operating leases have a weighted-average remaining term of 7.0 years. Scheduled payments under the Company's lease obligations are as follows (in thousands):

Remainder of 2024	$ 603
Year ended December 31, 2025	2,421
2026	2,157
2027	2,041
2028	2,088
2029	2,109
Thereafter	4,042
Total payments	15,461
Less: imputed interest	(5,403)
Current portion	(1,193)
Balance at September 30, 2024	$ 8,865

13. INCOME TAXES

The Company uses the estimated annual effective tax rate approach as prescribed by ASC 740-270, Interim Reporting, to calculate its interim tax provision. For the three and nine months ended September 30, 2024, the Company recorded income tax expense of $0.8 million and $5.2 million, respectively, resulting in an effective tax rate of 5.7% for the nine months ended September 30, 2024. The tax expense for the three and nine months ended September 30, 2024 represents federal and state tax liabilities that are not fully sheltered by net operating loss carryforwards ("NOLs") due to limitations from prior ownership changes and other limitations on NOLs incurred after 2017. The Company's effective tax rate differs from the federal statutory tax rate of 21% due primarily to the reversal of the valuation allowance on certain federal and state NOLs estimated to be realized in the current year and, to a lesser extent, the tax benefit associated with the employee exercise of stock options and vesting of RSUs.

Valuation Allowance

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, carryback and carryforward periods and the feasibility of ongoing tax strategies that could potentially enhance the likelihood of the realization of a deferred tax asset. The weight given to the positive and negative evidence is commensurate with the extent the evidence may be objectively verified. As such, it is generally difficult for positive evidence regarding projected future taxable income, exclusive of reversing taxable temporary differences, to outweigh objective negative evidence of recent financial reporting losses. Based on these criteria and the relative weighting of both the positive and negative evidence available, the Company continues to maintain a full valuation allowance against its net deferred tax assets.

Net Operating Losses

As of December 31, 2023, the Company had federal and state (post-apportioned basis) NOLs of $315.6 million and $216.4 million, respectively. Approximately $35.6 million and $95.1 million of the foregoing federal and state NOLs, respectively, will expire at various dates from 2028 through 2043, if not limited by triggering events prior to such time.

Under the provisions of the Internal Revenue Code, changes in ownership of the Company, in certain circumstances, would limit the amount of federal NOLs that can be utilized annually in the future to offset taxable income. In particular, Section 382 of the Internal Revenue Code ("Section 382") imposes limitations on an entity's ability to use NOLs upon certain changes in ownership. If the Company is limited in its ability to use its NOLs in future years in which it has taxable income, then the Company will pay more taxes than if it were otherwise able to fully utilize its NOLs. As of December 31, 2023, approximately $267.8 million of the foregoing federal NOLs are subject to limitation under Section 382 due to prior ownership changes.

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.

14. SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Supplemental cash flow information for the nine months ended September 30, 2024 and 2023 is as follows:

	2024	2023
	(In thousands)	
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 7,417	$ 13,896
Cash paid for income taxes	$ 8,895	$ -
Noncash Financing and Investing Activities:		
Equipment acquired reflected in accounts payable and accrued liabilities	$ 452	$ 270
Warrants issued in connection with notes payable	$ -	$ 5,595

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations, which refers to our historical results, should be read in conjunction with the other sections of this Quarterly Report on Form 10-Q, including "Risk Factors" and our unaudited consolidated financial statements and the notes thereto appearing elsewhere herein, and in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in our Annual Report on Form 10-K for the year ended December 31, 2023, filed on February 28, 2024 (the "2023 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 affected by the uncertainties and risk factors described throughout or referenced within this Quarterly Report on Form 10-Q. See "Special Note Regarding Forward-Looking Statements." Our actual results may differ materially from our current expectations.

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 No. 10,259,865 related to methods of treatment and prevention of *S. pneumonia* infection for an immunoglobulin manufactured to contain standardized antibodies to numerous serotypes of *S. pneumoniae*. We have successfully completed production of a pilot-scale batch and identified a laboratory partner to conduct forthcoming 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 annual revenues greater than $415 million in 2024 and $465 million in 2025. These revenue targets translate to potential fiscal year 2024 and 2025 net income exceeding $120 million and $165 million, respectively, and adjusted EBITDA exceeding $160 million and $215 million, respectively.

Through our ADMA BioCenters subsidiary, we currently operate ten source plasma collection facilities in the United States, 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 and hyperimmune plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase and market conditions at the time of sale. Plasma collected from ADMA BioCenters' facilities that is not used to manufacture our products is sold to third-party customers in the U.S. and in other locations outside the U.S. where we are approved under supply agreements or in the open "spot" market.

We sell plasma-derived intermediate fractions to certain customers, which are generated as part of our FDA-approved manufacturing process for IG and IVIG products, through a plasma intermediates supply agreement we entered into in October 2019. These intermediate by-products are used as the starting raw material to produce other plasma-derived biologics. In addition, from time to time we provide contract manufacturing services for certain third-party clients. We also provide laboratory contracting services to certain customers and anticipate providing contract filling, labeling and packing services utilizing our FDA-approved in-house fill-finish capabilities.

Our Products

ASCENIV

ASCENIV is a plasma-derived IVIG that contains naturally occurring polyclonal antibodies, which are proteins that are used by the body's immune system to neutralize microbes, such as bacteria and viruses, and prevent against infection and disease. We manufacture ASCENIV under HHS License No. 2019 using a process known as fractionation. The Centers for Medicare and Medicaid Services ("CMS") has issued a permanent, product-specific J-code for ASCENIV. Under the Healthcare Common Procedure Coding System ("HCPCS"), the J-code (J1554) became effective April 1, 2021. As part of our proprietary manufacturing process for ASCENIV, we leverage our unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and plasma from donors tested to have high levels of neutralizing antibody titers to Respiratory Syncytial Virus ("RSV") using our proprietary microneutralization testing assay. With our patented testing methods and assay, we are able to identify the high-titer or "hyperimmune" plasma that meets our internal and required specifications for ASCENIV. This type of high-titer plasma is typically found in less than 10% of the total donor collection samples we test.

ASCENIV is approved for the treatment of PIDD or PI, a class of inherited genetic disorders that causes a deficient or absent immune system in adults and adolescents (12 to 17 years of age). Our pivotal Phase III 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. In the future, we may elect to work with the FDA and the immunology and infectious disease community to design an appropriate clinical trial to evaluate the use of ASCENIV in this patient population. Following FDA approval in April 2019, commercial sales of ASCENIV commenced in October of 2019 and in 2023 ADMA commenced manufacturing ASCENIV at the 4,400-Liter production scale. This expansion has improved the product's margin profile and increases plant production capacity as fewer batches are needed to support our revenue goals. ASCENIV's prescriber and patient base continued to expand during 2023, which drove record utilization and pull-through for this product. These elevated demand trends have sustained into 2024, and ADMA currently expects that this product's rapid growth will continue throughout 2024 and beyond.

BIVIGAM

BIVIGAM is a plasma-derived IVIG that contains a broad range of antibodies similar to those found in normal human plasma. These antibodies are directed against bacteria and viruses and help to protect PI patients against serious infections. BIVIGAM is a purified, sterile, ready-to-use preparation of concentrated human Immunoglobulin G antibodies indicated for the treatment of PI, a group of genetic disorders. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These PIs are a group of genetic disorders. Based on recent estimates, these disorders are no longer considered to be very rare, with as many as one in every 1,200 people in the United States having some form of PI.

On May 9, 2019, the FDA approved the Prior Approval Supplement (the "PAS") for the use of our IVIG manufacturing process, thereby enabling us to re-launch and commercialize this product in the United States. We resumed production of BIVIGAM during the fourth quarter of 2017 and commercial production is ongoing, using our FDA-approved IVIG manufacturing process under U.S. Department of Health and Human Services ("HHS") License No. 2019. 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 United States 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 United States and we continue to manufacture Nabi-HB under HHS License No. 2019.

RESULTS OF OPERATIONS

Critical Accounting Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our condensed 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 certain other deductions from gross revenues, valuation of inventory, impairment of long-lived assets, assumptions used in the fair value of awards granted under our equity incentive plans and warrants issued in connection with the issuance of notes payable, estimates related to the valuation allowance for our deferred tax assets and our effective tax rate for the current fiscal year. For a description of our significant accounting policies, see Note 2 to the Consolidated Financial Statements included in the 2023 10-K.

Revenue Deductions for Rebates, Chargebacks and Sales Allowances

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 June 30, 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 the second quarter of 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 in the three months ended June 30, 2024 (see Note 2 to the Consolidated Financial Statements). The primary driver in the adjustment to our estimated rebates accrual at June 30, 2024 relates to a change in the assumption around the payor mix for our products, specifically the proportion of our revenue that is attributable to providers and patients utilizing Managed Medicaid, Medicaid and Medicare Part D, relative to our total sales. The change in this key assumption to our standing estimation model was based on the collection of additional historical data from our direct experience with selling our primary immunoglobulin products. 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.

Valuation of Inventory

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

Stock-Based Compensation and Valuation of Warrants

All equity-based payments, including grants of stock options and restricted stock units ("RSUs") are recognized at their estimated fair value at the date of grant, and compensation expense is recognized on a straight-line basis over the grantee's requisite vesting period. For the purpose of valuing stock options granted to our employees, directors and executive officers, we use the Black-Scholes option pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of publicly traded options, which have no vesting restrictions and are fully transferable. The Company's employee stock options have characteristics significantly different from those of traded options, and changes in the underlying Black-Scholes assumptions can materially affect the fair value estimate. To determine the risk-free interest rate, 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.

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

Impairment of Long-Lived Assets

We assess the recoverability of our long-lived assets, which include property and equipment and definite-lived intangible assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's carrying value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the three and nine months ended September 30, 2024 and 2023, we did not identify any impairment indicators for our long-lived assets, and as a result no impairment charges were recorded. Examples of events or circumstances that may be indicative of impairment that would require the use of significant judgment by management include:

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

Goodwill is not amortized but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. The testing of goodwill for impairment requires us to determine whether or not the fair value of the reporting unit associated with the goodwill is less than its carrying amount, including goodwill and other intangible assets. An impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value, with the impairment loss recognized not to exceed the total amount of goodwill allocated to that reporting unit. In order to determine the fair value of the reporting unit, we utilize the fair value of the Company as a whole, as determined by its market capitalization. Determination of the fair value and carrying value of each reporting unit, relative to the fair value of the Company, requires management to employ certain estimates, assumptions and judgment, which we believe are reasonable. However, any changes to these estimates and assumptions could impact our determination of whether or not our goodwill is impaired. We did not recognize any impairment charges related to goodwill for the three and nine months ended September 30, 2024 and 2023.

Deferred Tax Assets and Effective Tax Rate

We currently maintain 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 reflects our assessment of whether it is more likely than not that we will generate sufficient taxable income in the future to be able to utilize our deferred tax assets. In determining whether a valuation allowance is warranted, we evaluate factors such as prior earnings history, expected future earnings, carryback and carryforward periods and tax strategies. We consider all positive and negative evidence to estimate if sufficient future taxable income will be generated to realize our deferred tax assets. We consider cumulative losses in recent years to be a significant type of negative evidence. Based on our history of losses through December 31, 2023, at this time we have not included future projected taxable income as a source of income to recognize our deferred tax assets, despite our achievement of positive net income for the three and nine months ended September 30, 2024.

After consideration of all available positive and negative evidence regarding our estimates of future taxable income, we have elected to maintain a full valuation allowance for our deferred tax assets as of September 30, 2024. We will continue to monitor this evidence through the remainder of 2024 to determine if a reduction to the valuation allowance is warranted, which could potentially result in our recognition of an income tax benefit later in fiscal 2024.

Our income tax expense for the nine months ended September 30, 2024 is based on our estimated effective tax rate for the full year 2024, which is a function of our projected pre-tax income under U.S. GAAP, our estimates and assumptions regarding certain permanent and temporary differences between U.S. GAAP income and taxable income, and the limitations to our net operating loss carryforwards and their limitations under Section 382 of the Internal Revenue Code of 1986, as amended (see "Risk Factors" appearing elsewhere in this report and Note 13 to the Consolidated Financial Statements).

Three Months Ended September 30, 2024 Compared to Three Months Ended September 30, 2023

The following table presents a summary of the changes in our results of operations for the three months ended September 30, 2024, our third fiscal quarter, compared to the three months ended September 30, 2023:

	Three Months Ended September 30,		
(in thousands)	**2024**	**2023**	**Increase (Decrease)**
Revenues	$ 119,839	$ 67,275	$ 52,564
Cost of product revenue	60,180	42,622	17,558
Gross profit	59,659	24,653	35,006
Research and development expenses	412	596	(184)
Plasma center operating expenses	1,021	467	554
Amortization of intangibles	28	179	(151)
Selling, general and administrative expenses	18,560	14,726	3,834
Income from operations	39,638	8,685	30,953
Interest expense	(3,499)	(6,398)	2,899
Other income, net	610	278	332
Income before taxes	36,749	2,565	34,184
Provision for income taxes	840	-	840
Net income	$ 35,909	$ 2,565	$ 33,344
Adjusted EBITDA *	$ 45,367	$ 12,750	$ 32,617

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

Revenues

We recorded total revenues of $119.8 million for the three months ended September 30, 2024, as compared to $67.2 million for the three months ended September 30, 2023, an increase of $52.6 million, or approximately 78%. The increase is primarily related to increased sales of our ASCENIV IG product, as we continue to experience increased physician, payer and patient acceptance and utilization of ASCENIV.

We also experienced a $6.0 million increase in third-party plasma sales by our Plasma Collection Centers business segment, mainly due to an additional spot purchase of normal source plasma ("NSP") by our primary third-party customer in excess of the amount of NSP we are contractually committed to sell to this customer in fiscal 2024.

Cost of Product Revenue and Gross Profit

Cost of product revenue was $60.2 million for the three months ended September 30, 2024, as compared to $42.6 million for the three months ended September 30, 2023. This increase is primarily attributable to volume-driven increases in product revenue costs related to the increased sales of our IG products, including intermediates, and NSP of $13.0 million and $6.5 million, respectively, partially offset by decreases in other manufacturing costs totaling $1.9 million, mainly due to lower unabsorbed manufacturing expenses in 2024.

For the three months ended September 30, 2024, we had gross profit of $59.7 million, as compared to $24.7 million for the same period of a year ago, which represents a gross margin in the third quarter of 2024 of 49.8%, as compared to 36.6% in the third quarter of 2023. This 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 in the third quarter of 2024 as compared with the third quarter of 2023.

Research and Development Expenses

Research and development ("R&D") expenses totaled $0.4 million for the third quarter of 2024, as compared to $0.6 million for the third quarter of 2023. The decrease is primarily due to the absence of expenditures in 2024 related to the BIVIGAM post-marketing commitments, which were completed in June of 2023.

Plasma Center Operating Expenses

Plasma center operating expenses increased from approximately $0.5 million for the three months ended September 30, 2023 to $1.0 million for the three months ended September 30, 2024. The increase is primarily due to increases in donor fees of $0.9 million and softgoods and supplies of $0.3 million, partially offset by an increase in the capitalization of plasma center expenses into inventory of $0.4 million related to increased collections and to lower donor testing expenses of $0.2 million.

Amortization of Intangibles

Amortization expense mainly pertains to the amortization of intangible assets acquired in a 2017 acquisition transaction and was $28,000 and $0.2 million for the three months ended September 30, 2024 and 2023, respectively. The decrease is mainly due to the intangibles acquired in 2017 becoming fully amortized in June of 2024.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses were $18.6 million for the three months ended September 30, 2024, an increase of $3.8 million from the three months ended September 30, 2023. The increase reflects increases in employee-related costs, including salaries, benefits, stock-based compensation, relocation and recruiting, in the amount of $3.0 million, temporary labor and software maintenance expense of $0.3 million each and professional fees in the amount of $0.2 million. SG&A expenses as a percentage of net revenues fell from 21.9% in the third quarter of 2023 to 15.5% in the third quarter of 2024.

Income from Operations

Our operating income was $39.6 million for the third quarter of 2024, as compared to $8.7 million for the third quarter of 2023. The approximately $31.0 million improvement in operating income was due to the improved gross profit of $35.0 million, partially offset by an increase in total operating expenses of $4.1 million in 2024.

Interest Expense

Interest expense for the three months ended September 30, 2024 was $3.5 million, as compared to $6.4 million for the three months ended September 30, 2023. The decrease is due to the refinancing of our senior debt in December of 2023 (see "Liquidity and Capital Resources"). This transaction reduced our stated rate of interest from approximately 13.9% in the third quarter of 2023 to approximately 10.4% in the third quarter of 2024, and also resulted in a reduction to our outstanding debt principal of approximately $23.6 million. We also had lower amortization of debt discount in 2024 of approximately $0.5 million. In addition, our interest expense for the third quarter of 2024 was favorably impacted by the $30.0 million partial paydown of our senior debt on August 14, 2024.

Other Income, Net

Other income, net, which primarily consists of interest income on our cash balances, was $0.6 million and $0.3 million for the three months ended September 30, 2024 and 2023, respectively.

Provision for Income Taxes

We recorded income tax expense of $0.8 million for the three months ending September 30, 2024, with no comparable amount for the three months ending September 30, 2023. The provision for income taxes for the third quarter of 2024 represents an effective tax rate of 5.7% for the first nine months of 2024 and reflects federal and state income tax liabilities that are not fully sheltered by net operating losses 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" appearing elsewhere in this report and Note 13 to the Consolidated Financial Statements). Our effective tax rate for the three months ended September 30, 2024 differs from the federal statutory tax rate of 21%, mainly due to the reversal of the valuation allowance on certain federal and state net operating loss carryforwards expected to be realized in the current year and, to a lesser extent, the tax benefit associated with the employee exercise of stock options and vesting of RSUs.

Net Income

Our net income was $35.9 million for the third quarter of 2024, as compared to $2.6 million for the third quarter of 2023. The $33.3 million increase was primarily due to the increase in operating income of approximately $31.0 million discussed above and the reduction in interest expense for the third quarter of 2024.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

The following table presents a summary of the changes in our results of operations for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023:

	Nine Months Ended September 30,		
(in thousands)	**2024**	**2023**	**Increase (Decrease)**
Revenues	$ 308,905	$ 184,311	$ 124,594
Cost of product revenue	152,685	126,455	26,230
Gross profit	156,220	57,856	98,364
Research and development expenses	1,422	2,854	(1,432)
Plasma center operating expenses	2,968	3,581	(613)
Amortization of intangibles	363	537	(174)
Selling, general and administrative expenses	50,807	43,485	7,322
Income from operations	100,660	7,399	93,261
Interest expense	(11,051)	(18,812)	7,761
Other income, net	1,392	819	573
Income (loss) from before taxes	91,001	(10,594)	101,595
Provision for income taxes	5,224	-	5,224
Net income (loss)	$ 85,777	$ (10,594)	$ 96,371
Adjusted EBITDA *	$ 116,336	$ 21,653	$ 94,683

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

Revenues

We recorded total revenues of $308.9 million for the nine months ended September 30, 2024, as compared to $184.3 million for the nine months ended September 30, 2023, an increase of $124.6 million, or 68%. Excluding the $12.6 million adjustment we recorded in the second quarter of 2024 to decrease our accrual for U.S. Medicaid rebates (which had the effect of increasing net revenues by $12.6 million), revenue would have increased by approximately $112.0 million, or 61%. This increase is primarily related to increased sales of ASCENIV and our other IG products, as we continue to experience increased physician, payer and patient acceptance and utilization of ASCENIV. The revenue increase also includes an increase in NSP sales by our Plasma Collection Centers business segment in the amount of $1.1 million.

Cost of Product Revenue and Gross Profit

Cost of product revenue was $152.7 million for the first nine months of 2024, as compared to $126.5 million for the first nine months of 2023. This increase is primarily attributable to volume-driven increases in product revenue costs related to the increased sales of our IG products and NSP of $28.1 million and $2.3 million, respectively, partially offset by a reduction in other manufacturing costs, mainly unabsorbed manufacturing expenses, of $4.2 million.

For the nine months ended September 30, 2024, we had gross profit of $156.2 million, as compared to $57.9 million for the same period of a year ago, which represents a gross margin for the first nine months of 2024 of 50.6%, as compared to 31.4% in the first nine months of 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 first nine months of 2024 was approximately $143.5 million, representing a gross margin of 48.4%. 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.

Research and Development Expenses

R&D expenses totaled $1.4 million for the first nine months of 2024, as compared to $2.9 million for the first nine months of 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 post-marketing commitment in the amount of $0.3 million.

Plasma Center Operating Expenses

Plasma center operating expenses decreased from $3.6 million for the nine months ended September 30, 2023 to $3.0 million for the nine months ended September 30, 2024. The decrease is due to a 22% increase in the amount of plasma collected in the first nine months of 2024 as compared to the same period of a year ago, which resulted in a $7.8 million increase in the amount of plasma center costs we capitalized into inventory in 2024. This amount was partially offset by increases in donor fees of $4.4 million, softgoods and supplies of $1.4 million, donor testing expenses of $1.0 million, salaries, wages, benefits and temporary labor of $0.2 million and software maintenance expense of $0.2 million.

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 $0.5 million for the nine months ended September 30, 2024 and 2023, respectively.

Selling, General and Administrative Expenses

SG&A expenses were $50.8 million for the nine months ended September 30, 2024, an increase of $7.3 million from the nine months ended September 30, 2023. The increase reflects increases in employee-related costs, including salaries, benefits, stock-based compensation, relocation and recruiting, in the amount of $5.7 million, $3.1 million of which is stock-based compensation, repairs and maintenance expense of $0.6 million, software maintenance expense of $0.6 million and temporary labor expense of $0.5 million. SG&A expenses as a percentage of net revenues decreased from 23.6% in the first nine months of 2023 to 16.4% in the first nine months of 2024, or 17.2% excluding the revenue adjustment described above.

Income from Operations

Our operating income was $100.7 million for the first nine months of 2024, as compared to $7.4 million for the first nine months of 2023. The $93.3 million increase in operating income was mainly due to the improved gross profit, partially offset by $5.1 million of higher total operating expenses. The higher gross profit reflects the foregoing change in estimate which increased our revenues for the nine months ended September 30, 2024 by $12.6 million.

Interest Expense

Interest expense for the nine months ended September 30, 2024 was $11.1 million, as compared to $18.8 million for the nine months ended September 30, 2023. The decrease is due to the refinancing of our senior debt in December of 2023 (see "Liquidity and Capital Resources"). This transaction reduced our stated interest rate by approximately 360 basis points in 2024 compared to 2023, and also resulted in a reduction to our outstanding debt principal balance. In addition, we had lower amortization of debt discount in 2024 of approximately $1.2 million.

Other Income, Net

Other income, net, for the nine months ended September 30, 2024 was $1.4 million, as compared to $0.8 million for the nine months ended September 30, 2023. The increase is mainly due to an increase in interest income of $0.5 million in 2024.

Provision for Income Taxes

We recorded income tax expense of $5.2 million for the nine months ended September 30, 2024, with no comparable amount for the nine months ending September 30, 2023. The provision for income taxes for the first nine months of 2024 represents an effective tax rate of 5.7% and reflects federal and state income tax liabilities that are not fully sheltered by net operating losses 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" appearing elsewhere in this report and Note 13 to the Consolidated Financial Statements). After consideration of all available positive and negative evidence regarding our estimates of future taxable income, we have elected to maintain a full valuation allowance for our deferred tax assets as of September 30, 2024. We will continue to monitor this evidence through the balance of 2024 to determine if a reduction to the valuation allowance is required, which could potentially result in our recognition of an income tax benefit later in fiscal 2024.

Net Income/Loss

Our net income was $85.8 million for the first nine months of 2024, as compared to a net loss of $10.6 million for the first nine months of 2023. This $96.4 million improvement in our results of operations was primarily due to the increase in operating income of $93.3 million and lower interest expense of $7.8 million discussed above, partially offset by the provision for income taxes for the period. The foregoing change in estimate in our accrual for Medicaid rebates favorably impacted our net income for the first nine months of 2024 by approximately $12.0 million.

Non-GAAP Financial Measures

Earnings Before Interest, Taxes, Depreciation and Amortization ("EBITDA"), Adjusted EBITDA

EBITDA and Adjusted EBITDA are important non-GAAP financial measures used by our management and Board of Directors to assess our operating performance. We use EBITDA and Adjusted EBITDA as key performance measures because we believe that they facilitate operating performance comparisons from period to period that exclude 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 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 and Adjusted EBITDA to net income/loss, the most directly comparable financial measure calculated and presented in accordance with U.S. GAAP.

Because EBITDA and Adjusted EBITDA are measures not deemed to be in accordance with U.S. GAAP and are susceptible to varying calculations, our EBITDA and Adjusted EBITDA may not be comparable to similarly titled measures of other companies, including companies in our industry, because other companies may calculate EBITDA and Adjusted EBITDA in a different manner than we calculate these measurements. Although we use Adjusted EBITDA as one of several financial measures to assess our operating performance, its use is limited as it excludes certain significant operating expenses. EBITDA and Adjusted EBITDA are not intended to represent cash flows for the periods presented, nor have they been presented as an alternative to operating income, 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 income/loss to EBITDA and Adjusted EBITDA for the three and nine months ended September 30, 2024 and 2023:

	Three Months ended September 30,		Nine Months ended September 30,	
	2024	2023	2024	2023
	(In thousands)			
Net income (loss)	$ 35,909	$ 2,565	$ 85,777	$ (10,594)
Depreciation	1,912	1,913	5,738	5,686
Amortization	28	179	363	537
Income taxes	840	-	5,224	-
Interest expense	3,499	6,398	11,051	18,812
EBITDA	42,188	11,055	108,153	14,441
Stock-based compensation	3,179	1,695	8,183	4,442
IT systems disruption		-	-	2,770
Adjusted EBITDA	$ 45,367	$ 12,750	$ 116,336	$ 21,653

Adjusted EBITDA increased for the three and nine months ended September 30, 2024 by $32.6 million and $94.7 million, respectively, as compared to the same periods of a year ago. The improvement is driven primarily by the increased sales and gross profit in 2024, as well as continued operational oversight and cost containment efforts at both of our business segments.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2024, we had working capital of $273.3 million, primarily consisting of $171.8 million of inventory, cash and cash equivalents of $86.7 million and $50.1 million of accounts receivable, partially offset by current liabilities of $44.9 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. We had positive cash flows from operations for the nine months ended September 30, 2024 and the year ended December 31, 2023 of $68.5 million and $8.8 million, respectively. Prior to fiscal 2023, we funded our operations primarily from the sale of our equity and debt securities. Our material cash requirements are primarily comprised of:

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

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

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 fourth quarter of fiscal 2025 and beyond. Based on current operations and assuming continued market acceptance and utilization of our finished drug products, we do not anticipate the need to raise additional capital at this time. However, should the market for our products or political or economic conditions change, we may need to seek additional capital which may not be available due to a variety of potential factors beyond our control (see "Risk Factors" appearing elsewhere in this report).

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 credit agreement (the "Ares Credit Agreement") with Ares Capital Corporation and certain credit funds affiliated with Ares Capital Corporation (collectively, "Ares"). The Ares Credit Agreement provides for a total of $135.0 million in senior secured credit facilities (the "Ares Credit Facility") consisting of (i) a term loan in the aggregate principal amount of $62.5 million and (ii) a revolving credit facility in the aggregate principal amount of $72.5 million (collectively, the "Ares Loans"), both of which were fully drawn on the Ares Closing Date. The Ares Credit Facility has a maturity date of December 20, 2027 (the "Ares Maturity Date"). On the Ares Closing Date, we used the proceeds from the Ares Loans, along with a portion of our existing cash on hand, to terminate and pay in full all of the outstanding obligations under our previous senior credit facility (the "Hayfin Credit Facility") with Hayfin Services LLP ("Hayfin") including the outstanding principal in the amount of $158.6 million, a prepayment penalty in the amount $11.1 million, an exit fee of $1.6 million, all accrued and unpaid interest outstanding on the Hayfin Credit Facility as of the Ares Closing date, as well as certain fees and expenses related thereto. 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 September 30, 2024 was $42.5 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 initially bear interest at the adjusted Term SOFR for a three-month tenor in effect on the day that is two business days prior to the first day of the applicable calendar quarter plus 3.75% (the "SOFR Revolving Facility Applicable Margin"). As of September 30, 2024 and December 31, 2023, the interest rate on the term loan was approximately 11.36% and 11.88%, respectively, and the interest rate on the revolving facility was approximately 9.08% and 9.13%, respectively.

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 the Ares Credit Facility of approximately $2.8 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 prepay an amount under the revolving facility that is greater than 50% of the original $72.5 million outstanding balance (of which $30.0 million, or 41.4%, has been repaid to date), we will still be required to pay interest on 50% of this balance, or $36.3 million, through the term of the Ares Credit Facility. We may prepay the outstanding principal on the term loan, together with any accrued but unpaid interest on the prepaid principal amount, at any time and from time to time upon three business days' prior written notice, subject to the payment to Ares of a prepayment premium equal to (i) the present value as of such date of all remaining required interest payments on the principal amount being repaid plus 1.5% of the prepaid principal amount, if prepaid on or prior to the first anniversary of the Ares Closing Date, (ii) 1.5% of the prepaid principal amount, if prepaid after the first anniversary of the Ares Closing Date and on or prior to the second anniversary of the Ares Closing Date, or (iii) 1.0% of the prepaid principal amount, if prepaid on or prior to the third anniversary of the Ares Closing Date.

In connection with the closing of the Ares Credit Facility, we incurred fees and expenses related to the transaction of approximately $2.7 million, including a $1.7 million original issue discount payable to Ares, all of which was deducted from the Ares loan proceeds. In addition, we are also required to pay Ares an exit fee of $1.7 million upon the earlier of any prepayment date or the Ares Maturity Date, and this amount has been accrued as a separate liability in our consolidated balance sheet as of September 30, 2024 and December 31, 2023. As a result, we recognized an aggregate debt discount of $4.4 million as of the Ares Closing Date, and the weighted-average effective interest rate on the Ares Loans as of September 30, 2024 and December 31, 2023 was 11.73% and 11.39%, respectively.

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 September 30, 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.

Cash Flows

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

	Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**
Net cash provided by (used in) operating activities	$ 68,456	$ (8,797)
Net cash used in investing activities	(5,825)	(3,574)
Net cash (used in) provided by financing activities	(27,276)	6
Net change in cash and cash equivalents	35,355	(12,365)
Cash and cash equivalents - beginning of period	51,352	86,522
Cash and cash equivalents - end of period	$ 86,707	$ 74,157

Net Cash Provided by (Used in) Operating Activities

Cash provided by operations for the nine months ended September 30, 2024 was $68.5 million, as compared to cash used in operations of $8.8 million, for the same period of a year ago, mainly due to the increase in revenues, gross margin and net income in 2024, partially offset by higher unfavorable changes in accounts receivable and accounts payable and accrued expenses. The following table illustrates the primary components of and changes to our cash flows from operations:

	Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**
Net income (loss)	$ 85,777	$ (10,594)
Non-cash expenses, gains and losses	14,941	15,524
Changes in accounts receivable	(22,719)	(15,814)
Changes in inventories	1,105	164
Changes in accounts payable and accrued expenses	(5,176)	3,717
Other	(5,472)	(1,794)
Cash provided by (used in) operations	$ 68,456	$ (8,797)

Net Cash Used in Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2024 and 2023 was $5.8 million and $3.6 million, respectively, and is mainly comprised of capital expenditures at the Boca Facility. While we currently have no firm commitments for capital expenditures, we expect our total capital expenditures will be between $3.0 million and $5.0 million for the remainder of fiscal 2024, mainly for additional upgrades to the Boca Facility manufacturing operations and related operational systems.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $27.3 million for the nine months ended September 30, 2024, and was comprised of the $30.0 million repaid under the Ares Credit Facility and $4.3 million of taxes paid in connection with shares that were withheld from RSUs that vested during the period, partially offset by approximately $7.1 million in proceeds from the exercise of stock options. During the nine months ended September 30, 2023, proceeds from the exercise of stock options of $1.1 million was offset by $1.1 million of taxes paid in connection with shares withheld from RSUs that vested during the period.

Effect of Inflation

Inflation impacted a number of facets of our business during the nine months ended September 30, 2024 and for the years ended December 31, 2023 and 2022 at each of our business segments. We experienced price increases for, among other items, certain raw materials, consumable supplies, services for repairs and maintenance of our facilities, utilities, shipping and freight charges, fuel surcharges and labor costs, among other expenses. Based upon the macroeconomic environment, publicly available information and reports from the U.S. government, we expect this trend to continue in 2024 and potentially longer, which could potentially have a significant impact on our future results of operations. In addition, some of our third-party inventory purchase agreements provide for annual price increases that are tied to various consumer price indices, which have resulted in higher than historical percentage price increases and has resulted in and could continue to result in higher source plasma and other raw material and supplies costs in 2024 and beyond. Also, in a higher inflationary environment, we may not be able to raise the prices of our products to keep up with the rate of inflation. We are unable to predict when these external drivers of inflation will subside.

Off-Balance Sheet Arrangements

None.

Item 3. 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 September 30, 2024, we had $105.0 million outstanding under our senior credit facility that is subject to variable interest rates. As a result, the effect of a hypothetical, instantaneous and unfavorable change of 100 basis points in interest rates would have an approximate $1.0 million annualized negative impact on our earnings and cash flows.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We designed our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Under the supervision of and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures as of September 30, 2024. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of September 30, 2024 were effective to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding disclosures.

A control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. We do not expect that our disclosure controls and procedures or our internal control over financial reporting are able to prevent with certainty all errors and all fraud.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

We may become subject to certain legal proceedings and claims arising in connection with the normal course of our business. In the opinion of management, there are currently no material pending legal proceedings that would have a material adverse effect on our consolidated financial position, results of operations or cash flows.

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 Quarterly Report on Form 10-Q, the 2023 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 non-GAAP basis and generated positive cash flows for the year ended December 31, 2023 and generated positive net income and cash flows for the nine months ended September 30, 2024, we may not be able to maintain profitability and generate positive cash flows in the future.
- We have a history of losses and we may, in the future, need to raise additional capital or seek alternative financing in order to operate, expand or maintain our business, which may not be available on favorable terms, if at all.
- 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 supply 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.
- 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 estimates of market opportunity and forecasts of market and revenue growth included in our filings may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business could fail to grow at similar rates, if at all.
- Both of our business segments and our facilities are subject to periodic inspections by the FDA, which, depending on the outcome of such inspections, could result in certain FDA actions, including the issuance of observations, notices, citations, warning letters or other enforcement actions.
- Business interruptions could adversely affect our business.
- Although we have received approval from the FDA to market ASCENIV as a treatment for PIDD, our ability to market or seek approval for ASCENIV for alternative indications could be limited and FDA could require clinical trials beyond what we may deem to be reasonable. Unless additional clinical trials are successfully conducted and the FDA approves a Biologics License Application ("BLA") or other required submission for review, we may not be authorized to market ASCENIV for any other indication.
- With the approval to market ASCENIV, BIVIGAM and Nabi-HB, there can be no assurance that we will be successful in further developing and expanding commercial operations or balancing our research and development activities with our commercialization activities.
- We depend on third-party researchers, developers and vendors to develop, manufacture, supply materials for or test our products and product candidates, some of which are single-sourced, and such parties are outside of our control.

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

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

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

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

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

- Our 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. Any change in our accrual estimates 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 plasma with proper specifications or other necessary raw materials.

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

- 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

Through December 31, 2023, we have a history of losses and have historically needed to raise, and in the future may be required to raise, additional capital to operate our business.

Our long-term liquidity depends upon our ability to grow our commercial programs, expand our commercial operations at the Boca Facility, improve our supply chain capabilities, improve production yields, continue to build out our commercial infrastructure and meet our ongoing obligations. In addition, our end-to-end production cycle from procurement of raw materials to commercial release of finished product can take between seven and 12 months or potentially longer, requiring substantial investments in raw material plasma and other manufacturing materials.

We currently anticipate, based upon our projected revenue and expenditures, that our current cash, cash equivalents and accounts receivable, along with our projected future operating cash flow, will be sufficient to fund our operations, as currently conducted, through the end of the fourth quarter of fiscal 2025 and beyond. However, our current outlook on cash flows and profitability may change based upon our effectiveness in executing on our commercialization efforts and operational initiatives and whether or not the assumptions underlying our projected revenues and expenses are correct. Although we achieved net income and positive cash flows for the nine months ended September 30, 2024 and positive cash flow from operations for the first time in our history for the year ended December 31, 2023, at present we cannot be certain that we will be able to continue to generate positive cash flows from operations during the remainder of 2024 or beyond and if we cannot raise additional capital or obtain alternative financing if needed, we may have to delay, curtail or eliminate our commercialization efforts and product development activities. Even if we are able to raise additional capital, such equity or debt financings may only be available on unattractive terms, resulting in significant dilution of stockholders' interests and, in such event, the value and potential future market price of our common stock may decline. In addition, if we raise additional funds through license arrangements or through the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or assets or grant licenses on terms that are not favorable to us.

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

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

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 $85.8 million for the nine months ended September 30, 2024, for the years ended December 31, 2023, 2022 and 2021, we incurred net losses of $28.2 million, $65.9 million and $71.6 million, respectively. From our inception in 2004 through September 30, 2024, we have incurred an accumulated deficit of $420.5 million. We may not be able to maintain profitability for the remainder of or beyond 2024, and if we are unable to continue to consistently achieve positive cash flows we may need to continue to finance our operations through additional equity or debt financings or corporate collaboration and licensing agreements. We also expect to continue to incur significant operating and capital expenditures and anticipate that as our business continues to grow our operating expenses will increase accordingly as we:

- expand commercialization and marketing efforts;
- 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 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, embargos 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. Our business depends on, among other things, successful commercialization of our existing products, market acceptance of such products and ensuring that our products are safe and effective. Further, there can be no assurance that we will be able to generate the revenue that we believe our products and plasma collection facilities are capable of generating. As a result, we may not be able to accurately forecast or predict revenue. For these reasons, the estimates and forecasts in our filings relating to revenue generation and growth may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and forecasted growth, our business could fail to grow at similar rates, if at all.

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

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

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

We and our suppliers and contractors may be unable to comply with our specifications, cGMP requirements and with other FDA, state, and foreign regulatory requirements for commercial and clinical supply. The FDA and other regulatory authorities are authorized to perform inspections and remote regulatory assessments of our and our suppliers' facilities, including the Boca Facility. The FDA and other regulatory authorities also may inspect and approve our and our third-parties' facilities before they may be used for commercial production. If we or our suppliers are not able to comply with the applicable regulatory requirements, we or they may be subject to regulatory enforcement actions, which can materially impact our business. For instance, at the end of such an inspection, the FDA could issue a Form 483 Notice of Inspectional Observations, which could cause the FDA to not approve the use of the facility and cause us to modify certain activities identified during the inspection. Following such inspections, the FDA may issue an untitled letter as an initial correspondence that cites violations that do not meet the threshold of regulatory significance of a warning letter. FDA guidelines also provide for the issuance of warning letters for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. FDA also may issue warning letters and untitled letters in connection with events or circumstances unrelated to an FDA inspection. Depending on the seriousness of any findings, we or our suppliers may be subject to additional significant enforcement actions which could have a material impact on our business.

In the event of any enforcement actions, we and our third-party contractors would need to implement remedial actions which may be time-intensive or costly. We may not be able to timely resolve concerns raised by the applicable regulator as a result of an inspection or without expending significant resources. We are unable to control the timing of inspections, communications and actions, and will be required to respond to the regulator and make certain submissions within certain timeframes. We also do not know whether or not the regulator will change its requirements, guidance or expectations. If the regulator determines that we have not remediated the issues identified in a warning letter or any other inspection issues and deficiencies, any failure of ours to address or provide requested documentation of corrections for these issues could disrupt our business operations and the timing of our commercialization efforts and could have a material adverse effect on our financial condition and operating results.

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

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

Business interruptions could adversely affect our business.

Our operations, including our headquarters located in Ramsey, NJ, the Boca Facility and our plasma collection facilities, are vulnerable to interruption by fire, weather related events such as hurricanes, wind and rain, other acts of God or force majeure events, electric power loss, telecommunications failure, equipment failure 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 Investigational New Drug (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 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 or our having insufficient funds for a clinical trial or to pay the substantial user fees required by FDA upon the filing of a marketing application;
- Insufficient supply or inadequate quality of our product candidates or other materials necessary to conduct clinical trials;

- Inability to achieve sufficient study enrollment, subjects dropping out or withdrawing from our studies, delays in adding new investigators or clinical trial sites or a withdrawal of clinical trial sites;
- Flaws in our clinical trial design that are not discoverable until the clinical trial has progressed;
- Disagreement by the FDA or comparable foreign regulatory authorities with our intended indications or study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials, finding that a product candidate's benefits do not outweigh its safety risks or requiring that we conduct additional development or study work;
- The need to make changes to our product candidates that require additional testing or that cause our product candidates to perform differently than expected;
- Global trade policies that may impact our ability to obtain raw materials and/or finished product for commercialization;
- FDA or comparable regulatory authorities taking longer than we anticipate to make decisions on our products or product candidates; and
- Potential inability to demonstrate that a product or product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

In addition, our clinical trials involve a relatively small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results. In addition, certain portions of our clinical trials and product testing for our product candidates may be performed outside of the 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, revenues generated from new contract manufacturing arrangements with third parties and revenues generated from the sales of manufacturing intermediates. We cannot assure you that we will receive the approvals necessary to commercialize any product candidate we may acquire or develop in the future or that we will be able to maintain our current approvals. In order to obtain FDA approval of any product candidate requiring FDA approval, our clinical development must demonstrate that the product candidate is safe for humans and effective for its intended use, and we must successfully complete an FDA BLA review. Obtaining FDA approval of a product candidate generally requires significant research and testing, referred to as preclinical studies, as well as human tests, referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in products that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the product approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies or may require additional Chemistry, Manufacturing and Controls ("CMC") or other data and information, and the development and provision of this data and information may be time-consuming and expensive. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive revenues from, our product candidates;
- impose costly procedures on us; and

- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject our product candidate's BLA. In addition, the FDA could determine that we must test additional subjects and/or require that we conduct further studies with more subjects. We may never obtain regulatory approval for any future potential product candidate or label expansion activity. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without the ability to generate additional accretive revenues. There is no guarantee that we will ever be able to develop or acquire other product candidates. In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any products or product candidates outside the U.S. Foreign regulatory approval processes generally include all of the risks and uncertainties associated with the FDA review, inspection and approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any product candidate for sale outside the 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, require us to conduct specified post-marketing studies, including pediatric and safety studies. If, during the post-marketing period (after marketing approval) previously unknown adverse events emerge, there is the discovery that the product is less effective than previously thought, or other potential concerns regarding our products or their manufacturing processes emerge, or we are observed in any way to fail to comply with the numerous regulatory requirements to which we are subject, those circumstances may yield various results, including:

- restrictions on such products or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- clinical holds or termination of clinical trials;
- requirements to conduct further post-marketing studies or clinical trials, implement risk mitigation strategies, or to issue corrective information;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payers;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of products;
- FDA debarment, suspension and debarment from government programs, refusal of orders under existing government contracts, exclusion from participation in federal healthcare programs, consent decrees, deferred or non-prosecution agreements or corporate integrity agreements;
- product seizure or detention; or
- injunctions or the imposition of civil penalties or criminal fines.

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

For the nine months ended September 30, 2024, two customers, BioCARE, Inc. ("BioCare") and Priority Healthcare Distribution, Inc. d/b/a CuraScript SD Specialty Distribution ("Curascript"), represented an aggregate of approximately 71% of our consolidated revenues. For the year ended December 31, 2023, BioCare and Curascript represented an aggregate of 72% of our consolidated revenues.

As of September 30, 2024, four customers, BioCare, Reliance Life Sciences Pvt. Limited ("Reliance"), Healix Infusion Therapy, LLC ("Healix") and BioLife Plasma Services, L.P., represented an aggregate of approximately 91% of our consolidated accounts receivable. As of December 31, 2023, five customers, BioCare, Healix, Curascript, Cencora, Inc. (f/k/a AmerisourceBergen Corporation) and 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 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, state and local regulations, or due to testing results not meeting specifications. As a result, our operating results are subject to potentially significant variability from one reporting period to the next should such normal course losses occur in any given period. However, because our products and product candidates are plasma-based products, not only are we subject to the FDA's drug and biologic cGMP requirements, but we are also subject to special requirements for the collection, testing, handling, storage, and use of blood products. This adds an extra level of compliance and complexity to our operations, which we may not be able to successfully meet. Failure to meet any regulatory quality standards could have an adverse impact on our business.

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

Even if the FDA approves a product made by us, physicians, payers and patients may not accept and use it. Acceptance and use of our products depends on a number of factors including, but not limited to:

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

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

Our 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.

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. 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.

For example, during the nine months ended September 30, 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.

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, intermediate fractions and plasma attributable to the operations of ADMA BioCenters to support our operations.

Our ADMA BioCenters operations collect information from donors in the 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" ("BAA") with the service provider that receives PHI on behalf of the entity.

While we are not a covered entity or business associate subject to HIPAA, personal information that we obtain pursuant to a clinical trial may be subject to U.S. Federal Trade Commission (the "FTC") privacy regulation. Failing to take appropriate steps to keep consumers' personal information secure may constitute an unfair act or practice violating Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to, but less prescriptive than, what is required by the HIPAA Security Rule. In addition, states impose a variety of laws protecting consumer information, with certain sensitive information such as HIV/Sexually Transmitted Disease status subject to heightened standards. In addition, federal and state privacy, data security, and breach notification laws, rules and regulations, and other laws apply to the collection, use and security of personal information, including social security number, driver's license numbers, government identifiers, credit card and financial account numbers. For example, the CCPA was amended by the CPRA, effective January 1, 2023. The CCPA, among other things, imposes data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. We could be subject to enforcement action and litigation exposure if we fail to adhere to these data privacy and security laws. Virginia, Colorado, Connecticut and Utah have also enacted privacy laws that became effective in 2023 and are similar in many respects to the CCPA. Several other states have also enacted privacy laws similar to the CCPA that will become effective in the coming years, adding to potential privacy compliance obligations.

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

On December 18, 2023 (the "Ares Closing Date"), we entered into a credit agreement with Ares (the "Ares Credit Agreement") (see "Liquidity and Capital Resources"). The Ares Credit Agreement provides for a total of $135 million in senior secured credit facilities (the "Ares Credit Facility") consisting of (i) a term loan in the aggregate principal amount of $62.5 million and (ii) a revolving credit facility in the aggregate principal amount of $72.5 million (collectively, the "Ares Loans"), both of which were fully drawn on the Ares Closing Date. The Ares Credit Facility has a maturity date of December 20, 2027 (the "Ares Maturity Date"). On August 14, 2024, we repaid $30.0 million against the revolving credit facility. 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. 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 Federal Food, Drug, and Cosmetic Act, the Social Security Act (including the Anti-Kickback Statute), the Public Health Service Act, the civil and criminal federal False Claims Act, the civil monetary penalty statute, requirements regarding the reporting and repayment of overpayments, other fraud and abuse laws and any regulations promulgated under the authority of the preceding, may result in significant criminal and/or civil sanctions, including jail sentences, fines or exclusion from participation in or debarment from federal and state healthcare or government procurement programs, pursuant to enforcement actions by DOJ, Medicare, Medicaid, OIG and other regulatory authorities. Similarly, the violation of applicable laws, rules and regulations of states, including the State of Florida, with respect to the manufacture and marketing of our products and product candidates may result in significant criminal and/or civil sanctions, including jail sentences, fines or exclusion from participation in applicable state healthcare programs. There can be no assurance that our activities will not come under the scrutiny of federal and/or state regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

For example, under the Anti-Kickback Statute and similar state laws and regulations, the offer or payment of anything of value to induce or reward patient referrals, or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or in part by a federal healthcare program is prohibited. This places constraints on the marketing and promotion of products and on common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose products for patients, such as physicians and hospitals, and these practices can result in substantial legal penalties, including, among others, exclusion from participation in the Medicare and Medicaid programs. Arrangements with referral sources such as purchasers, group purchasing organizations, healthcare organizations, physicians and pharmacists must be structured with care to comply with applicable requirements. Legislators and regulators may seek to further restrict the scope of financial relationships that are considered appropriate. For example, HHS recently promulgated a regulation that is effective in two phases. First, the regulation excludes from the definition of "remuneration" limited categories of (a) PBM rebates or other reductions in price to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization plan reflected in point-of-sale reductions in price and (b) PBM service fees paid by a manufacturer to a PBM. Second, effective January 1, 2023, the regulation expressly provides that rebates to plan sponsors under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager, will not be protected under the Anti-Kickback Statute discounts safe harbor. Recent legislation and a final rule promulgated on December 29, 2023 delayed implementation of this portion of the rule until January 1, 2032.

Also, certain business practices, such as payments of consulting fees to healthcare professionals, sponsorship of educational or research grants, charitable donations, interactions with healthcare professionals who prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid any possibility of wrongfully influencing healthcare professionals to prescribe or purchase particular products or as a reward for past prescribing. Under the Healthcare Reform Law, payments and transfers of value by pharmaceutical manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to or at the request of covered recipients, such as, but limited to, U.S.-licensed physicians, physician assistants, nurse practitioners, clinical nurse specialists and certified registered nurse anesthetists and U.S. teaching hospitals, must be tracked and reported to CMS, and are publicly disclosed. Such "applicable manufacturers" are also required to report certain ownership interests held by physicians and their immediate family members. A number of states have similar laws in place. Additional and stricter prohibitions could be implemented by federal and state authorities. Where such practices have been found to be improper incentives to use such products, government investigations and sanctions against manufacturers have resulted in substantial fines, penalties and damages. Many manufacturers have been required to enter into consent decrees or orders that prescribe allowable corporate conduct and/or Corporate Integrity Agreements that impose ongoing compliance requirements on a manufacturer.

Failure to satisfy requirements under the Federal Food, Drug, and Cosmetic Act can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct. In addition, while regulatory authorities generally do not regulate physicians' discretion in their choice of treatments for their patients, they do restrict communications by manufacturers on unapproved uses of approved products or on the potential safety and efficacy of unapproved products in development. Companies in the 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 Federal Food, Drug, and Cosmetic Act and subjects us to civil and criminal sanctions. Furthermore, sanctions under the federal False Claims Act have been brought against companies accused of promoting off-label uses of drugs, because such promotion induces unapproved the use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for off-label promotion have been initiated by several states for Medicaid fraud. The Healthcare Reform Law significantly strengthened provisions of the federal False Claims Act, the federal Anti-Kickback Statute that applies to government healthcare programs, and other healthcare fraud provisions, leading to the possibility of greatly increased lawsuits by whistleblowers for perceived violations. Violations or allegations of violations of the foregoing restrictions could materially and adversely affect our business.

We are required to report detailed pricing information, net of included discounts, rebates and other concessions, to CMS for the purpose of calculating national reimbursement levels, certain federal prices and certain federal and state rebate obligations. Inaccurate or incomplete reporting of pricing information could result in criminal and/or civil liability under the federal False Claims Act, the federal Anti-Kickback Statute and various other laws, rules and regulations.

We have established systems for collecting and reporting this data accurately to CMS and have instituted a compliance program to assure that the information collected is complete in all respects. If we report pricing information that is not accurate to the federal government, we could be subject to fines and other sanctions that could adversely affect our business. If we choose to pursue clinical development and commercialization in the European Union or otherwise market and sell our products outside of the 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 necessary capital in order to properly capitalize and continue our operations.

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

Plasma is a raw material that is susceptible to damage and contamination and may contain human pathogens, any of which would render the plasma unsuitable as raw material for further manufacturing. For instance, improper storage of plasma, by us or third-party suppliers, may require us to destroy some of our raw material. If unsuitable plasma is not identified and discarded prior to the release of the plasma to the manufacturing process, it may be necessary to discard intermediate or finished product made from that plasma or to recall any finished product released to the market, resulting in a charge to cost of product revenue. The manufacture of our plasma products is an extremely complex process of fractionation, purification, testing, filling and finishing. Our products can become non-releasable or otherwise fail to meet our stringent specifications or regulatory agencies' specifications through a failure in one or more of these process steps. We may detect instances in which an unreleased product was produced without adherence to our manufacturing procedures or plasma used in our production process was not collected or stored in a compliant manner consistent with our cGMP or other regulations. Such an event of noncompliance would likely result in our determination that the implicated products should not be released or maybe replaced or withdrawn from the market and therefore should be destroyed. Once manufactured, our plasma-derived products must be handled carefully and kept at appropriate temperatures. Our failure, or the failure of third parties that supply, test, ship or distribute our products or product components to properly care for our products, may require that those products be destroyed. Even if handled properly, biologics may form or contain particulates or have other issues or problems after storage which may require products to be destroyed or recalled. While we expect to write off certain amounts of raw materials and work-in-process inventory in the ordinary course of business due to the complex nature of plasma, our processes and our products, unanticipated events may lead to write-offs and other costs materially in excess of our expectations and the reserves we have established for these purposes. Such write-offs or losses and other costs could cause material fluctuations in our results of operations. Product or component quality issues may also result in regulatory enforcement actions, liability, corrective actions and recalls, among other actions, as described elsewhere in this Quarterly Report on Form 10-Q.

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

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

Despite overlapping safeguards, including the screening of donors and other steps to remove or inactivate viruses and other infectious disease-causing agents, the risk of transmissible disease through blood plasma products cannot be entirely eliminated. For example, since plasma-derived therapeutics involves the use and purification of human plasma, there has been concern raised about the risk of transmitting HIV, prions, West Nile virus, H1N1 virus or "swine flu" and other blood-borne pathogens through plasma-derived products. There are also concerns about the future transmission of H5N1 virus, or "bird flu." In the 1980s, thousands of hemophiliacs worldwide were infected with HIV through the use of contaminated Factor VIII. Other producers of Factor VIII, though not us, were defendants in numerous lawsuits resulting from these infections. New infectious diseases emerge in the human population from time to time. If a new infectious disease has a period during which time the causative agent is present in the bloodstream but symptoms are not present, it is possible that plasma donations could be contaminated by that infectious agent. Typically, early in an outbreak of a new disease, tests for the causative agent do not exist. During this early phase, we must rely on screening of donors for behavioral risk factors or physical symptoms to reduce the risk of plasma contamination. Screening methods are generally less sensitive and specific than a direct test as a means of identifying potentially contaminated plasma units. During the early phase of an outbreak of a new infectious disease, our ability to manufacture safe products would depend on the manufacturing process' capacity to inactivate or remove the infectious agent. To the extent our manufacturing processes are inadequate to inactivate or remove an infectious agent, our ability to manufacture and distribute our products would be impaired. If a new infectious disease were to emerge in the human population or if there were a reemergence of an infectious disease, the regulatory and public health authorities could impose precautions to limit the transmission of the disease that would impair our ability to procure plasma, manufacture our products or both. Such precautionary measures could be taken before there is conclusive medical or scientific evidence that a disease poses a risk for plasma-derived products. In recent years, new testing and viral inactivation methods have been developed that more effectively detect and inactivate infectious viruses in collected plasma. There can be no assurance, however, that such new testing and inactivation methods will adequately screen for, and inactivate, infectious agents in the plasma used in the production of our products.

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

In order for plasma to be used in the manufacturing of our products, the individual centers at which the plasma is collected must generally be licensed by the FDA and approved by the regulatory authorities of any country in which we may wish to commercialize our products. When we open a new plasma center, and on an ongoing basis after licensure, it must be inspected by the FDA for compliance with cGMP and other regulatory requirements. Therefore, even if we are able to construct new plasma collection centers to complement our current plasma collection facilities, an unsatisfactory inspection could prevent a new center from being licensed or risk the suspension or revocation of an existing license, among other enforcement actions. Additionally, although we achieved plasma supply self-sufficiency with the approval of our tenth plasma collection center in November 2023, we remain reliant on the purchase of plasma from third parties and the collection of plasma from our FDA-licensed plasma collection centers to manufacture our products. We can give no assurances that appropriate plasma will be available to us through our own plasma collection facilities or on commercially reasonable terms, or at all, to manufacture our products, 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.

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

Our ability to commercialize our products, alone or with collaborators, will depend in part upon the extent to which reimbursement will be available from governmental agencies, health administration authorities, private health maintenance organizations and health insurers and other healthcare payers, and also depends upon the approval, timing and representations by the FDA or other governmental authorities for our product candidates.

Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of insurance coverage. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, as well as to the timing, language, specifications and other details pertaining to the approval of such products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for products. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such product. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our products, once approved, market acceptance of such product could be reduced. Prices in many countries, including many in Europe, are subject to local regulation and certain pharmaceutical products, such as plasma-derived products, are subject to price controls in several of the world's principal markets, including many countries within the European Union. In the 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

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

Although we generated positive cash flow from operations of $68.5 million for the nine months ended September 30, 2024 and $8.8 million for the year ended December 31, 2023, our operations have consumed substantial amounts of cash since inception, and for the year ended December 31, 2022 we had negative cash flows from operations of $59.5 million. We expect to continue to spend substantial amounts for collecting plasma at our plasma collection centers, maintaining our plasma collection centers, procurement of raw material plasma and other raw materials necessary to scale up our manufacturing operations, commercial product launches, infrastructure upgrades and capacity expansion at the Boca Facility. In addition, our end-to-end production cycle from collecting and procuring raw material source plasma to commercial release of finished product can take between seven and 12 months or potentially longer, requiring substantial investments in raw material plasma and other manufacturing materials. We had a net loss of $28.2 million for the year ended December 31, 2023 and although we achieved net income of $85.8 million for the nine months ended September 30, 2024, at present we cannot be certain that we will be able to maintain profitability on an ongoing basis. If we are unable to generate positive cash flow beyond fiscal 2024, we may need to continue to finance our operations through additional equity or debt financings or corporate collaboration and licensing agreements. We currently anticipate, based upon our projected revenue and expenditures, that our current cash, cash equivalents and accounts receivable, along with our projected future operating cash flow, will be sufficient to fund our operations, as currently conducted, through the end of fiscal 2025 and beyond. Our current outlook with respect to cash flows and profitability may change based upon how effective we are in continuing to execute on our commercialization efforts and operational initiatives and whether or not the assumptions underlying our projected revenues and expenses are correct. If we are required to raise additional capital and if such capital is not available due to widespread liquidity constraints or significant market instability that could result from widespread economic or geopolitical conditions or other factors beyond our control, we may have to delay, curtail or eliminate our commercialization efforts or our product development activities.

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

The Ares Credit Facility provides for total senior secured loans in an aggregate principal amount of up to $135.0 million, of which $105.0 million is currently outstanding. Borrowings under the Ares Credit Facility currently bear interest at a weighted-average rate of approximately 10.4% per annum, which reflects the three-month term SOFR rate; provided, however, that upon, and during the continuance of, an event of default, the interest rate will automatically increase by an additional 200 basis points. We are currently required to make quarterly payments of interest during the term of the Ares Credit Facility of approximately $2.8 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 achieve sufficient positive cash flow to repay our outstanding debt obligations as they mature, we will need to obtain additional financing in the amounts necessary to repay our outstanding debt obligations when due. If we are unable to repay our outstanding debt obligations when they mature, our creditors would be able to accelerate all of the amounts due and, in the case of the Ares Credit Facility, seek to enforce their security interests, which could lead to our creditors taking immediate possession of and selling substantially all of our assets with no return provided to our stockholders.

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

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

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

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

If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could result in investors losing confidence in the accuracy and completeness of our financial statements, harm our operating results and negatively affect the market price of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and related rules (the "Sarbanes-Oxley Act"), we are required to maintain internal control over financial reporting and our management is required to report on the effectiveness of our internal control over financial reporting, including any material weaknesses in such internal controls. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we have been required to upgrade, and 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 will be time-consuming, and there is a risk of noncompliance. Further, the costs associated with the compliance with and implementation of procedures under these and future laws and related rules could have a material impact on our results of operations.

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

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

We have incurred substantial losses during our history. As of December 31, 2023, we had federal and state NOLs of $315.6 million and $216.4 million, respectively. Federal and state NOLs of approximately $35.6 million and $95.1 million, respectively, will begin to expire at various dates beginning in 2028, if not limited by triggering events prior to such time. Under the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), changes in our ownership, in certain circumstances, will limit the amount of federal NOLs that can be utilized annually in the future to offset taxable income. In particular, Section 382 of the Code ("Section 382") imposes limitations on a company's ability to use NOLs upon certain changes in such ownership. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs. The acquisition transaction that we completed on June 6, 2017 resulted in a change in ownership of ADMA under Section 382 and, as a result, we were required to write off $57.6 million of federal NOLs. On October 25, 2021, we completed a public offering of our common stock whereby we issued 57,500,000 shares of our common stock resulting in another change of ownership for ADMA under section 382 of the Code, resulting in an additional write-off of $3.0 million of federal NOLs, $28.1 million of state NOLs and $1.0 million of research and development credits. Although we did not experience any ownership changes for the years ended December 31, 2023 and 2022, we may experience ownership changes in the future as a result of subsequent changes in our stock ownership that we cannot predict or control that could result in further limitations being placed on our ability to utilize our federal NOLs.

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 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 2024 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 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 net operating loss carryforwards 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 November 1, 2024, most of our 236,390,253 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 September 30, 2024, BlackRock Inc., Vanguard Group and our directors and executive officers and their affiliates owned approximately 27% 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 September 30, 2024, there were 35,862,328 shares remaining available for issuance, after giving effect to 12,386,492 shares of our common stock that were subject to outstanding stock options, RSUs and warrants as of September 30, 2024 that may be issued by us without stockholder approval, as well as an additional 15,372,573 shares reserved for the future issuance of awards under our equity compensation plans.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. 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 represent a non-Rule 10b5-1 trading arrangement under the Exchange Act. During the quarter ended September 30, 2024, no such plans or other arrangements were adopted or terminated.

Item 6. Exhibits.

See the Exhibit Index immediately following the signature page of this Quarterly Report on Form 10-Q.

SIGNATURES

Pursuant to the requirements 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: November 7, 2024

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

Date: November 7, 2024

By: /s/ Brad Tade
Name: Brad Tade
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
10.1	Employment Agreement, dated July 24, 2024, by and between ADMA Biologics, Inc. and Brad Tade (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 26, 2024).
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from ADMA Biologics, Inc.'s Form 10-Q for the quarter ended September 30, 2024, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2024 (Unaudited) and December 31, 2023, (ii) Condensed Consolidated Statements of Operations (Unaudited) for the three and nine months ended September 30, 2024 and 2023, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited) for the three and nine months ended September 30, 2024 and 2023, (iv) Condensed Consolidated Statements of Cash Flows (Unaudited) for the nine months ended September 30, 2024 and 2023, and (v) Notes to (Unaudited) Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** In accordance with SEC Release 33-8238, Exhibits 32.1 and 32.2 are being furnished and not filed.